CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 202194Orig1s000

Name: Lansoprazole Delayed-release Capsules USP 15 mg (OTC)

Sponsor: Dr. Reddy's Laboratories, Inc.

Approval Date: May 18, 2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202194

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kimberly Ernst
Director, Global Regulatory Affairs
200 Somerset Corporate Boulevard, 7th Floor
Bridgewater, NJ 08807-2862

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 9, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC).

Reference is also made to your amendments dated October 22 and November 3, 2010; January 17, May 3, December 2 (2), and December 13, 2011; and January 25, February 9, February 20, and March 5, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) to be bioequivalent to the reference listed drug product (RLD), Prevacid 24 HR Delayed-release Capsules, 15 mg, of Novartis Consumer Health, Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same USP method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution Testing should be conducted using the USP method: 500 mL of 0.1 N HCl at the acid stage in one hour followed by 900 mL of pH 6.8 Phosphate Buffer with 5 mM SDS at 37°C ± 0.5°C using USP apparatus II at 75 rpm). The product should meet the following "interim" dissolution specifications:

Acid Stage: Not more than (b)(4) of the labeled amount of Lansoprazole is dissolved in 60 minutes, and

Buffer Stage: Not less than (b)(4) (Q) of the labeled amount Of Lansoprazole is dissolved in 60 minutes.

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" when there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

05/18/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

LABELING

Lansoprazole Delayed-Release Capsules USP, 15 mg

Acid Reducer

- **May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours**

Please read the entire package insert before taking Lansoprazole Delayed-Release Capsules. Save for future reference.

How Lansoprazole Delayed-Release Capsules treats your frequent heartburn
Lansoprazole Delayed-Release Capsules stops acid production at the source - the **pumps** that release acid into the stomach. Lansoprazole Delayed-Release Capsule is taken once a day (every 24 hours), every day for 14 days.

What you can expect when taking Lansoprazole Delayed-Release Capsules.
Frequent heartburn can occur anytime during the 24-hour period (day or night). Take Lansoprazole Delayed-Release Capsules in the morning before eating. Lansoprazole Delayed-Release Capsule is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take Lansoprazole Delayed-Release Capsule every day for 14 days to treat your frequent heartburn.

Who should take Lansoprazole Delayed-Release Capsules
Adults (18 years and older) with **frequent heartburn** when you have heartburn 2 or more days a week.

Who should NOT take Lansoprazole Delayed-Release Capsules
People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to take Lansoprazole Delayed-Release Capsules

14-DAY Course of Treatment
- Swallow 1 capsule with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 capsule a day.
- Swallow whole. Do not crush or chew capsules.
- Do not use for more than 14 days unless directed by your doctor.

When to take Lansoprazole Delayed-Release Capsules again
You may repeat a 14-day course of therapy every 4 months.

When to talk to your doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and when to ask your doctor
Allergy alert: Do not use if you are allergic to lansoprazole

Do not use
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

(continued on other side)

(continued from previous side)

- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **(1-800-222-1222)**

Tips for managing heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Clinical studies prove Lansoprazole Delayed-Release Capsules effectively treats frequent heartburn

In three clinical studies, Lansoprazole Delayed-Release Capsules was shown to be significantly better than placebo in treating frequent heartburn.

How Lansoprazole Delayed-Release Capsule is sold

Lansoprazole delayed-release capsules are available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments about Lansoprazole Delayed-Release Capsules Call 1-888-375-3784

Manufactured by:
Dr. Reddy's Laboratories Limited
Bachepalli - 502 325 INDIA

Issued: 0212

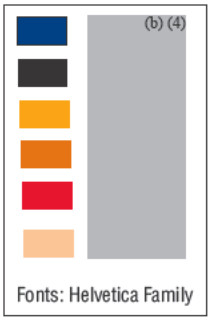
DR.REDDY'S

Final Container Label: Lansoprazole Delayed-Release Capsules USP, 15 mg
14's count
Label size : 95 mm x 30 mm

Double-layer Label
Top Panel Front

Top Panel Back

Labeling Format Information:	
Fonts:	Helvetica condensed
Drug Facts:	7 pt
Header:	6 pt
Subheader:	5 pt
Body Text:	5 pt
Drug Facts (continued):	7 pt
Leading:	6 pt
Bullets:	3 pt
Barlines:	NA
Hairlines:	NA



Final Container Carton Label
Lansoprazole Delayed-Release Capsules USP, 15 mg - 14's count
Actual Label Size: 128 mm x 45 mm x 72 mm

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION

TAMPER-EVIDENT BOTTLE
DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

1 BOTTLE INSIDE
14 CAPSULES TOTAL

Drug Facts

Active ingredient (in each capsule)	Purpose
Lansoprazole USP, 15 mg	Acid reducer

Use
- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to lansoprazole

Do not use
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.

Drugs Facts (continued)
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, ask a health professional before use.

Drugs Facts (continued)
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **(1-800-222-1222)**

Directions
- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)
- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Drugs Facts (continued)
Other information
- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20°– 25°C (68°– 77°F)
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients
FD&C Blue No.2, gelatin, hydroxypropyl cellulose, iron oxide black, iron oxide red, iron oxide yellow, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol 6000, polysorbate 80, sodium lauryl sulphate, starch (corn), sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?
call **1-888-375-3784**

Manufactured by:
Dr. Reddy's Laboratories Limited
Bachepalli - 502 325 INDIA

DR. REDDY'S

NDC 55111-739-52

Lansoprazole Delayed-Release Capsules USP, 15 mg

Pantone (b) (4)

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

24 Hour

14 CAPSULES
One 14-Day Course of Treatment

Pantone (b) (4)

Lot

Exp

N 3 55111 73952 4

Labeling Format Information:

Fonts:	Helvetica cond. medium, bold, narrow bold italic
Drug Facts:	13 pt
Header:	9 pt
Subheader :	7 pt
Body Text:	7 pt
Drugs Facts (continued):	11 pt
Leading:	8 pt
Bullets:	5 pt
Barlines:	2.5 pt
Hairlines:	0.5 pt

Note: This container carton label is fit to paper print

(b) (4)

Fonts: Helvetica Family

Final Container Carton Label
Lansoprazole Delayed-Release Capsules USP, 15 mg - 28's count
Actual Label Size: 128 mm x 45 mm x 72 mm

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION

TAMPER-EVIDENT BOTTLE
DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

2 BOTTLES INSIDE
28 CAPSULES TOTAL

Drug Facts

Active ingredient (in each capsule)	Purpose
Lansoprazole USP, 15 mg	Acid reducer

Use
- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to lansoprazole

Do not use
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.

Drugs Facts (continued)
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, ask a health professional before use.

Drugs Facts (continued)
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **(1-800-222-1222)**

Directions
- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)
- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Drugs Facts (continued)
Other information
- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20°– 25°C (68°– 77°F)
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients
FD&C Blue No. 2, gelatin, hydroxypropyl cellulose, iron oxide black, iron oxide red, iron oxide yellow, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol 6000, polysorbate 80, sodium lauryl sulphate, starch (corn), sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?
call **1-888-375-3784**

Manufactured by:
Dr. Reddy's Laboratories Limited
Bachepalli - 502 325 INDIA

DR. REDDY'S

NDC 55111-739-27

Lansoprazole Delayed-Release Capsules USP, 15 mg
Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

24 Hour

28 CAPSUELS
Two 14-Day Courses of Treatment

Pantone (b) (4)

Pantone (b) (4)

Lot

Exp

3 55111 73927 2

Labeling Format Information:

Fonts:	Helvetica cond. medium, bold, narrow bold italic
Drug Facts:	13 pt
Header:	9 pt
Subheader :	7 pt
Body Text:	7 pt
Drugs Facts (continued):	11 pt
Leading:	8 pt
Bullets:	5 pt
Barlines:	2.5 pt
Hairlines:	0.5 pt

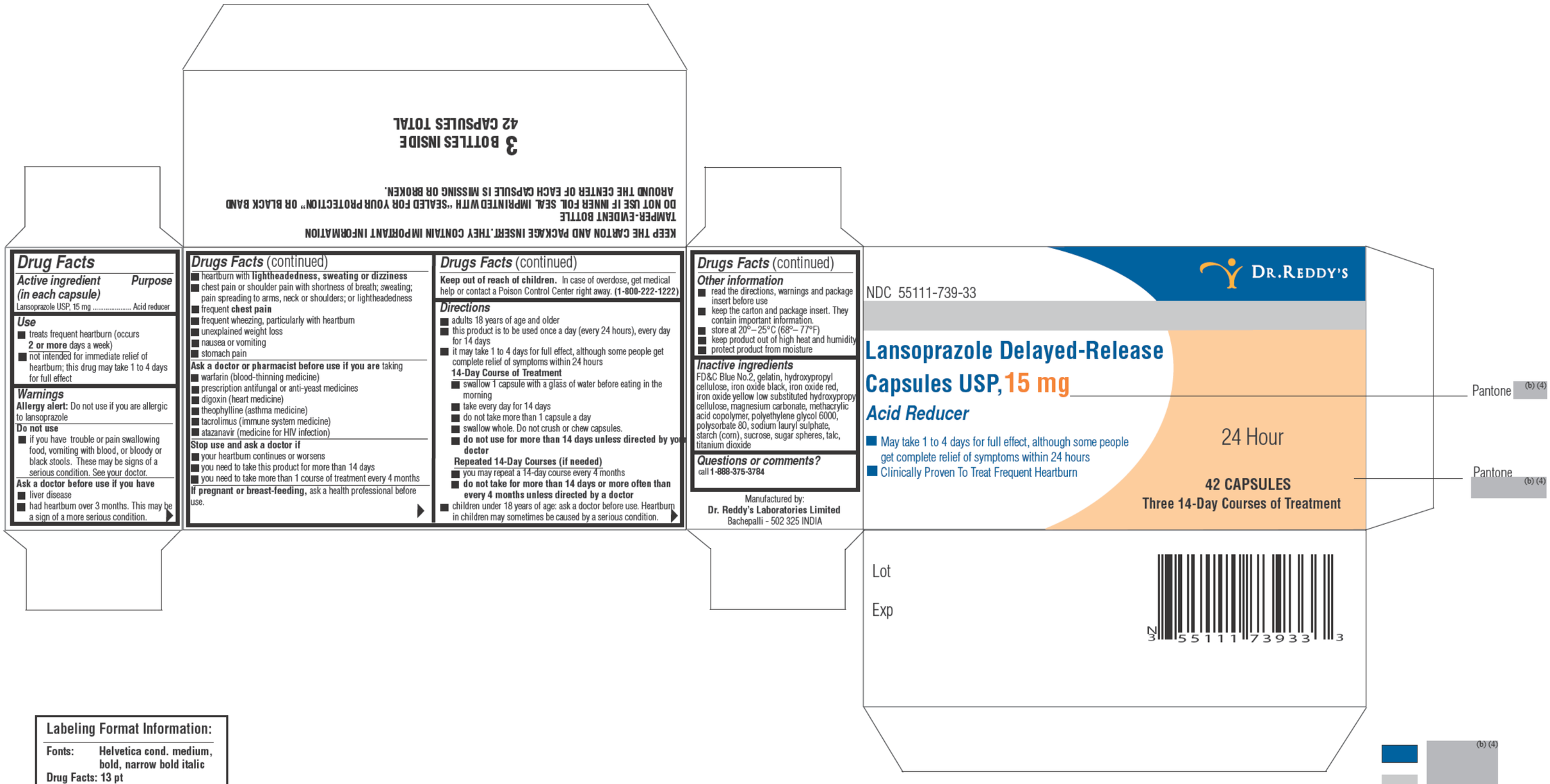
Note: This container carton label is fit to paper print

(b) (4)

Fonts: Helvetica Family

Final Container Carton Label
Lansoprazole Delayed-Release Capsules USP, 15 mg - 42's count (3x14)

Actual Label Size: 128 mm x 45 mm x 72 mm



Labeling Format Information:	
Fonts:	Helvetica cond. medium, bold, narrow bold italic
Drug Facts:	13 pt
Header:	9 pt
Subheader :	7 pt
Body Text:	7 pt
Drugs Facts (continued):	11 pt
Leading:	8 pt
Bullets:	5 pt
Barlines:	2.5 pt
Hairlines:	0.5 pt

Note: This container carton label is fit to paper print

(b) (4)

Fonts: Helvetica Family

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

LABELING REVIEWS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 202194 Date of Submission: August 9, 2010

Applicant's Name: Dr. Reddys Laboratories Limited

Established Name: Lansoprazole Delayed-Release Capsules USP, 15 mg

Labeling Deficiencies:

1. CONTAINER – 14s (b) (4)

   a. Please confirm that your container/closure system employs a tamper-evident inner foil seal printed with "SEALED for YOUR PROTECTION".

   b. We recommend that you include the phone number for the Poison Control Center.

   c. (b) (4)

2. CARTON – 1 x 14s, 2 x 14s, and 3 x 14s

   a. See comments under CONTAINER, whichever applicable.

   b. We recommend that you increase the prominence of the text "xxx 14-DAY COURSE OF TREATMENT". Please ensure that this text be closely associated with the net quantity statement, the packaging of 42s in particular.

   c. We strongly recommend that you include the text "One Bottle Inside", "Two Bottles Inside" or "Three Bottles Inside" in a prominent manner for the packaging of 14s, 28s, and 42s, respectively. Please include this text in association with the net quantity statement.

   d. Inactive Ingredients:

      We recommend that you specify the botanical source for "Starch, *i.e.* Starch (Corn)".

3. (b) (4)

4.

[redacted] (b) (4)

5. INSERT

Please delete the [redacted] (b) (4) as it is not appearing in the updated labeling for the "Prevacid®24 Capsules.

Revise the labeling as described above and submit final printed labeling electronically. Please provide the labeling in the Structured Product Labeling (SPL) as well as pdf. format.

Prior to approval, it may be necessary to revise your labeling subsequent to approved changes for the reference listed drug. In order to keep ANDA labeling current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address - http://service.govdelivery.com/service/subscribe.html?code=USFDA_17

To facilitate review of your next submission please provide a side-by-side comparison of your proposed labeling with your last labeling submission with all differences annotated and explained.

If you have any questions, please call Chan Park at 240-276-8951 or send e-mail to chan.park@fda.hhs.gov

{See appended electronic signature page}

_____

William Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

NOTES/QUESTIONS TO THE CHEMIST:

None

FOR THE RECORD:

1. MODEL LABELING – Prevacid®24 hours Capsules (NDA 022327/S-017), approved 10/31/2011. As for the PI, the Prevacid®24 Hours, which was last approved on 4/19/2011 (NDA 22327/S-013), was used for review.

2. Prevacid® 24 Hours Capsules is available for both Rx (NDA 020406) and OTC (NDA 022327). However, these two drug products have different indications.

3. This drug product is the subject of a USP monograph.

4. The listing of inactive ingredients in the DESCRIPTION section of the carton appears to be consistent with the listing of inactive ingredients found in the statement of composition in the CMC section.

   Magnesium Carbonate USP [redacted] (b) (4), **Low substituted hydroxypropyl cellulose** [redacted] (b) (4) NF **Sucrose** NF, **Starch** NF (Corn Starch), **Hydroxypropyl Cellulose** NF [redacted] (b) (4) **Sugar Spheres** NF [redacted] (b) (4), **Methacrylic acid copolymer** [redacted] (b) (4) NF [redacted] (b) (4), **Polyethylene Glycol 6000** NF, **Talc USP, Titanium dioxide USP, Polysorbate 80** NF

Empty Hard Gelatin Capsules Size '3' [redacted] **Gelatin** NF [redacted] **Ferric Oxide** (Iron Oxide, Black) [redacted]

The total daily intake of Elemental Iron:

The total iron content due to iron oxide black in each capsule is [redacted] Since the usual dosage is one capsule per day, the total daily maximum intake of elemental iron is [redacted]

5. PATENTS/EXCLUSIVITIES

There are no unexpired patents for this product in the Orange Book Database.

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration	Labeling Impact
N022327	001	NP	May 18, 2012	None

6. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON

RLD - Store at 20 to 25°C (68 to 77°F).

ANDA: Store at 20 to 25°C (68 to 77°F).

USP - Preserve in tight containers, and store at controlled room temperature.

7. PACKAGING CONFIGURATIONS

RLD – 14s, 28s, and 48s

ANDA – Bottle of 14s, 28s (2 x 14s) and 42s (3 x 14s)
[redacted]

8. The description of the capsules from the CMC information:

White to pale yellow colored enteric coated pellets filled **in black color banded**, size'3' hard gelatin capsules [redacted] pink opaque body, imprinted with [redacted].

9. CONTAINER/CLOSURE

Following this page, 1 page withheld in full (b)(4)

(b) (4)

10. Manufacturer

Corporate Headquarters
Dr. Reddy's Laboratories Limited
7-1-27 Ameerpet
Hyderabad 500016
Andhra Pradesh
India

The product will be manufactured by:
Dr. Reddy's Laboratories Limited
Formulation Tech Ops-III
Bachupally 502325
Andhra Pradesh
India

11. Font size of the Container, Carton and PI for OTC:

21 CFR 201.66 states as follows:

The term “Drug Facts” – 8 pts.
Questions and Comments with a phone Number – 6 pts
Text – 6 pts
Bullet Point Statement – 5 pts.

ANDA
The term “Drug Facts” –11 pts.
Questions and Comments with a phone Number – 9 pts
Text – 7 pts
Bullet Point Statement – 7 pts

Date of Review: 2/2/2012 **Date of Submission: 8/9/2010**

Primary Reviewer: Chan Park **Date:**

Team Leader: Koung Lee **Date:**

C:\Documents and Settings\parkc\My Documents\202194.NA1.L.doc

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHAN H PARK
02/03/2012

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 202194 Date of Submission: February 9, 2012

Applicant's Name: Dr. Reddys Laboratories Limited

Established Name: Lansoprazole Delayed-Release Capsules USP, 15 mg

Labeling Deficiencies:

1. CONTAINER – 14s

   Satisfactory in FPL as of the 2/9/2012 submission

2. CARTON – 1 x 14s, 2 x 14s, and 3 x 14s

   We note that you included [redacted] (b) (4) .

3. INSERT

   Satisfactory in FPL as of the 2/9/2012 submission

Revise the labeling as described above and submit final printed labeling electronically. Please provide the labeling in the Structured Product Labeling (SPL) as well as pdf. format.

Prior to approval, it may be necessary to revise your labeling subsequent to approved changes for the reference listed drug. In order to keep ANDA labeling current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address - http://service.govdelivery.com/service/subscribe.html?code=USFDA_17

To facilitate review of your next submission please provide a side-by-side comparison of your proposed labeling with your last labeling submission with all differences annotated and explained.

If you have any questions, please call Chan Park at 240-276-8951 or send e-mail to chan.park@fda.hhs.gov

{See appended electronic signature page}

William Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

NOTES/QUESTIONS TO THE CHEMIST:

From: Park, Chan H
Sent: Friday, February 10, 2012 1:42 PM
To: Rege, Bhagwant
Cc: Park, Chan H
Subject: ANDA 202194 (Lansoparazole D-R Capsules)

Hello Bhagwant,

It is to let you know that the applicant [redacted] (b) (4) [redacted] (b) (4). Thanks,

Chan

FOR THE RECORD:

1. MODEL LABELING – Prevacid®24 hours Capsules (NDA 022327/S-017), approved 10/31/2011. As for the PI, the Prevacid®24 Hours, which was last approved on 4/19/2011 (NDA 22327/S-013), was used for review.

2. Prevacid® 24 Hours Capsules is available for both Rx (NDA 020406) and OTC (NDA 022327). However, these two drug products have different indications.

3. This drug product is the subject of a USP monograph.

4. The listing of inactive ingredients in the DESCRIPTION section of the carton appears to be consistent with the listing of inactive ingredients found in the statement of composition in the CMC section.

   Magnesium Carbonate USP [redacted] (b) (4), **Low substituted hydroxypropyl cellulose** [redacted] (b) (4) NF **Sucrose** NF, **Starch** NF (Corn Starch), **Hydroxypropyl Cellulose** NF [redacted] (b) (4) **Sugar Spheres** NF [redacted] (b) (4), **Methacrylic acid copolymer** [redacted] (b) (4) NF [redacted] (b) (4) **Polyethylene Glycol 6000** NF, **Talc USP, Titanium dioxide USP, Polysorbate 80** NF

   Empty Hard Gelatin Capsules Size '3' [redacted] (b) (4) pink opaque body, imprinted with [redacted] (b) (4), **Gelatin** NF [redacted] (b) (4), **Ferric Oxide** (Iron Oxide, Black) [redacted] (b) (4)

   The total daily intake of Elemental Iron:

   The total iron content due to iron oxide black in each capsule is [redacted] (b) (4) Since the usual dosage is one capsule per day, the total daily maximum intake of elemental iron is [redacted] (b) (4).

5. PATENTS/EXCLUSIVITIES

   There are no unexpired patents for this product in the Orange Book Database.

   Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration	Labeling Impact
N022327	001	NP	May 18, 2012	None

6. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON

   RLD - Store at 20 to 25°C (68 to 77°F).

   ANDA: Store at 20 to 25°C (68 to 77°F).

   USP - Preserve in tight containers, and store at controlled room temperature.

7. PACKAGING CONFIGURATIONS

   RLD – 14s, 28s, and 48s

ANDA – One bottle of 14s (1 x 14s), Two bottles of 14s (2 x 14s) and three bottles of 14s ((3 x 14s)

(b) (4)

8. The description of the capsules from the CMC information:

White to pale yellow colored enteric coated pellets filled **in black color banded**, size'3' hard gelatin capsules (b) (4) pink opaque body, imprinted with (b) (4).

9. CONTAINER/CLOSURE

The sponsor confirmed that their container/closure system employs a tamper-evident inner foil seal printed with "SEALED for YOUR PROTECTION"

(b) (4)

10. Manufacturer

Corporate Headquarters
Dr. Reddy's Laboratories Limited
7-1-27 Ameerpet
Hyderabad 500016
Andhra Pradesh
India

The product will be manufactured by:
Dr. Reddy's Laboratories Limited
Formulation Tech Ops-III
Bachupally 502325
Andhra Pradesh
India

11. Font size of the Container, Carton and PI for OTC:

21 CFR 201.66 states as follows:

The term "Drug Facts" – 8 pts.
Questions and Comments with a phone Number – 6 pts
Text – 6 pts
Bullet Point Statement – 5 pts.

ANDA
The term "Drug Facts" –11 pts.
Questions and Comments with a phone Number – 9 pts
Text – 7 pts
Bullet Point Statement – 7 pts
Insert – 8 pts

12. Regarding potential safety issue associated with PPIs (Proton Pump Inhibitors), see below email:

From: Lee, Koung U
Sent: Thursday, February 09, 2012 12:33 PM
To: 'Valerie Gallagher'; Park, Chan H
Cc: (b) (6); Park, Sarah Soojung; (b) (6)
Subject: RE: ANDA 202319 - Lansoprazole OTC Capsules - Safety Announcement

Hi Valerie,

We do not know how this will affect your application. We will communicate to you as soon as possible if additional changes are needed.

Koung

From: Valerie Gallagher [mailto:Valerie.Gallagher@perrigo.com]
Sent: Thursday, February 09, 2012 11:02 AM
To: Park, Chan H
Cc: Lee, Koung U; (b) (6) Park, Sarah Soojung; Valerie Gallagher; (b) (6)
Subject: RE: ANDA 202319 - Lansoprazole OTC Capsules - Safety Announcement
Importance: High

We are ready to file our response. You should receive it later today.

I have an urgent request. Please comment on the impact to Perrigo's final printed labeling being submitted today in light of FDA's Safety Communication issued this morning (See below). Will we be allowed to gain approval and launch as submitted? Please advise as soon as possible.

Thanks,
Valerie

FDA Drug Safety Communication: *Clostridium difficile*-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)

Safety Announcement
Additional Information for Patients and Consumers
Additional Information for Healthcare Professionals
Data Summary (Tables)

Safety Announcement

[02-08-2012] The U.S. Food and Drug Administration (FDA) is informing the public that the use of stomach acid drugs known as proton pump inhibitors (PPIs) may be associated with an increased risk of *Clostridium difficile*–associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve.

Patients should immediately contact their healthcare professional and seek care if they take PPIs and develop diarrhea that does not improve.

Clostridium difficile (C. difficile) is a bacterium that can cause diarrhea that does not improve.[1] Symptoms include watery stool, abdominal pain, and fever, and patients may go on to develop more serious intestinal conditions. The disease can also be spread in the hospital. Factors that may predispose an individual to developing CDAD include advanced age, certain chronic medical conditions, and taking broad spectrum antibiotics. Treatment for CDAD includes the replacement of fluids and electrolytes and the use of special antibiotics.

The FDA is working with manufacturers to include information about the increased risk of CDAD with use of PPIs in the drug labels.

FDA is also reviewing the risk of CDAD in users of histamine H_2 receptor blockers. H_2 receptor blockers are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and heartburn. H_2 receptor blockers are marketed under various brand and generic drug names (see Tables 3 and 4) as prescription and OTC products.

Facts about Proton Pump Inhibitor (PPI) Drugs

- Marketed under various brand and generic drug names (see Tables 1 and 2) as prescription and over-the-counter (OTC) products.
- Work by reducing the amount of acid in the stomach.
- Prescription PPIs are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus.
- Over-the-counter PPIs are used to treat frequent heartburn.

Today's communication is in keeping with FDA's commitment to inform the public about the Agency's ongoing safety review of drugs. FDA will communicate any new information on PPIs or H_2 receptor blockers and the risk of CDAD when it becomes available.

Additional Information for Patients and OTC Consumers:

- Seek immediate care if you use PPIs and develop diarrhea that does not improve. This may be a sign of *Clostridium difficile*–associated diarrhea (CDAD).
- Your healthcare professional may order laboratory tests to check if you have CDAD.
- Do not stop taking your prescription PPI drug without talking to your healthcare professional.
- Discuss any questions or concerns about your PPI drug with your healthcare professional.
- If you take an OTC PPI drug, follow the directions on the package carefully.
- Report any side effects you experience to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of the page.

Additional Information for Healthcare Professionals

- A diagnosis of CDAD should be considered for PPI users with diarrhea that does not improve.
- Advise patients to seek immediate care from a healthcare professional if they experience watery stool that does not go away, abdominal pain, and fever while taking PPIs.
- Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.
- Report adverse events involving PPIs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Data Summary

FDA has reviewed reports from the FDA's Adverse Event Reporting System (AERS) and the medical

literature for cases of *Clostridium difficile*-associated diarrhea (CDAD) in patients undergoing treatment with PPIs. Many of the adverse event reports involved patients who were elderly, had chronic and/or concomitant underlying medical conditions, or were taking broad spectrum antibiotics that could have predisposed them to developing CDAD. Although these factors could have increased their risk of CDAD, the role of PPI use cannot be definitively ruled out in these reviewed reports. Patients who have one or more of these risk factors may have serious outcomes from CDAD with concomitant PPI use.

FDA also reviewed a total of 28 observational studies described in 26 publications. Twenty-three of the studies showed a higher risk of *C. difficile* infection or disease, including CDAD, associated with PPI exposure compared to no PPI exposure.[2-27] Although the strength of the association varied widely from study to study, most studies found that the risk of *C. difficile* infection or disease, including CDAD, ranged from 1.4 to 2.75 times higher among patients with PPI exposure compared to those without PPI exposure. In the five studies that provided information on clinical outcomes, colectomies, and rarely deaths, were reported in some patients [4,6,11,12,21]

The published studies varied in their ability to assess the association between *C. difficile* infection or CDAD and prior PPI use. There were limited data on the relationship between the risk of *C. difficile* infection or CDAD and PPI dose and duration of use. There also was little information on the use of OTC PPIs in community settings in these studies. Nevertheless, the weight of evidence suggests a positive association between the use of PPIs and *C. difficile* infection and disease, including CDAD.

Table 1: Prescription Proton Pump Inhibitor (PPI) Drugs

Generic name	Found in brand name(s)
dexlansoprazole	Dexilant
esomeprazole magnesium	Nexium
esomeprazole magnesium and naproxen	Vimovo
lansoprazole	Prevacid
omeprazole	Prilosec
omeprazole and Sodium bicarbonate	Zegerid
pantoprazole sodium	Protonix
rabeprazole sodium	AcipHex

Table 2: Over-the-Counter (OTC) Proton Pump Inhibitor (PPI) Drugs

Generic name	Found in brand name(s)
lansoprazole	Prevacid 24HR
omeprazole magnesium	Prilosec OTC
omeprazole and sodium bicarbonate	Zegerid OTC
omeprazole	Omeprazole

Table 3: Prescription H_2 Receptor Blocker Drugs

Generic name	Found in brand name(s)
cimetidine	Tagamet
famotidine	Pepcid, Duexis
nizatidine	Axid, Nizatidine
ranitidine	Zantac, Tritec

Table 4: Over-the-Counter (OTC) H_2 Receptor Blocker Drugs

Generic name	Found in brand name(s)

Generic name	Found in brand name(s)
cimetidine	Tagamet HB
famotidine	Pepcid Complete, Pepcid AC
nizatidine	Axid AR
ranitidine	Zantac

-

Related Information

- FDA Drug Safety Podcast for Healthcare Professionals: *Clostridium difficile*-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)[1]
  2/8/2012
- Proton Pump Inhibitors Information

Contact FDA
1-800-332-1088
1-800-FDA-0178 Fax
Report a Serious Problem

MedWatch Online[3]

Regular Mail: Use postage-paid FDA Form 3500[4]

Mail to: MedWatch 5600 Fishers Lane

Rockville, MD 20857

Date of Review: 2/10/2012 **Date of Submission: 2/9/2012**

Primary Reviewer: Chan Park **Date:**

Team Leader: Koung Lee **Date:**

C:\Documents and Settings\parkc\My Documents\202194.NA2.L.doc

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHAN H PARK
02/14/2012

(APPROVAL SUMMARY)
REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 202194 Date of Submission: February 20, 2012

Applicant's Name: Dr. Reddys Laboratories Limited

Established Name: Lansoprazole Delayed-Release Capsules USP, 15 mg

REMS Check Boxes
RISK EVALUATION AND MITIGATIONSTRATEGY

REMS required? No

MedGuides and/or PPIs (505-1(e))	☐ Yes	☒ No
Communication plan (505-1(e))	☐ Yes	☒ No
Elements to assure safe use (ETASU) (505-1(f)(3))	☐ Yes	☒ No
Implementation system if certain ETASU (505-1(f)(4))	☐ Yes	☒ No
Timetable for assessment (505-1(d))	☐ Yes	☒ No

ANDA REMS acceptable?
☐ Yes ☐ No ☒ n/a

CONTAINER LABELS – 14s

Satisfactory in FPL as of the 2/20/2012 submission

CARTON LABELING – 1 x14s, 2 x 14s, and 3 x 14s

Satisfactory in FPL as of the 2/20/2012 submission

INSERT LABELING

Satisfactory in FPL as of the 2/9/2012 submission

REVISIONS NEEDED POST-APPROVAL:

See FTR #15 for the safety information associated with this drug product. See below for potential impact on the labeling. The below information was also posted on the MedWatch website on 2/8/2012. The FDA is working with manufacturers to include information about the increased risk of CDAD with use of PPIs in the drug labels.

FDA Drug Safety Podcast for Healthcare Professionals: *Clostridium difficile*-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)

Listen [1]

Welcome to the FDA Drug Safety Podcast for Healthcare Professionals from the Division of Drug Information. *Today's topic: Clostridium difficile*-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)

I'm Steve Jackson, a pharmacist in the Division.

On February 8, 2012, the Food and Drug Administration issued a Drug Safety Communication informing the public that the use of stomach acid drugs known as PPIs may be associated with an increased risk of *Clostridium difficile*–associated diarrhea, also known as CDAD. A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve.

Patients should immediately contact their healthcare professional and seek care if they take PPIs and develop diarrhea that does not improve.

Clostridium difficile is a bacterium that can cause diarrhea that does not improve.Symptoms include watery stool, abdominal pain, and fever, and patients may go on to develop more serious intestinal conditions. The disease can also be spread in the hospital. Factors that may predispose an individual to developing CDAD include advanced age, certain chronic medical conditions, and taking broad spectrum antibiotics. Treatment for CDAD includes the replacement of fluids and electrolytes and the use of special antibiotics.

The FDA is working with manufacturers to include information about the increased risk of CDAD with use of PPIs in the drug labels.

FDA is also reviewing the risk of CDAD in users of histamine H_2 receptor blockers. H_2 receptor blockers are used to treat conditions such as gastroesophageal reflux disease, stomach and small intestine ulcers, and heartburn. H_2 receptor blockers are marketed under various brand and generic drug names as prescription and OTC products.

Today's communication is in keeping with FDA's commitment to inform the public about the Agency's ongoing safety review of drugs. FDA will communicate any new information on PPIs or H_2 receptor blockers and the risk of CDAD when it becomes available.

At this time, FDA recommends that Healthcare Professionals be aware that:

- A diagnosis of CDAD should be considered for PPI users with diarrhea that does not improve.
- Patients should be advised to seek immediate care from a healthcare professional if they experience watery stool that does not go away, abdominal pain, and fever while taking PPIs.
- Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.
- Adverse events involving PPIs should be reported to the FDA MedWatch program at www.fda.gov/medwatch[2].

Thank you for listening. The FDA is committed to keeping healthcare professionals informed of the latest safety information. A link to this communication, including the complete Data Summary and Tables, can be found at www.fda.gov/DrugSafetyCommunications[3]. If you have drug questions, you can reach us at druginfo@fda.hhs.gov.

Follow us on Twitter @FDA_Drug_Info for up to the minute important drug information. Know the moment it happens.

NOTES/QUESTIONS TO THE CHEMIST:

From: Park, Chan H
Sent: Friday, February 10, 2012 1:42 PM
To: Rege, Bhagwant
Cc: Park, Chan H
Subject: ANDA 202194 (Lansoparazole D-R Capsules)

Hello Bhagwant,

It is to let you know that the applicant withdrew the proposal for the blister packaging as stated in the labeling amendment of 2/9/2012. Thanks,

Chan

FOR THE RECORD:

1. MODEL LABELING – Prevacid®24 hours Capsules (NDA 022327/S-017), approved 10/31/2011. As for the PI, the Prevacid®24 Hours, which was last approved on 4/19/2011 (NDA 22327/S-013), was used for review.

2. Prevacid® Capsules is available for both Rx (NDA 020406) and OTC (Prevacid®24H, NDA 022327). However, these two drug products have different indications.

3. This drug product is the subject of a USP monograph.

4. The listing of inactive ingredients in the DESCRIPTION section of the carton appears to be consistent with the listing of inactive ingredients found in the statement of composition in the CMC section.

   Magnesium Carbonate USP (b) (4), **Low substituted hydroxypropyl cellulose** (b) (4) NF **Sucrose** NF, **Starch** NF (Corn Starch), **Hydroxypropyl Cellulose** NF (b) (4) **Sugar Spheres** NF (b) (4), **Methacrylic acid copolymer** (b) (4) NF (b) (4), **Polyethylene Glycol 6000** NF, **Talc USP, Titanium dioxide USP, Polysorbate 80** NF

   Empty Hard Gelatin Capsules Size '3' (b) (4) pink opaque body, imprinted with (b) (4) **Gelatin** NF (b) (4), **Ferric Oxide** (Iron Oxide, Black) (b) (4)

   The total daily intake of Elemental Iron:

   The total iron content due to iron oxide black in each capsule is (b) (4). Since the usual dosage is one capsule per day, the total daily maximum intake of elemental iron is (b) (4)

5. PATENTS/EXCLUSIVITIES

   There are no unexpired patents for this product in the Orange Book Database.

   Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration	Labeling Impact
N022327	001	NP	May 18, 2012	None

6. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON

   RLD - Store at 20 to 25°C (68 to 77°F).

   ANDA: Store at 20 to 25°C (68 to 77°F).

   USP - Preserve in tight containers, and store at controlled room temperature.

7. PACKAGING CONFIGURATIONS

   RLD – 14s, 28s, and 48s

   ANDA – One bottle of 14s (1 x 14s), Two bottles of 14s (2 x 14s) and three bottles of 14s ((3 x 14s)

   (b) (4)

8. The description of the capsules from the CMC information:

White to pale yellow colored enteric coated pellets filled **in black color banded**, size'3' hard gelatin capsules (b) (4) pink opaque body, imprinted with (b) (4).

9. CONTAINER/CLOSURE

The sponsor confirmed that their container/closure system employs a tamper-evident inner foil seal printed with "SEALED for YOUR PROTECTION".

(b) (4)

The sponsor withdrew blister packaging.

10. Manufacturer

Corporate Headquarters
Dr. Reddy's Laboratories Limited
7-1-27 Ameerpet
Hyderabad 500016
Andhra Pradesh
India

The product will be manufactured by:
Dr. Reddy's Laboratories Limited
Formulation Tech Ops-III
Bachupally 502325
Andhra Pradesh
India

11. Font size of the Container, Carton and PI for OTC:

21 CFR 201.66 states as follows:

The term “Drug Facts” – 8 pts.
Questions and Comments with a phone Number – 6 pts
Text – 6 pts
Bullet Point Statement – 5 pts.

ANDA
The term “Drug Facts” –11 pts.
Questions and Comments with a phone Number – 9 pts
Text – 7 pts
Bullet Point Statement – 7 pts
Insert – 8 pts

12. The sponsor included the term “24 Hour” on the container and carton labeling, but not associated with the drug product name. See below emails to/from the ONDQA and sponsor:

From: Park, Chan H
Sent: Wednesday, February 15, 2012 1:03 PM
To: Stewart, Sherry
Cc: Park, Chan H; Park, Sarah Soojung; Lee, Koung U
Subject: Prevacid24HR (NDA 022327)
Importance: High

Hi Sherry,

Please advise whether the term (b) (4) is a part of the proprietary name for this drug product. I note that "Prevacid" is a Rx drug while (b) (4) is an OTC drug. A generic sponsor would like to use the term (b) (4) for their OTC drug product label, so I would like to confirm that the term (b) (4) should not be used by the generic sponsor. I would appreciate your prompt response. Thank you for your help,

Chan

From: Stewart, Sherry
Sent: Wednesday, February 15, 2012 1:30 PM
To: Park, Chan H
Cc: Park, Sarah Soojung; Lee, Koung U
Subject: RE: Prevacid24HR (NDA 022327)

The proprietary name of the NDA you referenced above is "Prevacid 24 HR". It is not within my purview to determine whether the term (b) (4) could be used by a generic sponsor, and I am not sure who can answer that for you. Let me know if I can be of further assistance,
Thanks
Sherry

Sherry Stewart, PharmD

Regulatory Project Manager

FDA/CDER/ODE IV/DNCE

301-796-9618

From: rzade@drreddys.com [mailto:rzade@drreddys.com]
Sent: Wednesday, February 15, 2012 1:46 PM
To: Park, Chan H
Subject: Fw: Email Address

Hello Mr Chan,
Regarding the (b) (4) text on PDP for Lansoprazole 15mg OTC (ANDA 202194), if we change to '**24 Hour**' instead, would that be acceptable? I know you are waiting for New Drug Division to comment, but we just wanted to run the alternative text by you.

Regards

Reena Zade

Dr Reddy's Laboratories Inc.
200 Somerset Corporate Blvd, Floor 7
Bridgewater NJ 08807
Ph: 908-203-4908
Email: rzade@drreddys.com

From: Park, Chan H
Sent: Thursday, February 16, 2012 10:09 AM
To: 'rzade@drreddys.com'
Cc: Park, Chan H
Subject: RE: Email Address
Importance: High

Hi Reena,

It was confirmed that the term (b) (4) is a part of the RLD's proprietary name. However, we are not sure that the term (b) (4) is protected by the patent or not. Since your proposal does not include the term (b) (4) directly in association with your drug product name, it may be acceptable to include this term as proposed by you provided that it is not protected. I agree that it would be better to use the term "24 Hour" on container and carton rather than (b) (4) although we are not convinced that the inclusion of this term would be beneficial to the customers as they would not know what it means. I will leave the decision up to your discretion. Please let me know whether you would submit the labeling amendment in response to this email or not. Thanks, Chan

13. Regarding potential safety issue associated with PPIs (Proton Pump Inhibitors), see below email. This safety information was posted in the MedWatch website on 2/8/2012.

From: Lee, Koung U
Sent: Thursday, February 09, 2012 12:33 PM
To: 'Valerie Gallagher'; Park, Chan H
Cc: (b) (6) Park, Sarah Soojung; (b) (6)
Subject: RE: ANDA 202319 - Lansoprazole OTC Capsules - Safety Announcement

Hi Valerie,

We do not know how this will affect your application. We will communicate to you as soon as possible if additional changes are needed.

Koung

From: Valerie Gallagher [mailto:Valerie.Gallagher@perrigo.com]
Sent: Thursday, February 09, 2012 11:02 AM
To: Park, Chan H
Cc: Lee, Koung U; (b) (6) Park, Sarah Soojung; Valerie Gallagher; (b) (6)
Subject: RE: ANDA 202319 - Lansoprazole OTC Capsules - Safety Announcement
Importance: High

We are ready to file our response. You should receive it later today.

I have an urgent request. Please comment on the impact to Perrigo's final printed labeling being submitted today in light of FDA's Safety Communication issued this morning (See below). Will we be allowed to gain approval and launch as submitted? Please advise as soon as possible.

Thanks,
Valerie

FDA Drug Safety Communication: *Clostridium difficile*-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)

Safety Announcement

[02-08-2012] The U.S. Food and Drug Administration (FDA) is informing the public that the use of stomach acid drugs known as proton pump inhibitors (PPIs) may be associated with an increased risk of *Clostridium difficile*–associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve.

Patients should immediately contact their healthcare professional and seek care if they take PPIs and develop diarrhea that does not improve.

Clostridium difficile (C. difficile) is a bacterium that can cause diarrhea that does not improve.[1] Symptoms include watery stool, abdominal pain, and fever, and patients may go on to develop more serious intestinal conditions. The disease can also be spread in the hospital. Factors that may predispose an individual to developing CDAD include advanced age, certain chronic medical conditions, and taking broad spectrum antibiotics. Treatment for CDAD includes the replacement of fluids and electrolytes and the use of special antibiotics.

Facts about Proton Pump Inhibitor (PPI) Drugs

- Marketed under various brand and generic drug names (see Tables 1 and 2) as prescription and over-the-counter (OTC) products.
- Work by reducing the amount of acid in the stomach.
- Prescription PPIs are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus.
- Over-the-counter PPIs are used to treat frequent heartburn.

The FDA is working with manufacturers to include information about the increased risk of CDAD with use of PPIs in the drug labels.

FDA is also reviewing the risk of CDAD in users of histamine H_2 receptor blockers. H_2 receptor blockers are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and heartburn. H_2 receptor blockers are marketed under various brand and generic drug names (see Tables 3 and 4) as prescription and OTC products.

Today's communication is in keeping with FDA's commitment to inform the public about the Agency's ongoing safety review of drugs. FDA will communicate any new information on PPIs or H_2 receptor blockers and the risk of CDAD when it becomes available.

Additional Information for Patients and OTC Consumers:

- Seek immediate care if you use PPIs and develop diarrhea that does not improve. This may be a sign of *Clostridium difficile*–associated diarrhea (CDAD).
- Your healthcare professional may order laboratory tests to check if you have CDAD.
- Do not stop taking your prescription PPI drug without talking to your healthcare professional.
- Discuss any questions or concerns about your PPI drug with your healthcare professional.
- If you take an OTC PPI drug, follow the directions on the package carefully.

- Report any side effects you experience to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of the page.

Additional Information for Healthcare Professionals

- A diagnosis of CDAD should be considered for PPI users with diarrhea that does not improve.
- Advise patients to seek immediate care from a healthcare professional if they experience watery stool that does not go away, abdominal pain, and fever while taking PPIs.
- Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.
- Report adverse events involving PPIs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Data Summary

FDA has reviewed reports from the FDA's Adverse Event Reporting System (AERS) and the medical literature for cases of *Clostridium difficile*-associated diarrhea (CDAD) in patients undergoing treatment with PPIs. Many of the adverse event reports involved patients who were elderly, had chronic and/or concomitant underlying medical conditions, or were taking broad spectrum antibiotics that could have predisposed them to developing CDAD. Although these factors could have increased their risk of CDAD, the role of PPI use cannot be definitively ruled out in these reviewed reports. Patients who have one or more of these risk factors may have serious outcomes from CDAD with concomitant PPI use.

FDA also reviewed a total of 28 observational studies described in 26 publications. Twenty-three of the studies showed a higher risk of *C. difficile* infection or disease, including CDAD, associated with PPI exposure compared to no PPI exposure.[2-27] Although the strength of the association varied widely from study to study, most studies found that the risk of *C. difficile* infection or disease, including CDAD, ranged from 1.4 to 2.75 times higher among patients with PPI exposure compared to those without PPI exposure. In the five studies that provided information on clinical outcomes, colectomies, and rarely deaths, were reported in some patients [4,6,11,12,21]

The published studies varied in their ability to assess the association between *C. difficile* infection or CDAD and prior PPI use. There were limited data on the relationship between the risk of *C. difficile* infection or CDAD and PPI dose and duration of use. There also was little information on the use of OTC PPIs in community settings in these studies. Nevertheless, the weight of evidence suggests a positive association between the use of PPIs and *C. difficile* infection and disease, including CDAD.

Table 1: Prescription Proton Pump Inhibitor (PPI) Drugs

Generic name	Found in brand name(s)
dexlansoprazole	Dexilant
esomeprazole magnesium	Nexium
esomeprazole magnesium and naproxen	Vimovo
lansoprazole	Prevacid
omeprazole	Prilosec
omeprazole and Sodium bicarbonate	Zegerid
pantoprazole sodium	Protonix
rabeprazole sodium	AcipHex

Table 2: Over-the-Counter (OTC) Proton Pump Inhibitor (PPI) Drugs

Generic name	Found in brand name(s)
lansoprazole	Prevacid 24HR

Generic name	Found in brand name(s)
omeprazole magnesium	Prilosec OTC
omeprazole and sodium bicarbonate	Zegerid OTC
omeprazole	Omeprazole

Table 3: Prescription H_2 Receptor Blocker Drugs

Generic name	Found in brand name(s)
cimetidine	Tagamet
famotidine	Pepcid, Duexis
nizatidine	Axid, Nizatidine
ranitidine	Zantac, Tritec

Table 4: Over-the-Counter (OTC) H_2 Receptor Blocker Drugs

Generic name	Found in brand name(s)
cimetidine	Tagamet HB
famotidine	Pepcid Complete, Pepcid AC
nizatidine	Axid AR
ranitidine	Zantac

-

Related Information

- FDA Drug Safety Podcast for Healthcare Professionals: *Clostridium difficile*-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)[1]
  2/8/2012
- Proton Pump Inhibitors Information

Contact FDA
1-800-332-1088
1-800-FDA-0178 Fax
Report a Serious Problem

MedWatch Online[3]

Regular Mail: Use postage-paid FDA Form 3500[4]

Mail to: MedWatch 5600 Fishers Lane

Rockville, MD 20857

Date of Review: 2/10/2012 **Date of Submission: 2/9/2012**

Primary Reviewer: Chan Park **Date:**

Team Leader: Koung Lee **Date:**

C:\Documents and Settings\parkc\My Documents\202194.AP.L.doc

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHAN H PARK
03/09/2012

KOUNG U LEE
03/09/2012
For Wm. Peter Rickman

MEMORANDUM

ANDA: 202194
DRUG PRODUCT: Lansoprazole D-R Capsules USP, 15 mg (OTC)
APPLICANT : Dr. Reddy's Laboratories Limited
REVIEWER: Chan Park
DATE: April 10, 2012

This is an addendum to the labeling review of March 9, 2012. The sponsor revised the capsule colors and imprinting code of the capsules in the amendment of December 2, 2012. The change is as follows:

Original Proposal – [redacted] (b) (4)

Revised proposal - Empty Hard Gelatin capsules o Size "3" (Opaque pink colored cap and Opaque green colored body, imprinted "RDY" on cap and "398" on body with white ink)

The revised Components of Drug product is as follows;

Components

1. Lansoprazole USP [redacted] (b) (4)
2. Magnesium Carbonate USP [redacted] (b) (4)
3. Low substituted hydroxypropyl cellulose [redacted] (b) (4) NF
4. Sucrose NF
5. Starch NF (Com Starch)
6. Hydroxypropyl Cellulose NF [redacted] (b) (4)
7. Sugar Spheres NF [redacted] (b) (4)
8. [redacted] (b) (4)
9. Methacrylic acid copolymer dispersion NF [redacted] (b) (4)
10. Polyethylene Glycol 6000 NF
11. Talc USP
12. Titanium dioxide USP
13. Polysorbate 80 NF
14. Empty Hard Gelatin Capsules Size '3' opaque pink colored cap and opaque green colored body, imprinted 'RDY' on cap and '398' on body with white ink*.
15. Gelatin NF [redacted] (b) (4)
16. Ferraso ferric oxide (Iron Oxide, Black)

[redacted] (b) (4)

* Qualitative and Quantitative Composition of Capsule Shell and the imprinting ink [redacted] (b) (4) used for printing on the Cap has been enclosed herewith:

The labeling reviewed on March 9, 2012 reflects the revised components accurately. However, in the FTR, the sections of "Description of the Finished Drug Product" and "Listing of Inactive Ingredients" were not updated to reflect the amendment, rather contains the original proposal. These sections should have been revised accordingly to reflect the amendment of December 2, 2011.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHAN H PARK
04/10/2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

CHEMISTRY REVIEWS

ANDA 202194

Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

Dr. Reddy's Laboratories Ltd.

Bhagwant Rege, Ph.D.
Division of Chemistry II

Table of Contents

Chemistry Review Data Sheet

1. ANDA #: 202194

2. REVIEW #: 1

3. REVIEW DATE: 6/8/2011

4. REVIEWER: Bhagwant Rege, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Document(s)	Document Date
NA	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	8/9/2010
Amendment	10/22/2010
Amendment	11/03/2010
Amendment	01/17/2011

7. NAME & ADDRESS OF APPLICANT:

Name:	Dr. Reddy's Laboratories Ltd. (US Agent: Dr. Reddy's Laboratories, Inc.)
Address:	200 Somerset Corporate Blvd, 7th Floor, Bridgewater, NJ 08807
Representative:	Kumara Sekar, Ph. D.
Telephone:	908-203-4937

Fax: 908-203-4980

Email: ksekar@drreddys.com

8. DRUG PRODUCT NAME/CODE/TYPE:

Proprietary Name: NA
Non-Proprietary Name (USAN): Lansoprazole Delayed Release Capsules USP

- Chem. Type: NA
- Submission Priority: NA

9. LEGAL BASIS FOR SUBMISSION:

RLD: PREVACID® 24 HOUR (Lansoprazole) Delayed-Release Capsules, 15 mg
NDA Holder: Novartis (NDA# 022327).

Please note the RLD, NDA 022327 is OTC version of NDA 20-406 (Lansoprazole Delayed-Release Capsules).

There are no unexpired patents for the RLD in the Orange Book Database.

The applicant also certifies that they won't launch the generic product until expiration of the New Product (NP) exclusivity for the RLD on May 18, 2012.

10. PHARMACOL. CATEGORY: Anti-ulcer agent

11. DOSAGE FORM: Delayed Release Capsules

12. STRENGTH/POTENCY: 15 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: ___Rx _x__OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

___x___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

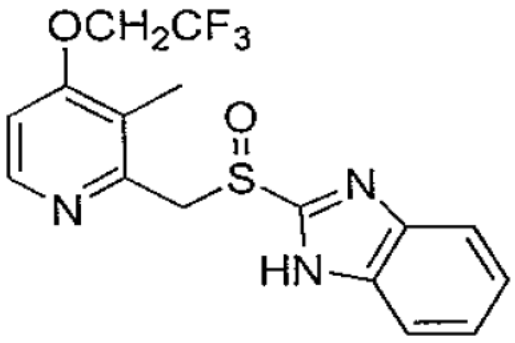
Generic Name : Lansoprazole

Chemical Name : 1H-Benzimidazole,2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfiny]

2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfinyl] benzimidazole

C.A.S Registry No. : [103577-45-3]

Structural Formula :



Molecular Formula : $C_{16}H_{14}F_3N_3O_2S$

Molecular Weight : 369.4

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
21426	II	Dr. Reddy's	Lansoprazole USP	1	Adequate	06/08/2011	B. Rege
(b) (4)	IV		(b) (4)	4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		

(b) (4)	III	(b) (4)	4	NA		
	III		4	NA		

Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 –Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	022327	RLD
ANDA	091269	Prescription version of the OTC ANDA product being reviewed.
NDA	020406	Prescription version of the RLD NDA

18. STATUS

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER

Microbiology	NA		
EES	Acceptable	02/11/2011	
Methods Validation	NA		
Labeling	Pending		
Bioequivalence	Acceptable	05/20/2011	P. Ren
EA	Categorical Exclusion		
Radiopharmaceutical	NA		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __x__ Yes ____ No If no, explain reason(s) below:

Chemistry Review for ANDA 202194

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Not approvable based on MINOR deficiencies.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

NA

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Lansoprazole drug substance and Lansoprazole Delayed-Release Capsules are official in the USP.

Lansoprazole is a white to brownish white powder with a molecular weight of 369.4. It is freely soluble in DMF and practically insoluble in water. The pH of 1% aqueous solution is 5.49 and the pKa is 9.94.

Each Lansoprazole capsule (OTC) intended for oral administration contains Lansoprazole 15 mg, magnesium carbonate, L-HPC, sucrose, starch, HPC (b) (4), (b) (4) PEG 6000, talc, titanium dioxide, polysorbate 80, and sugar spheres filled into a size 3 hard gelatin capsule. The capsules are banded using a gelatin band which contains gelatin (b) (4), polysorbate 80, ferric oxide, and titanium dioxide. The drug product is proposed to be packaged in HDPE bottles with desiccant (b) (4)

B. Description of How the Drug Product is Intended to be Used

Lansoprazole Delayed Release Capsule USP, 15 mg (OTC) is indicated for the treatment of frequent heartburn. One capsule is to be swallowed with a

glass of water before eating in the morning for 14 days. The MDD for this product is 15 mg.

Basis for Approvability or Not-Approval Recommendation

There application is not approvable due to minor deficiencies. The prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg (ANDA # 91-269) was approved by the Agency on 10/15/2010. The formulation and manufacturing process is same for both the prescription and OTC drug product manufactured by Dr. Reddy's Laboratories Limited. The only difference between these two drug products is (b) (4) Drug substance used in the Rx ANDA and the proposed ANDA by Dr. Reddy's is same (Drug substance has been manufactured with same route of synthesis, same facility and from the same manufacturer/source of supply, DMF # 21426). A common pellets batch for prescription drug product-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg of batch size (b) (4) has been executed. Based on the approved deviation, an amount of (b) (4) has been utilized for capsule filling followed by capsule banding for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) and the remaining quantity of (b) (4) has been utilized for prescription drug product. The data enclosed in this summary is same as that has been submitted for prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg, which has been provided again for ready reference to the agency. Updated information related to drug substance part and the relevant data at each stage related to the capsule banding part has also been provided in this summary.

Chemistry Assessment

(b) (4)

Following this page, 66 pages withheld in full (b)(4)

III. List Of Deficiencies To Be Communicated

CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 202194

APPLICANT: Dr. Reddy's Laboratories Ltd.

DRUG PRODUCT: Lansoprazole Delayed Release Capsules USP, 15 mg

The deficiencies presented below represent **MINOR** deficiencies.

Drug Substance

1. We recommend that you qualify (b) (4)

Drug Product

2. (b) (4)
3.
4.
5.

Following this page, 2 pages withheld in full (b)(4)

- Please clarify how you calculate the expiration date of your product (b) (4) [redacted]
- Please provide the updated long term stability data.
- Please provide samples of the ANDA product along with the RLD. The samples should be sent to the attention of Dr. Frank J. Nice, HFD-645, FDA, CDER-OGD, 7500 Standish Place, Rockville, MD 20855

Sincerely yours,

{See appended electronic signature}

Glen J. Smith
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

Endorsements:

Chemist/ Bhagwant Rege / 06/21/2011 / 08/05/2011
Team Leader/ Radhika Rajagopalan/Yanping Pan for RRajagopalan/ 8/5/11 (after tertiary concurrence)
Project Manager/ Frank Nice /8/5/11

NA- Minor

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BHAGWANT D REGE
08/07/2011

FRANK J NICE
08/08/2011

RADHIKA RAJAGOPALAN
08/08/2011

ANDA 202194

Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

Dr. Reddy's Laboratories Ltd.

Bhagwant Rege, Ph.D.
Division of Chemistry II

Table of Contents

There appears to be a numbering error. This is Chemistry Review #2.

Chemistry Review Data Sheet

1. ANDA #: 202194

2. REVIEW #: 2

3. REVIEW DATE: 12/27/2011

4. REVIEWER: Bhagwant Rege, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Document(s)	Document Date
Original	8/9/2010
Amendment	10/22/2010
Amendment	11/03/2010
Amendment	01/17/2011

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Amendment	12/02/2011
Amendment	12/13/2011

7. NAME & ADDRESS OF APPLICANT:

Name:	Dr. Reddy's Laboratories Ltd. (US Agent: Dr. Reddy's Laboratories, Inc.)
Address:	200 Somerset Corporate Blvd, 7th Floor, Bridgewater, NJ 08807
Representative:	Kimberly Ernst
Telephone:	908-203-7022

Fax: 908-203-4980

Email: kernst@drreddys.com

8. DRUG PRODUCT NAME/CODE/TYPE:

Proprietary Name: NA
Non-Proprietary Name (USAN): Lansoprazole Delayed Release Capsules USP

- Chem. Type: NA
- Submission Priority: NA

9. LEGAL BASIS FOR SUBMISSION:

RLD: PREVACID® 24 HOUR (Lansoprazole) Delayed-Release Capsules, 15 mg
NDA Holder: Novartis (NDA# 022327).

Please note the RLD, NDA 022327 is OTC version of NDA 20-406 (Lansoprazole Delayed-Release Capsules).

There are no unexpired patents for the RLD in the Orange Book Database.

The applicant also certifies that they won't launch the generic product until expiration of the New Product (NP) exclusivity for the RLD on May 18, 2012.

10. PHARMACOL. CATEGORY: Anti-ulcer agent

11. DOSAGE FORM: Delayed Release Capsules

12. STRENGTH/POTENCY: 15 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: ___Rx _x__OTC

15a. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__x__Not a SPOTS product

15b. NANO TECHNOLOGY (ON-LINE TRACKING):

NANO product – Form Completed

__x__Not a Nano product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

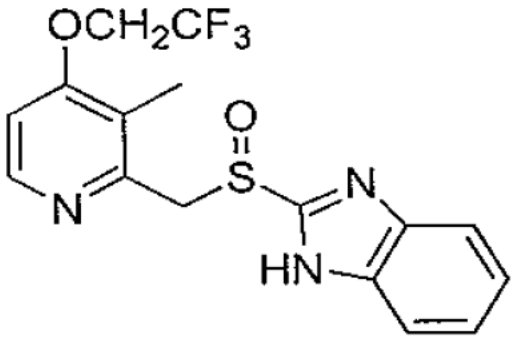
Generic Name : Lansoprazole

Chemical Name : 1H-Benzimidazole,2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfiny]

2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfinyl] benzimidazole

C.A.S Registry No. : [103577-45-3]

Structural Formula :



Chemistry Review Data Sheet

Molecular Formula	:	$C_{16}H_{14}F_3N_3O_2S$
Molecular Weight	:	369.4

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
21426	II	Dr. Reddy's	Lansoprazole USP	1	Adequate	1/4/2012	B. Rege
(b) (4)	IV		(b) (4)	4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		

(b) (4)	III	(b) (4)	4	NA		
	III		4	NA		

[1] Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 –Type 1 DMF

3 – Reviewed previously and no revision since last review

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5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	022327	RLD
ANDA	091269	Prescription version of the OTC ANDA product being reviewed.
NDA	020406	Prescription version of the RLD NDA

18. STATUS

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER

Microbiology	NA		
EES	Pending	1/6/12	
Methods Validation	NA		
Labeling	Pending		
Bioequivalence	Acceptable	05/20/2011	P. Ren
EA	Categorical Exclusion		
Radiopharmaceutical	NA		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __x__ Yes ____ No If no, explain reason(s) below:

Chemistry Review for ANDA 202194

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Not approvable based on MINOR deficiencies.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

NA

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Lansoprazole drug substance and Lansoprazole Delayed-Release Capsules are official in the USP.

Lansoprazole is a white to brownish white powder with a molecular weight of 369.4. It is freely soluble in DMF and practically insoluble in water. The pH of 1% aqueous solution is 5.49 and the pKa is 9.94.

Each Lansoprazole capsule (OTC) intended for oral administration contains Lansoprazole 15 mg, magnesium carbonate, L-HPC, sucrose, starch, HPC (b) (4) (b) (4) PEG 6000, talc, titanium dioxide, polysorbate 80, and sugar spheres filled into a size 3 hard gelatin capsule. The capsules are banded using a gelatin band which contains gelatin (b) (4), polysorbate 80, ferric oxide, and titanium dioxide. The drug product is proposed to be packaged in HDPE bottles with desiccant (b) (4).

B. Description of How the Drug Product is Intended to be Used

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glass of water before eating in the morning for 14 days. The MDD for this product is 15 mg.

Basis for Approvability or Not-Approval Recommendation

There application is not approvable due to minor deficiencies. The prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg (ANDA # 91-269) was approved by the Agency on 10/15/2010. The formulation and manufacturing process is same for both the prescription and OTC drug product manufactured by Dr. Reddy's Laboratories Limited. The only difference between these two drug products is (b) (4) Drug substance used in the Rx ANDA and the proposed ANDA by Dr. Reddy's is same (Drug substance has been manufactured with same route of synthesis, same facility and from the same manufacturer/source of supply, DMF # 21426). A common pellets batch for prescription drug product-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg of batch size (b) (4) has been executed. Based on the approved deviation, an amount of (b) (4) has been utilized for capsule filling followed by capsule banding for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) and the remaining quantity of (b) (4) has been utilized for prescription drug product. The data enclosed in this summary is same as that has been submitted for prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg, which has been provided again for ready reference to the agency. Updated information related to drug substance part and the relevant data at each stage related to the capsule banding part has also been provided in this summary.

Following this page, 73 pages withheld in full (b)(4)

(b) (4)

[redacted]

R REGIONAL INFORMATION

R.1 Executed Batch Records: Reviewed.

R.2 Comparability Protocols: N/A.

R.3 Methods Validation Package: Reviewed.
These were presented earlier in Section S.4.3 and P.5.3.

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1

A. Labeling & Package Insert: Review pending.

B. Environmental Assessment Or Claim Of Categorical Exclusion

The applicant provided a categorical exclusion request in Section 1.12.14.

III. List Of Deficiencies To Be Communicated

CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 202194

APPLICANT: Dr. Reddy's Laboratories Ltd.

DRUG PRODUCT: Lansoprazole Delayed Release Capsules USP, 15 mg

The deficiencies presented below represent **MINOR** deficiencies.

Drug Product

1. You have proposed to [redacted] (b) (4)

2. Your response indicating that [redacted] (b) (4)

3. Please justify [redacted] (b) (4) .

4. We recommend that you [redacted] (b) (4)

5. You have indicated that microbial limit test at stability will be performed as per stability protocol. Please provide an updated stability protocol that includes in a tabular form the tests, criteria, and stability time points, including microbial limits. Please also provide the updated long term stability data with the microbial limit test results.

6. Please provide drug product analytical method transfer reports to your alternate site in (b) (4).

7. You have proposed (b) (4) .

Sincerely yours,

{See appended electronic signature}

Glen J. Smith
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

Endorsements:

Chemist/ Bhagwant Rege / 01/03/2012
Team Leader/ Radhika Rajagopalan/1/5/2012
Project Manager/ Frank Nice/1/9/12

NA- Minor

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BHAGWANT D REGE
01/09/2012

FRANK J NICE
01/09/2012

RADHIKA RAJAGOPALAN
01/09/2012

ANDA 202194

Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

Dr. Reddy's Laboratories Ltd.

Bhagwant Rege, Ph.D.
Division of Chemistry II

Table of Contents

Chemistry Review Data Sheet

1. ANDA #: 202194

2. REVIEW #: 3

3. REVIEW DATE: 02/24/2012, 3/5/2012

4. REVIEWER: Bhagwant Rege, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Document(s)	Document Date
Original	8/9/2010
Amendment	10/22/2010
Amendment	11/03/2010
Amendment	01/17/2011
Amendment	12/02/2011
Amendment	12/13/2011
T-deficiency	3/2/2012

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Telephone Amendment	03/05/2012
Amendment	02/09/2012
Amendment	01/25/2012

7. NAME & ADDRESS OF APPLICANT:

Name:	Dr. Reddy's Laboratories Ltd. (US Agent: Dr. Reddy's Laboratories, Inc.)
Address:	200 Somerset Corporate Blvd, 7th Floor, Bridgewater, NJ 08807

Representative: Kimberly Ernst

Telephone: 908-203-7022

Fax: 908-203-4980

Email: kernst@drreddys.com

8. DRUG PRODUCT NAME/CODE/TYPE:

Proprietary Name: NA
Non-Proprietary Name (USAN): Lansoprazole Delayed Release Capsules USP

- Chem. Type: NA
- Submission Priority: NA

9. LEGAL BASIS FOR SUBMISSION:

RLD: PREVACID® 24 HOUR (Lansoprazole) Delayed-Release Capsules, 15 mg
NDA Holder: Novartis (NDA# 022327).

Please note the RLD, NDA 022327 is OTC version of NDA 20-406 (Lansoprazole Delayed-Release Capsules).

There are no unexpired patents for the RLD in the Orange Book Database.

The applicant also certifies that they won't launch the generic product until expiration of the New Product (NP) exclusivity for the RLD on May 18, 2012.

10. PHARMACOL. CATEGORY: Anti-ulcer agent

11. DOSAGE FORM: Delayed Release Capsules

12. STRENGTH/POTENCY: 15 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: ___Rx _x__OTC

15a. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

___x___Not a SPOTS product

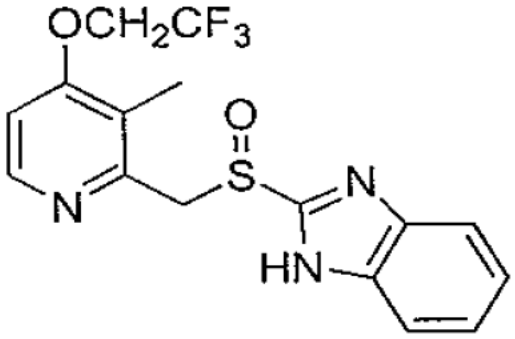
15b. NANO TECHNOLOGY (ON-LINE TRACKING):

NANO product – Form Completed

___x___Not a Nano product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Generic Name	:	Lansoprazole
Chemical Name	:	1H-Benzimidazole,2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfiny] 2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfinyl] benzimidazole
C.A.S Registry No.	:	[103577-45-3]
Structural Formula	:	



Molecular Formula	:	$C_{16}H_{14}F_3N_3O_2S$
Molecular Weight	:	369.4

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
21426	II	Dr. Reddy's	Lansoprazole USP	1	Adequate	1/4/2012	B. Rege
(b) (4)	IV		(b) (4)	4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		

(b) (4)	III	(b) (4)	4	NA		
	III		4	NA		

Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 –Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	022327	RLD
ANDA	091269	Prescription version of the OTC ANDA product being reviewed.
NDA	020406	Prescription version of the RLD NDA

18. STATUS

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER

Microbiology	NA		
EES	Pending	2/29/12	
Methods Validation	NA		
Labeling	Deficient; see AP summary	02/14/2012	C. Park
Bioequivalence	Acceptable	05/20/2011	P. Ren
EA	Categorical Exclusion		
Radiopharmaceutical	NA		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __x__ Yes ____ No If no, explain reason(s) below:

Chemistry Review for ANDA 202194

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Approvable pending revision of in-process specification.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

NA

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Lansoprazole drug substance and Lansoprazole Delayed-Release Capsules are official in the USP.

Lansoprazole is a white to brownish white powder with a molecular weight of 369.4. It is freely soluble in DMF and practically insoluble in water. The pH of 1% aqueous solution is 5.49 and the pKa is 9.94.

Each Lansoprazole capsule (OTC) intended for oral administration contains Lansoprazole 15 mg, magnesium carbonate, L-HPC, sucrose, starch, HPC (b) (4), (b) (4) PEG 6000, talc, titanium dioxide, polysorbate 80, and sugar spheres filled into a size 3 hard gelatin capsule. The capsules are banded using a gelatin band which contains gelatin (b) (4) polysorbate 80, ferric oxide, and titanium dioxide. The drug product is proposed to be packaged in HDPE bottles with desiccant (b) (4)

B. Description of How the Drug Product is Intended to be Used

Lansoprazole Delayed Release Capsule USP, 15 mg (OTC) is indicated for the treatment of frequent heartburn. One capsule is to be swallowed with a

glass of water before eating in the morning for 14 days. The MDD for this product is 15 mg.

Basis for Approvability or Not-Approval Recommendation

There application is approvable for CMC. The prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg (ANDA # 91-269) was approved by the Agency on 10/15/2010. The formulation and manufacturing process is same for both the prescription and OTC drug product manufactured by Dr. Reddy's Laboratories Limited. The only difference between these two drug products is (b) (4) . Drug substance used in the Rx ANDA and the proposed ANDA by Dr. Reddy's is same (Drug substance has been manufactured with same route of synthesis, same facility and from the same manufacturer/source of supply, DMF # 21426). A common pellets batch for prescription drug product-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg of batch size (b) (4) has been executed. Based on the approved deviation, an amount of (b) (4) has been utilized for capsule filling followed by capsule banding for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) and the remaining quantity of (b) (4) has been utilized for prescription drug product. The data enclosed in this summary is same as that has been submitted for prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg, which has been provided again for ready reference to the agency. Updated information related to drug substance part and the relevant data at each stage related to the capsule banding part has also been provided in this summary.

CMC is completed.

Following this page, 74 pages withheld in full (b)(4)

(b) (4)

[redacted]

R REGIONAL INFORMATION

R.1 Executed Batch Records: Reviewed.

R.2 Comparability Protocols: N/A.

R.3 Methods Validation Package: Reviewed.
These were presented earlier in Section S.4.3 and P.5.3.

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1

A. Labeling & Package Insert: Review pending.

B. Environmental Assessment Or Claim Of Categorical Exclusion

The applicant provided a categorical exclusion request in Section 1.12.14.

III. List Of Deficiencies To Be Communicated

None

Endorsements:

Chemist/ Bhagwant Rege / 03/07/2012
Team Leader/ Radhika Rajagopalan/3/8/2012
Project Manager/ Frank Nice/ 3/8/12

CMC acceptable.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BHAGWANT D REGE
03/08/2012

RADHIKA RAJAGOPALAN
03/08/2012

FRANK J NICE
03/08/2012

ANDA 202194

Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

Dr. Reddy's Laboratories Ltd.

Bhagwant Rege, Ph.D.
Division of Chemistry II

Table of Contents

Chemistry Review Data Sheet

1. ANDA #: 202194

2. REVIEW #: 3a

3. REVIEW DATE: 04/09/2012

4. REVIEWER: Bhagwant Rege, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Document(s)	Document Date
Original	8/9/2010
Amendment	10/22/2010
Amendment	11/03/2010
Amendment	01/17/2011
Amendment	12/02/2011
Amendment	12/13/2011
Amendment	02/09/2012
Amendment	01/25/2012

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Telephone Amendment	03/05/2012

7. NAME & ADDRESS OF APPLICANT:

Name:	Dr. Reddy's Laboratories Ltd. (US Agent: Dr. Reddy's Laboratories, Inc.)
Address:	200 Somerset Corporate Blvd, 7th Floor, Bridgewater, NJ 08807

Representative: Kimberly Ernst

Telephone: 908-203-7022

Fax: 908-203-4980

Email: kernst@drreddys.com

8. DRUG PRODUCT NAME/CODE/TYPE:

Proprietary Name: NA
Non-Proprietary Name (USAN): Lansoprazole Delayed Release Capsules USP

- Chem. Type: NA
- Submission Priority: NA

9. LEGAL BASIS FOR SUBMISSION:

RLD: PREVACID® 24 HOUR (Lansoprazole) Delayed-Release Capsules, 15 mg
NDA Holder: Novartis (NDA# 022327).

Please note the RLD, NDA 022327 is OTC version of NDA 20-406 (Lansoprazole Delayed-Release Capsules).

There are no unexpired patents for the RLD in the Orange Book Database.

The applicant also certifies that they won't launch the generic product until expiration of the New Product (NP) exclusivity for the RLD on May 18, 2012.

10. PHARMACOL. CATEGORY: Anti-ulcer agent

11. DOSAGE FORM: Delayed Release Capsules

12. STRENGTH/POTENCY: 15 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: ___Rx _x__OTC

15a. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

___x___Not a SPOTS product

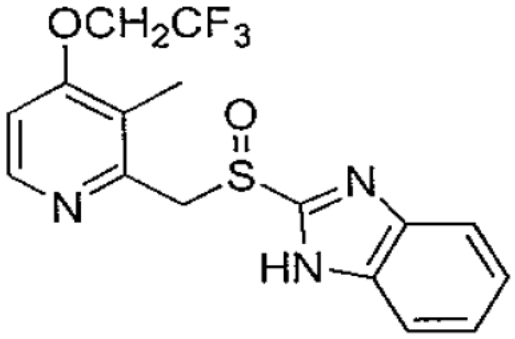
15b. NANO TECHNOLOGY (ON-LINE TRACKING):

NANO product – Form Completed

___x___Not a Nano product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Generic Name	:	Lansoprazole
Chemical Name	:	1H-Benzimidazole,2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfiny] 2-[[[3-methyl-4-(2,2,2-trifluro-ethoxy)-2-pyridinyl] methyl] sulfinyl] benzimidazole
C.A.S Registry No.	:	[103577-45-3]
Structural Formula	:	



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	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		
	III			4	NA		

(b) (4)	III	(b) (4)	4	NA		
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DOCUMENT	APPLICATION NUMBER	DESCRIPTION
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18. STATUS

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER

Microbiology	NA		
EES	Pending	2/29/12	
Methods Validation	NA		
Labeling	Acceptable	03/09/2012	C. Park
Bioequivalence	Acceptable	05/20/2011	P. Ren
EA	Categorical Exclusion		
Radiopharmaceutical	NA		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __x__ Yes ____ No If no, explain reason(s) below:

Chemistry Review for ANDA 202194

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Approvable. The firm has provided adequate response to the telephone deficiency on 3/5/2012.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

NA

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Lansoprazole drug substance and Lansoprazole Delayed-Release Capsules are official in the USP.

Lansoprazole is a white to brownish white powder with a molecular weight of 369.4. It is freely soluble in DMF and practically insoluble in water. The pH of 1% aqueous solution is 5.49 and the pKa is 9.94.

Each Lansoprazole capsule (OTC) intended for oral administration contains Lansoprazole 15 mg, magnesium carbonate, L-HPC, sucrose, starch, HPC (b) (4), (b) (4) PEG 6000, talc, titanium dioxide, polysorbate 80, and sugar spheres filled into a size 3 hard gelatin capsule. The capsules are banded using a gelatin band which contains gelatin (b) (4), polysorbate 80, ferric oxide, and titanium dioxide. The drug product is proposed to be packaged in HDPE bottles with desiccant (b) (4)

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glass of water before eating in the morning for 14 days. The MDD for this product is 15 mg.

Basis for Approvability or Not-Approval Recommendation

There application is approvable for CMC. The prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg (ANDA # 91-269) was approved by the Agency on 10/15/2010. The formulation and manufacturing process is same for both the prescription and OTC drug product manufactured by Dr. Reddy's Laboratories Limited. The only difference between these two drug products is (b) (4) . Drug substance used in the Rx ANDA and the proposed ANDA by Dr. Reddy's is same (Drug substance has been manufactured with same route of synthesis, same facility and from the same manufacturer/source of supply, DMF # 21426). A common pellets batch for prescription drug product-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg of batch size (b) (4) has been executed. Based on the approved deviation, an amount of (b) (4) has been utilized for capsule filling followed by capsule banding for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) and the remaining quantity of (b) (4) has been utilized for prescription drug product. The data enclosed in this summary is same as that has been submitted for prescription ANDA-Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg, which has been provided again for ready reference to the agency. Updated information related to drug substance part and the relevant data at each stage related to the capsule banding part has also been provided in this summary.

CMC is acceptable. This is an addendum to CR#3.

The applicant has provided side by side comparison of in process specification for capsule weights of Rx product and OTC product. The limits are similar and acceptable. The applicant also clarified that "actual" capsule weight mentioned in the specification is the target weight adjusted for assay. The applicant is currently maintaining these in process limits in approved Rx product as per their in house SOP in the batch records. Therefore, it is also acceptable for the OTC product (with concurrence from Glen Smith, Division Director).

The final drug product release specifications are given below.

Following this page, 2 pages withheld in full (b)(4)

III. List Of Deficiencies To Be Communicated

None

Endorsements:

Chemist/ Bhagwant Rege / 04/09/2012
Team Leader/ Radhika Rajagopalan/4/9/2012

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BHAGWANT D REGE
04/09/2012

RADHIKA RAJAGOPALAN
04/09/2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

BIOEQUIVALENCE REVIEW

DIVISION OF BIOEQUIVALENCE REVIEW

ANDA No.	202194
Drug Product Name	Lansoprazole Delayed-Release Capsules USP (OTC)
Strength(s)	15 mg
Applicant Name	Dr. Reddy's Laboratories Limited
Address	Bachepally-502 325 India
Applicant's Point of Contact	Kumara Sekar Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd, 7th Floor Bridgewater, NJ 0880
Contact's Telephone Number	908-203-4937
Contact's Fax Number	908-203-4980
Original Submission Date(s)	09/08/2010
Submission Date(s) of Amendment(s) Under Review	05/03/2011 (Amendment for the dissolution data of acid stage in the 15 mg of test and reference OTC)
Reviewer	Ping Ren, Ph.D.

Study Number (s)	**N/A**		
Study Type (s)	Waiver (based on BE studies submitted in ANDA 91269)		
Strength(s)	**15 mg (OTC)**		
OVERALL REVIEW RESULT	**ADEQUATE**		
BIOEQUIVALENCE STUDY TRACKING/SUPPORTING DOCUMENT #	**STUDY/TEST TYPE**	**STRENGTH**	**REVIEW RESULT**
2	**DISSOLUTION**	15 mg	**ADEQUATE**
1	**FORMULATION**	15 mg	**ADEQUATE**
1	**FASTING STUDY**	30 mg in ANDA 91269	**ADEQUATE**
1	**FED STUDY**	30 mg in ANDA 91269	**ADEQUATE**
1	**SPRINKLED FASTING STUDY**	30 mg in ANDA 91269	**ADEQUATE**

1 EXECUTIVE SUMMARY

Dr. Reddy submitted both Rx (15 mg and 30 mg in ANDA091269) and over-the-counter (OTC) (15 mg in ANDA202194) product lines of Lansoprazole Delayed-Release Capsules USP. In the current application in accordance with 21 CFR 320.22 (d) (2), the firm has submitted a request for a bio-waiver of in vivo bioequivalence (BE) requirement for the test product, Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) based on acceptable BE studies submitted in the sister ANDA091269 for the 30 mg strength, the comparative dissolution data and formulation proportionality between 15-mg (OTC) and 30 mg test products.

In the sister ANDA091269, the firm has submitted the fasting, fed, and sprinkled fasting BE studies on Lansoprazole Delayed-Release Capsules USP (Rx), 30 mg strength [DARRTS: REV-BIOEQ-01 (General Review) ANDA091269, Final date: 12/22/2009]. The Division of Bioequivalence (DBE) has reviewed ANDA091269 and found the fasting, fed, and sprinkled fasting BE studies on the 30 mg strength capsule to be acceptable [DARRTS: REV-BIOEQ-01 (General Review) ANDA091269, Final date: 03/24/2010]. ANDA 91269 was approved on Oct.15, 2010.

As per the DBE control review (CD# 90520) for Lansoprazole Delayed-Release Capsules (OTC), 15 mg, the firm can cross reference the acceptable BE studies on the 30 mg strength of Rx product submitted in a separate ANDA. The DBE may deem the 15 mg strength of Lansoprazole Delayed-Release Capsules (OTC) bioequivalent to the corresponding strength of the reference product (OTC) under CFR 320.24(b)(6) provided that the following criteria are met (1) acceptable in vivo BE studies on the 30 mg strength (Rx); (2) acceptable dissolution testing across all strengths; and (3) the formulation of the 15 mg strength (OTC) is proportionally similar to that of the 30 mg strength (Rx).

To support its bio-waiver request, the firm has conducted acceptable comparative dissolution testing on the 15 mg (OTC) and 30 mg strengths (Rx) using the USP method (500 mL of 0.1 N HCl at the acid stage in one hour followed by 900 mL of pH 6.8 Phosphate Buffer with 5 mM SDS at 37ºC ± 0.5ºC using USP apparatus II at 75 rpm). The firm's dissolution testing data are acceptable at A1 level (acid stage-NMT 10% in 60 minutes) and B1 level [buffer stage-NLT 80% (Q) in 60 minutes]. The Division of Bioequivalence (DBE) acknowledges that the firm will follow the USP method and specifications.

The strength of 15 mg OTC in the test product is compositionally proportional similar to the strength of 30 mg Rx. The DBE deems the 15 mg strength of Lansoprazole Delayed-Release Capsules (OTC) bioequivalent to Novartis's Prevacid® 24 HR (Lansoprazole) Delayed-Release Capsules, 15 mg (OTC) under CFR 320.24(b)(6).

The application is acceptable.

2 TABLE OF CONTENTS

3 SUBMISSION SUMMARY

3.1 Drug Product Information

Test Product	Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)
Reference Product	Prevacid® 24 HR (Lansoprazole) Delayed-Release Capsules, 15 mg (OTC)
RLD Manufacturer	Novartis
NDA No.	022327
RLD Approval Date	May 18, 2009
Indication	Over-the-counter (OTC) use. Short-term treatment of frequent heartburn (occurs 2 or more days a week) in adults aged 18 years and older.

3.2 PK/PD Information[1]

Bioavailability	Delayed-Release Oral Capsules contain an enteric-coated granule formulation of lansoprazole. Absorption of lansoprazole begins only after the granules leave the stomach. Absorption is rapid and relatively complete with absolute bioavailability over 80 %.
Food Effect	Both Cmax and AUC are diminished by about 50 % to 70% if the drug is given 30 minutes after food as opposed to the fasting condition. There is no significant food effect if the drug is given before meals.
Tmax	1.7 hrs
Metabolism	Lansoprazole is extensively metabolized in the liver through the cytochrome P450 system. Two metabolites have been identified in measurable quantities in plasma (the hydroxylated sulfinyl and sulfone derivatives of lansoprazole). These metabolites have very little or no antisecretory activity. Lansoprazole is thought to be transformed into two active species which inhibit acid secretion by (H+,K+)-ATPase within the parietal cell canaliculus, but are not present in the systemic circulation.
Excretion	Following single-dose oral administration of lansoprazole, virtually no unchanged lansoprazole was excreted in the urine. Approximately two-third of Lansoprazole metabolites may be excreted by biliary system.
Half-life	1.5 hrs
Drug Specific Issues (if any)	Animal study demonstrated that Lansoprazole produced dose-related gastric enterochromaffin-like cell (ECL) hyperplasia and ECL cell carcinoids in both sexes. No patients showed evidence of ECL cell effects similar to these observed in animal studies.

3.3 OGD Recommendations for Drug Product

Number of studies recommended:	2, fasting and fed

[1] RLD label for PREVACID® (LANSOPRAZOLE) Delayed- Release Capsule, Rx

1.	**Type of study:**	Fasting
	Design:	Single-dose, two-treatment, two-period crossover in-vivo
	Strength:	15 mg OTC [RLD: Prevacid® 24 HR (Lansoprazole) Delayed-Release Capsules, 15 mg, manufactured by Novartis Consumer Health, Inc.]
	Subjects:	Normal healthy males and females, general population
	Additional Comments:	It is evident that lansoprazole is a highly variable drug substance/product. Therefore, the firm may consider conducting bioequivalence study using a replicate design approach. Alternatively, a single-dose, randomized, three-period reference-scaled approach would also be acceptable. The reference-scaled approach adjusts the bioequivalence limits of highly variable drugs/products by scaling to the within-subject variability of the reference product in the study, and imposes a limit of 0.8 to 1.25 on the geometric mean ratio. The within-subject variability of the reference product will be determined in a 3-way modified replicate-design study in which the reference product is given twice and the test product is given once. For details on the reference-scaled approach, the firm may refer to the recently published article, Haider et al, Bioequivalence Approaches for Highly Variable Drugs and Drug Products. Pharm. Res. 25:237-241(2008). However, prior to using the alternative approach, the firm is encouraged to submit the study protocols for review by the DBE.

2.	**Type of study:**	Fed
	Design:	Single-dose, two-treatment, two-period crossover in-vivo
	Strength:	15 mg OTC (see above)
	Subjects:	Normal healthy males and females, general population
	Additional Comments:	See above

Analytes to measure (in plasma):	Only the parent drug, lansoprazole, be measured in plasma for bioequivalence studies
Bioequivalence based on:	90% CI of Lansoprazole (Cmax and AUC)
Waiver request of in-vivo testing:	If the firm will market both Rx and OTC product lines, the firm may cross reference the acceptable BE studies on the 30 mg strength of Rx product. The DBE may deem the 15 mg strength of Lansoprazole Delayed-Release Capsules (to be marketed as an OTC product) bioequivalent to the corresponding strength of the reference product (OTC) under CFR 320.24(b)(6) provided that the following criteria are met (1) acceptable in vivo BE studies on the 30 mg strength (to be marketed as a prescription drug product); (2) acceptable dissolution testing across all strengths; and (3) the formulation of the 15 mg strength (OTC) is proportionally similar to that of the 30 mg strength.

Source of most recent recommendations:	Control review: CD#90520 (b) (4). As per the DBE control review (CD#090520), the formulation of the 15 mg (OTC) reference product is the same as that of the 15 mg (Rx) reference product except minor changes in the composition of the two-piece gelatin capsules and the addition of a gelatin tamper evidence band.
Summary of OGD or DBE History (for details, see Appendix 4.3):	Presently, there is no generic product approved for the OTC lansoprazole DR capsules The Office of Generic Drugs (OGD) has received following ANDAs for Lansoprazole Delayed-Release Capsules (Rx): 77255, Teva; 90331, Sandoz; 090763, Matrix Labs; 91212, KRKA Tovarna Zdravil; 91269, Dr. Reddy's Lab; and 91509, Sun Pharma Global. The protocols received by the DBE on Lansoprazole Delayed-Release Capsules: 08061, (b) (4) 08075, (b) (4) and 09003, (b) (4) Control list for Rx product please see Appendix 4.3

3.4 Contents of Submission

Study Types	Yes/No?	How many?
Single-dose fasting	No	N/A
Single-dose fed	No	N/A
In vitro dissolution	Yes	2
Waiver requests	Yes	1
BCS Waivers	No	N/A
Amendments	Yes	1 (acid stage dissolution data)

3.5 Formulation

Location in appendix	Section 4.1, Page 9
If a tablet, is the RLD scored?	No
If a tablet, is the test product biobatch scored	No
Is the formulation acceptable?	**FORMULATION ACCEPTABLE**
If not acceptable, why?	

3.6 In Vitro Dissolution

Location of DBE Dissolution Review	DARRT: REV-BIOEQ-02 (Dissolution Review) ANDA-091269 Final date 08/13/2009 (15 mg and 30 mg Rx)
Source of Method (USP, FDA or Firm)	USP
Medium	Acid Resistance Stage: 0.1 N HCl

	Buffer Stage: pH 6.8 Phosphate Buffer with 5 mM SDS
Volume (mL)	Acid Resistance Stage: 500 mL Buffer Stage: 900 mL
USP Apparatus type	USP Apparatus Type II (Paddle)
Rotation (rpm)	75 rpm
DBE-recommended specifications	Acid Resistance Stage: NMT 10% dissolved in 60 min. Buffer Stage: NLT 80% (Q) dissolved in 60 min.
If a modified-release tablet, was testing done on ½ tablets?	No
F2 metric calculated?	No
If no, reason why F2 not calculated	Rapidly dissolved in 10 min
Is method acceptable?	**METHOD ACCEPTABLE**
If not then why?	

Comments: There is a USP method for this product. The firm's dissolution testing data with the USP method are acceptable at A1 level (acid stage NMT 10% in 60 minutes) and B1 level (buffer stage NLT 80% (Q) in 60 minutes). The firm's proposed specifications are the same as the USP specifications. Therefore, the dissolution section of this application is acceptable.

3.7 Waiver Request(s)

Strengths for which waivers are requested	15 mg (OTC)
Proportional to strength tested in vivo?	Yes
Is dissolution acceptable?	Acceptable
BE for lower strength under CFR 320.24(b)(6) ?	**Yes**
If not then why?	

3.8 Deficiency Comments

None

3.9 Recommendations

1. The firm's in vitro dissolution testing is acceptable. The firm should conduct dissolution testing using the current USP dissolution method (500 mL of 0.1 N HCl at the acid stage in one hour followed by 900 mL of pH 6.8 Phosphate Buffer with 5 mM SDS at 37°C ± 0.5°C using USP apparatus II at 75 rpm). The test product should meet the following USP specifications:

   Acid stage: Not more than 10% (Q) of the labeled amount of Lansoprazole in the dosage form is dissolved in 60 minutes

Buffer stage: Not less than 80% (Q) of the labeled amount of Lansoprazole in the dosage form is dissolved in 60 minutes.

2. The firm has conducted acceptable in vivo BE testing (submitted in a separate ANDA091269 dated on 02/27/2009) comparing Lansoprazole Delayed-Release Capsules USP, 30 mg, to PREVACID® Capsules (Lansoprazole Delayed-Release) Capsule, 30 mg, manufactured by Takeda Pharms. The formulation for the strength of 15 mg OTC is proportionally similar to the 30 mg strength of the test product which underwent bioequivalence testing. The DBE deems the 15 mg strength of Lansoprazole Delayed-Release Capsules (to be marketed as an OTC product) bioequivalent to Novartis's Prevacid® 24 HR (Lansoprazole) Delayed-Release Capsules, 15 mg (OTC) under CFR 320.24(b)(6).

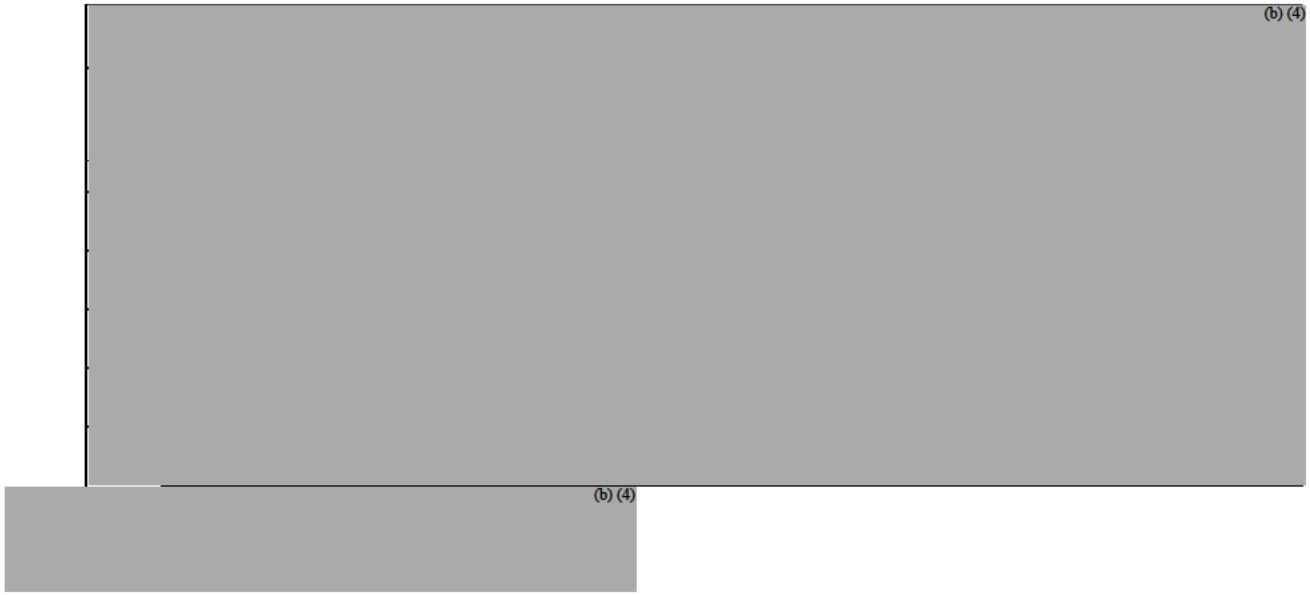
3.10 Comments for Other OGD Disciplines

Discipline	Comment
No	N/A

4 APPENDIX

4.1 Formulation Data

S No	Ingredients	% W/W	15 mg (OTC) (mg/unit)	30mg (mg/unit)
DRUG LAYERING				
1.	Lansoprazole USP	8.13	15.00	30.00
				(b) (4)



Is there an overage of the active pharmaceutical ingredient (API)?	NO
If the answer is yes, has the appropriate chemistry division been notified?	N/A
If it is necessary to reformulate to reduce the overage, will bioequivalence be impacted?	N/A
Comments on the drug product formulation:	Acceptable

Composition of Capsule Shell of 15 mg OTC

Hard Gelatin Capsule shell composition of 15 mg Rx[2]

[2] DARRTS: REV-BIOEQ-01 (General Review), ANDA-091269 Final date 12/19/2010

Following this page, 1 page withheld in full (b)(4)

Comments: Quantities of all excipients in Lansoprazole Delayed-Release Capsules, 15 mg (OTC), fall well below the IIG limits for this oral route of administration. The formulation of 15 mg product (OTC) is proportionally similar to the formulation of the 30 mg strength product with respect to both API and excipients. Color additives of (b) (4) are within Code of Federal Regulations (CFR) limits per 21 CFR, 74.101(a)(1) and (b) and 74.1328 (a)(1) and (b), respectively. The daily intake of elemental iron (b) (4) mg/day) does not exceed the limit of 5 mg/day [CRF 73.1200 (C)]. Therefore, the formulation is acceptable.

4.2 Dissolution Data

Dissolution Review Path	DARRT: REV-BIOEQ-02 (Dissolution Review) ANDA-091269 Final date 08/13/2009 (15 mg and 30 mg Rx)

Table 1. Dissolution Data

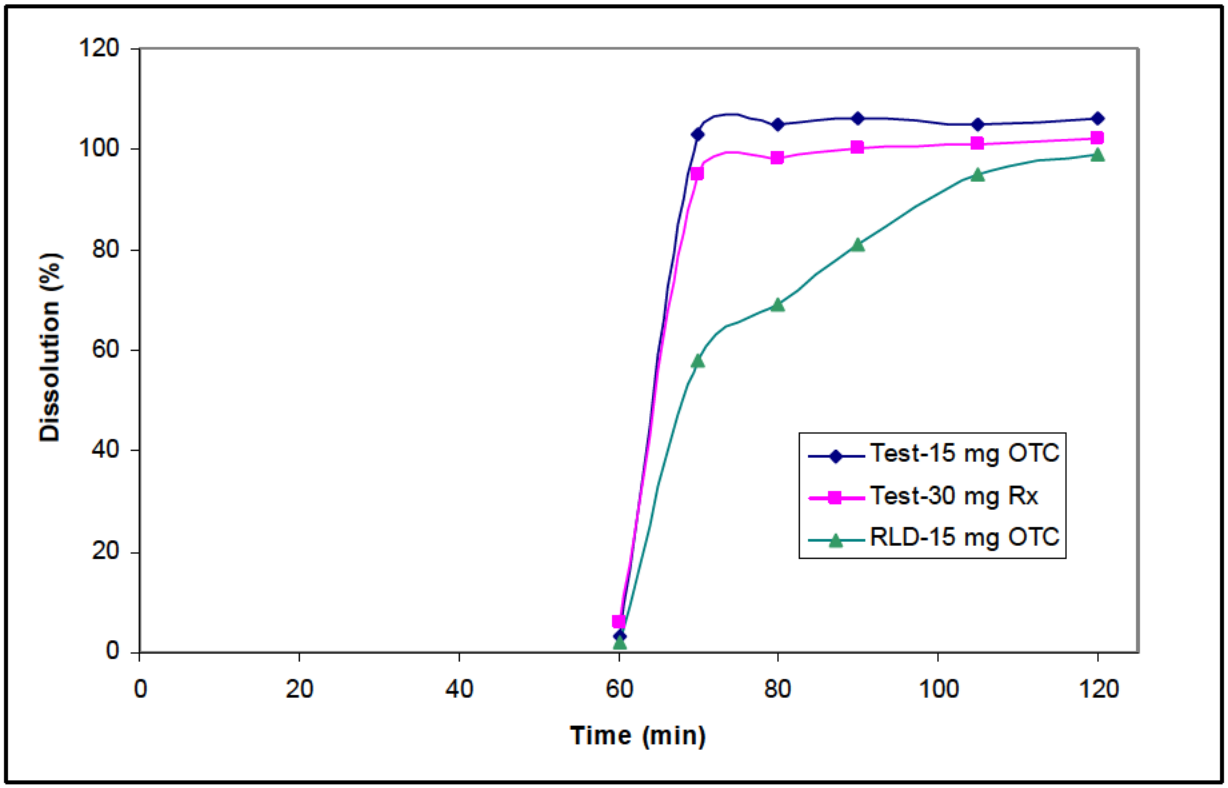
Dissolution Conditions	**Apparatus:**	USP Apparatus II (Paddles)
	Speed of Rotation:	75 rpm
	Medium:	Acid stage: 500 mL of 0.1N HCl for 60 min and followed by 900 mL of pH 6.8 Phosphate Buffer with 5 mM SDS for 60 min
	Volume:	Acid stage: 500 mL; Buffer stage: 900 mL.
	Temperature:	37°C ± 0.5 °C
Firm's Proposed Specifications	NMT 10 % of drug is dissolved in 60 minutes in acid stage and NLT 80% (Q) of drug is dissolved in 60 minutes in buffer stage.	
Dissolution Testing Site (Name, Address)		

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Acid***	**Buffer stage**					**Study Report Location**
						60 min	**10 min**	**20 min**	**30 min**	**45 min**	**60 min**	
Study Report #:		Test Product: Lansoprazole Delayed-Release Capsules 15 mg (OTC) Batch No. EC10123 Mfg Date:	15 mg Capsule	12	Mean	3	103	105	106	105	106	3.2.P.2.2.1
					Range	(b) (4)						
					%CV	86.5	2.4	2.2	1.2	1.9	2.0	
Study Report #:		Test Product: Lansoprazole Delayed-Release Capsules, 30 mg Batch No. EC8289	30 mg Capsule	12	Mean	6	95	98	100	101	102	
					Range	(b) (4)						
					%CV	16.1	1.2	1.0	1.2	1.4	2.2	
Study		Reference Product: Prevacid®	15 mg	12	Mean	2	58	69	81	95	99	

Report #:		24 HR (Lansoprazole) Delayed-Release Capsules, 15 mg (OTC) Batch No. 10074096	Capsule		Range	(b) (4)						
					%CV	110.2	11.2	10.3	6.5	3.4	4.0	

*The dissolution data for the 30 mg strength are obtained from DARRTS: REV-BIOEQ-01 (General Review) ANDA091269 Final date 08/13/2009 and the dissolution data of acid stage for the 15 mg strength are obtained from the amendment dated 05/03/2011 in the current application..

Figure 1. Dissolution Profiles



4.3 Detailed Regulatory History (If Applicable)

Control:

Ctl No	Applicant
02-706	(b) (4)
03-316	
03-942	
04-090	Teva
04-1056	(b) (4)
04-1155	
04-1185	
04-135	
04-154	
04-193	
04-351	
04-369	
04-553	Mylan
04-908	(b) (4)
04-971	
05-0364	
05-0572	Teva
05-0631	Dr. Reddy's
05-0754	(b) (4)
05-1041	
05-1151	
05-1339	
06-0116	
06-0172	
06-0277	
06-0391	
06-0402	
06-0592	
06-0925	
06-1101	SUN

06-1198	(b) (4)
06-1224	
06-1330	
07-0079	
07-0211	
07-0428	
07-0485	
07-0573	
07-0593	
07-0996	
07-1142	
07-1192	Dr. Reddy's
07-1208	(b) (4)
07-1236	
08-0279	Sandoz
08-0934	(b) (4)
08-0945	
08-0966	

4.4 Consult Reviews

None

4.5 Additional Attachments

None

BIOEQUIVALENCE COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 202194

APPLICANT: Dr. Reddy's Laboratories Limited

DRUG PRODUCT: Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

The Division of Bioequivalence (DBE) has completed its review and has no further questions at this time.

The DBE acknowledges that you will conduct dissolution testing using the USP dissolution method and specifications for your Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC).

Please note that the bioequivalence comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalence information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

{See appended electronic signature page}

Barbara M. Davit, Ph.D., J.D.
Acting Director
Division of Bioequivalence II
Office of Generic Drugs
Center for Drug Evaluation and Research

4.6 Outcome Page

ANDA: 202194

Reviewer: Ren, Ping **Date Completed:**

Verifier: , **Date Verified:**

Division: Division of Bioequivalence

Description: Lansoprazole Delayed-Release Capsules, 15 mg (OTC)

Productivity:

ID	*Letter Date*	*Productivity Category*	*Sub Category*	*Productivity*	*Subtotal*		
13866	9/9/2010	Dissolution Data	Dissolution Review	1	1	Edit	Delete
13866	9/9/2010	Other	Study Amendment	1	1	Edit	Delete
				Bean Total:	2		

Enter Review Productivity and Generate Report

Study Bio-waiver and dissolution	
Study bio-waiver	1
Study dissolution testing	1
Study Amendment Total	*2*

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

PING REN
05/17/2011

XIAOJIAN JIANG
05/17/2011

ETHAN M STIER on behalf of BARBARA M DAVIT
05/20/2011

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202194Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI.

DR. REDDY'S

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

August 09, 2010

Office of Generic Drugs
Food and Drug Administration
Center for Drug Evaluation and Research
Document Control Room
Metro Park North II
7620 Standish Place
Rockville, Maryland 20855

Ref: Pre-Assigned ANDA # 202194, eCTD Seq No. 0000
Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)
Original ANDA Application
Submitted Via Electronic Submission Gateway

Dear Sir/ Madam:

Dr. Reddy's Laboratories Inc., (Dr. Reddy's) U.S. agent to Dr. Reddy's Laboratories Ltd., herewith submits an abbreviated new drug application (ANDA) for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) pursuant to Section 505 (j) of the Federal Food, Drug, and Cosmetic Act.

Basis for Submission

The enclosed abbreviated new drug application (ANDA) for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) refers to the listed drug, NOVARTIS's PREVACID® 24 HOUR (Lansoprazole) Delayed-Release Capsules, 15 mg (NDA # N022327).

The active ingredient, route of administration, dosage form and strength of Dr. Reddy's Laboratories Limited's Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) is same as that of NOVARTIS's PREVACID® 24 HOUR (Lansoprazole) Delayed-Release Capsules, 15 mg.

Based on the above facts and under the provisions of 21 CFR § 314, Dr. Reddy's Laboratories Limited submits this ANDA Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC).

This application contains the following information:

Chemistry, Manufacturing & Controls

Dr. Reddy's proposed drug product has the same route of administration, dosage form, active ingredient, strength and labeling (Except for Description and HOW SUPPLIED) as that for **NOVARTIS**'s PREVACID®24 HOUR (Lansoprazole Delayed-Release Capsules, 15 mg).

The manufacturer of the drug substance, Lansoprazole USP Dr Reddy's Laboratories Limited, Chemical Technical Operations- Unit VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh, India- 532 409.

Dr. Reddy's Laboratories Limited., Formulation Technical Operations-III, Bachupally, India-502 325, provided the Purchasing, Receiving, Production Planning, Pilot Production, Stability Testing, Production, Packaging, Quality Assurance, Quality Control, Compliance, Label Inventory, Labeling, Regulatory Affairs, Training, Warehousing, Shipping and Administration for the proposed drug product. The commercial drug product will be manufactured in accordance with 21 CFR § 210 and 211.

The proposed drug product is stable and a two year expiration dating period is requested. This expiration dating period is supported by satisfactory stability data generated for three months at accelerated conditions (40°C ± 2°C and 75% ± 5% RH) in the container-closure system proposed for marketing. The stability studies were conducted as per the stability protocol that is in conformance with current FDA stability guidelines.

Bioequivalence

Dr. Reddy's Laboratories Limited has filed a prescription ANDA for the drug product- Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg on February 27, 2009 (ANDA # 91-269). The Reference Listed Drug is TAKEDA PHARMA's PREVACID [Lansoprazole Delayed-Release Capsules, 30 mg; NDA # 020406].

Dr. Reddy's Laboratories Limited's prescription drug product [Lansoprazole Delayed-Release Capsules USP, 30 mg] is bioequivalent to TAKEDA PHARMA's PREVACID [Lansoprazole Delayed-Release Capsules, 30 mg].

As per the information available in SBOA for PREVACID 24 HOUR (NDA 22-327), the formulations of TAKEDA PHARMA's PREVACID (Rx; NDA 020406) and NOVARTIS's PREVACID 24 HOUR (OTC) are the same.

Dr. Reddy's formulations of Lansoprazole Delayed-Release Capsules USP, 30 mg (Rx) and Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) are dose proportional. The in-vitro dissolution release profiles of Dr. Reddy's formulations of Lansoprazole Delayed-Release Capsules USP, 30 mg (Rx) and Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) are comparable. The dissolution profiles have been provided in **Module 3.2.P.2.2.1**.

DR. REDDY'S

Based on the above and in accordance with 21 CFR 320.22 (d) (2), Dr. Reddy's requests a waiver for in vivo bioavailability / bioequivalence studies for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC).

Administrative Information

The original ANDA is provided as a complete Electronic submission. The ANDA has been organized in accordance with the following FDA guidance documents:

- "Guidance for Industry: Providing Regulatory Submissions in Electronic Format – General Considerations (January 1999)".
- "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications (04/19/2006)".
- "Providing Regulatory Submissions in Electronic format – General Considerations (10/22/2003)".

Also please note that the Dr. Reddy's Laboratories Ltd., has submitted a letter for non-repudiation to the agency to allow submission of electronically signed document or documents with scanned signatures in lieu of paper signatures.

This eCTD submission is submitted through electronic submission gateway. We also certify that all the files include in this submission were checked and verified to be free of viruses using McAfee® Virus Scan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of August 09, 2010.

Please contact the undersigned at by phone on 908-203-4937 or by fax at 908-203-4980 or by email at ksekar@drreddys.com if you have any questions regarding this submission.

Sincerely,

DR. REDDY'S LABORATORIES, INC.

Kumara Sekar, Ph.D.,
Sr. Director, Global Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202194

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

Please refer to your abbreviated new drug application (ANDA) dated September 9, 2010, submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Lansoprazole Delayed-release Capsules USP, 15 mg.

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to receive this ANDA under 21 CFR 314.101(d)(3) for the following reasons:

You have used [redacted] (b) (4) to fulfill the requirement of minimum [redacted] (b) (4) packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product [redacted] (b) (4). Alternatively, you may [redacted] (b) (4) for which you have provided the accelerated stability data to total a minimum of [redacted] (b) (4).

You should submit module 2.3 QOS in an MS Word file.

You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Technical Operations-II. State whether this facility will provide testing for commercial operation. If so, you should provide the full address, contact name, telephone and fax numbers.

You should submit a samples statement of availability for the finished drug product.

You should submit an engineering diagram for the [redacted] (b) (4).

Thus, it will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Upon receipt of this communication, you may either amend your application to correct the deficiencies or withdraw your application under 21 CFR 314.99. If you have any questions please call:

Peter Chen
Project Manager
240-276-8977

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARTIN H Shimer
10/14/2010
Signing for Wm Peter Rickman

ANDA CHECKLIST FOR CTD or eCTD FORMAT
FOR COMPLETENESS and ACCEPTABILITY of an APPLICATION FOR FILING

For More Information on Submission of an ANDA in Electronic Common Technical Document (eCTD) Format please go to: http://www fda.gov/cder/regulatory/ersr/ectd.htm
***For a Comprehensive Table of Contents Headings and Hierarchy please go to:**
http://www fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf
**** For more** CTD and eCTD informational links **see the final page of the ANDA Checklist**
*** **A model Quality Overall Summary for an immediate release tablet and an extended release capsule can be found on the OGD webpage** http://www.fda.gov/cder/ogd/ ***

ANDA #: 202194 **FIRM NAME**: DR. REDDY'S LABORATORIES LTD

PIV: NO **Electronic or Paper Submission:** ELECTRONIC (GATEWAY)

RELATED APPLICATION(S): NA

First Generic Product Received? NO

DRUG NAME: LANSOPRAZOLE
DOSAGE FORM: DELAYED-RELEASE CAPSULES USP, 15 MG

Review Team: (Bolded/Italicized & Checked indicate Assignment or DARRTS designation)

Quality Team: DC2 Team 7 ☒***Activity***	***Bio Team 7: Jiang Xiaojian*** ☒***Activity***
ANDA/Quality RPM:Frank Nice ☒ ***FYI***	Bio PM: Chitra Mahadevan ☐ ***FYI***
Quality Team Leader: Rajagopalan, Radhika No assignment needed in DARRTS	***Clinical Endpoint Team Assignment: (No)*** ☐***Activity***
Labeling Reviewer: Sarah Park ☒***Activity***	***Micro Review (No)*** ☐***Activity***

*****Document Room Note: for New Strength amendments and supplements, if specific reviewer(s) have already been assigned for the original, please assign to those reviewer(s) instead of the default random team(s). *****

Letter Date: AUGUST 9, 2010 **Received Date**: AUGUST 9, 2010

Comments: EC - 1 YES **On Cards:** YES
Therapeutic Code: 8019000 MISCELLANEOUS ULCER AGENT

Archival copy: ELECTRONIC (GATEWAY) **Sections** I
Review copy: NA E-Media Disposition: NA
Not applicable to electronic sections

PART 3 Combination Product Category N Not a Part3 Combo Product
(Must be completed for ALL Original Applications) Refer to the Part 3 Combination Algorithm

Reviewing CSO/CST Peter Chen **Date 9/17/2010**	**Recommendation:** ☐ **FILE** ☒ **REFUSE to RECEIVE**
Supervisory Concurrence/Date: ____	**Date:** ____

1. Edit Application Property Type in DARRTS where applicable for
   a. First Generic Received
      ☐ Yes ☒ No
   b. Market Availability
      ☒ Rx ☐ OTC
   c. Pepfar
      ☐ Yes ☒ No
   d. Product Type
      ☐ Small Molecule Drug (usually for most ANDAs except protein drug products)
   e. USP Drug Product (at time of filing review)
      ☐ Yes ☒ No
2. Edit Submission Patent Records
   ☒ Yes
3. Edit Contacts Database with Bioequivalence Recordation where applicable
   ☐ Yes
4. Requested EER
   ☐ Yes

ADDITIONAL COMMENTS REGARDING THE ANDA:

5. You have used (b) (4) *to fulfill the requirement of minimum* (b) (4) *packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product* (b) (4) *Alternatively, you may* (b) (4) *for which you have provided the accelerated stability data to total a minimum of* (b) (4)

1. Please submit module 2.3 QOS in an MS Word file.

2. You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Tech Operations-II. Please state whether this facility will provide testing for commercial operation. If so, please pro the full address, contact person, telephone and fax numbers.

3. Please submit a samples statement of availability for the finished drug product

4. Please submit an engineering diagram for the (b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Dr. Reddy's Laboratories Limited	09/08/2010
TELEPHONE NO. *(Include Area Code)* 0091-40-23045206	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)* 0091-40-23045238

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*

Dr. Reddy's Laboratories Limited
Bachepally -502 325
INDIA

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

Kumara Sekar

Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd,
7th Floor, Bridgewater, NJ 0880,Tel: 908-203-4937, Fax: 908-203-4980

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)*: 202194

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Lansoprazole	None

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
See Attachment-1	None

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Delayed-Release Capsules	15 mg	Oral

(PROPOSED) INDICATION(S) FOR USE: Indicated for the treatment of frequent heart burn

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☑ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug: PREVACID®24 HOUR Holder of Approved Application: NOVARTIS

TYPE OF SUBMISSION *(check one)*
☑ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION: Original ANDA Submission-Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

PROPOSED MARKETING STATUS *(check one)* ☐ PRESCRIPTION PRODUCT (Rx) ☑ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: 1 THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☑ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attachment 2 and 3

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See Attachment 4

This application contains the following items: *(Check all that apply)*

☐	1. Index
☑	2. Labeling *(check one)* ☑ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☑	4. Chemistry section
☑	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☑	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☑	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☑	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☑	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☐	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.
The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
Sign	Kumara Sekar, Ph.D., Sr. Director, Global Regulatory Affairs	09/08/2010

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
200 Somerset Corporate Blvd, Floor 7, Bridgewater NJ 08807	908-203-4937

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

MODULE 1
ADMINISTRATIVE

ACCEPTABLE

1.1	**1.1.2 Signed and Completed Application Form (356h) (original signature)** (Check Rx/OTC Status) OTC YES	☒
1.2	**Cover Letter** Dated: AUGUST 9, 2010	☒

1.2.1	**Form FDA 3674 (PDF) YES**	☒
*	**Table of Contents (paper submission only)** YES	☒
1.3.2	**Field Copy Certification (original signature)** NA **(N/A for E-Submissions)**	☒
1.3.3	**Debarment Certification-GDEA (Generic Drug Enforcement Act)/Other:** 1. Debarment Certification (original signature) YES 2. List of Convictions statement (original signature) SAME	☒
1.3.4	**Financial Certifications** Bioavailability/Bioequivalence Financial Certification (Form FDA 3454) NA Disclosure Statement (Form FDA 3455, submit copy to Regulatory Branch Chief) NA	☒
1.3.5	**1.3.5.1 Patent Information** Patents listed for the RLD in the Electronic Orange Book Approved Drug Products with Therapeutic Equivalence Evaluations **1.3.5.2 Patent Certification** 1. Patent number(s) No Relevant patents certification 2. Paragraph: (Check all certifications that apply) MOU ☐ PI ☐ PII ☒ PIII ☐ PIV ☐ (Statement of Notification) ☐ 3. Expiration of Patent(s): NA a. Pediatric exclusivity submitted? b. Expiration of Pediatric Exclusivity? 4. Exclusivity Statement: YES	☒
1.4.1	**References** Letters of Authorization 1. DMF letters of authorization a. Type II DMF authorization letter(s) or synthesis for Active Pharmaceutical Ingredient submitted Type II DMF No. 21426 b. Type III DMF authorization letter(s) for container closure submitted 2. US Agent Letter of Authorization (U.S. Agent [if needed, countersignature on 356h]) submitted	☒
1.12.11	**Basis for Submission** NDA# : 22-327 Ref Listed Drug: PREVACID 24 Hours Firm: NOVARTIS ANDA suitability petition required? NA If Yes, then is change subject to PREA (change in dosage form, route or active ingredient) see section 1.9.1	☒

MODULE 1 (Continued)
ADMINISTRATIVE

ACCEPTABLE

1.12.12	**Comparison between Generic Drug and RLD-505(j)(2)(A)** 1. Conditions of use Same as RLD 2. Active ingredients Same as RLD 3. Inactive ingredients submitted 4. Route of administration Same as RLD 5. Dosage Form Same as RLD 6. Strength Same as RLD	☒
1.12.14	**Environmental Impact Analysis Statement** YES	☒
1.12.15	**Request for Waiver** Request for Waiver of In-Vivo BA/BE Study(ies): YES ON 15 MG -See control 09-0440 -Sponsor states formulation is dose proportional to formulation in ANDA 91-269 -Biostudy performed in ANDA 91-269 is acceptable	☒
1.14.1	**Draft Labeling (Mult Copies N/A for E-Submissions)** **1.14.1.1** 4 copies of draft (each strength and container) submitted **1.14.1.2** 1 side by side labeling comparison of containers and carton with all differences annotated and explained submitted **1.14.1.3** 1 package insert (content of labeling) submitted electronically submitted ***Was a proprietary name request submitted? no (If yes, send email to Labeling Reviewer indicating such.)	☒
1.14.3	**Listed Drug Labeling** **1.14.3.1** 1 side by side labeling (package and patient insert) comparison with all differences annotated and explained submitted **1.14.3.3** 1 RLD label and 1 RLD container label submitted	☒

How Lansoprazole Delayed-Release Capsule is sold

Lansoprazole delayed-release capsules are available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

MODULE 2
SUMMARIES ACCEPTABLE

2.3	**Quality Overall Summary (QOS)** **E-Submission: PDF** submitted **Word Processed e.g., MS Word** *1. Please submit module 2.3 QOS in an MS Word file.* A model Quality Overall Summary for an immediate release tablet and an extended release capsule can be found on the OGD webpage http://www fda.gov/cder/ogd/ **Question based Review (QbR)** **2.3.S** **Drug Substance (Active Pharmaceutical Ingredient)** **2.3.S.1 General Information** **2.3.S.2 Manufacture** **2.3.S.3 Characterization** **2.3.S.4 Control of Drug Substance** **2.3.S.5 Reference Standards or Materials** **2.3.S.6 Container Closure System** **2.3.S.7 Stability** **2.3.P** **Drug Product** **2.3.P.1 Description and Composition of the Drug Product** **2.3.P.2 Pharmaceutical Development** **2.3.P.2.1 Components of the Drug Product** **2.3.P.2.1.1 Drug Substance** **2.3.P.2.1.2 Excipients** **2.3.P.2.2 Drug Product** **2.3.P.2.3 Manufacturing Process Development** **2.3.P.2.4 Container Closure System** **2.3.P.3 Manufacture** **2.3.P.4 Control of Excipients** **2.3.P.5 Control of Drug Product** **2.3.P.6 Reference Standards or Materials** **2.3.P.7 Container Closure System** **2.3.P.8 Stability**	☐
2.7	**Clinical Summary (Bioequivalence)** **Model Bioequivalence Data Summary Tables** **E-Submission: PDF** **Word Processed e.g., MS Word** **2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods** **2.7.1.1 Background and Overview** Table 1. Submission Summary Table 4. Bioanalytical Method Validation Table 6. Formulation Data **2.7.1.2 Summary of Results of Individual Studies** Table 5. Summary of In Vitro Dissolution **2.7.1.3 Comparison and Analyses of Results Across Studies** Table 2. Summary of Bioavailability (BA) Studies Table 3. Statistical Summary of the Comparative BA Data **2.7.1.4 Appendix** **2.7.4.1.3 Demographic and Other Characteristics of Study Population** Table 7. Demographic Profile of Subjects Completing the Bioequivalence Study **2.7.4.2.1.1 Common Adverse Events** Table 8. Incidence of Adverse Events in Individual Studies	☐

MODULE 3

3.2.S DRUG SUBSTANCE ACCEPTABLE

<table>
<tr><td>3.2.S.1</td><td>General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties</td><td>☒</td></tr>
<tr><td>3.2.S.2</td><td>Manufacturer
3.2.S.2.1
Manufacturer(s) (This section includes contract manufacturers and testing labs)
Drug Substance (Active Pharmaceutical Ingredient)
1. Name and Full Address(es)of the Facility(ies) submitted
2. Function or Responsibility submitted
3. Type II DMF number for API submitted
4. CFN or FEI numbers submitted
2. You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Technical Operations-II. Please state whether this facility will provide testing for commercial operation. If so, please provide the full address, contact person, telephone and fax numbers.</td><td>☐</td></tr>
<tr><td>3.2.S.3</td><td>Characterization submitted</td><td>☒</td></tr>
<tr><td>3.2.S.4</td><td>Control of Drug Substance (Active Pharmaceutical Ingredient)
3.2.S.4.1 Specification
Testing specifications and data from drug substance manufacturer(s) submitted
3.2.S.4.2 Analytical Procedures submitted
3.2.S.4.3 Validation of Analytical Procedures
1. Spectra and chromatograms for reference standards and test samples submitted
2. Samples-Statement of Availability and Identification of:
a. Drug Substance submitted
b. Same lot number(s) A.R. Nos.: 80000132469,80000143926 and 80000131939
<u>Drug substance used in the Exhibit batch:</u>
<table><tr><th>SNO</th><th>Applicant analytical report number for the drug substance used in Exhibit batch</th><th>Manufacturer Certificate of analysis batch number</th></tr><tr><td>1</td><td>80000143926</td><td>AFCA0349</td></tr><tr><td>2</td><td>80000131939</td><td>AFCA0268</td></tr><tr><td>3</td><td>80000132469</td><td>AFCA0282</td></tr></table>3.2.S.4.4 Batch Analysis
1. COA(s) specifications and test results from drug substance mfgr(s) submitted
2. Applicant certificate of analysis submitted
3.2.S.4.5 Justification of Specification
submitted</td><td>☒</td></tr>
<tr><td>3.2.S.5</td><td>Reference Standards or Materials submitted</td><td>☒</td></tr>
<tr><td>3.2.S.6</td><td>Container Closure Systems submitted</td><td>☒</td></tr>
<tr><td>3.2.S.7</td><td>Stability submitted</td><td>☒</td></tr>
</table>

MODULE 3

3.2.P DRUG PRODUCT ACCEPTABLE

3.2.P.1	**Description and Composition of the Drug Product** 1. Unit composition submitted 2. Inactive ingredients and amounts are appropriate per IIG yes	☒
3.2.P.2	**Pharmaceutical Development** Pharmaceutical Development Report submitted	☒
3.2.P.3	**Manufacture** **3.2.P.3.1 Manufacture(s)** (Finished Dosage Manufacturer and Outside Contract Testing Laboratories) 1. Name and Full Address(es)of the Facility(ies) submitted 2. CGMP Certification: YES 3. Function or Responsibility submitted 4. CFN or FEI numbers **3.2.P.3.2 Batch Formula** submitted Exhibit Commercial (b) (4) **3.2.P.3.3 Description of Manufacturing Process and Process Controls** 1. Description of the Manufacturing Process submitted 2. Master Production Batch Record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified submitted 3. If sterile product: Aseptic fill / Terminal sterilization na 4. Reprocessing Statement submitted **3.2.P.3.4 Controls of Critical Steps and Intermediates submitted** **3.2.P.3.5 Process Validation and/or Evaluation** 1. Microbiological sterilization validation na 2. Filter validation (if aseptic fill) na	☒
3.2.P.4	**Controls of Excipients (Inactive Ingredients)** Source of inactive ingredients identified submitted **3.2.P.4.1 Specifications** 1. Testing specifications (including identification and characterization) submitted 2. Suppliers' COA (specifications and test results) submitted **3.2.P.4.2 Analytical Proceduressubmitted** **3.2.P.4.3 Validation of Analytical Procedures** **3.2.P.4.4 Justification of Specifications** Applicant COA submitted	☒

MODULE 3
3.2.P DRUG PRODUCT

ACCEPTABLE

3.2.P.5	**Controls of Drug Product** **3.2.P.5.1 Specification(s)** submitted **3.2.P.5.2 Analytical Procedures** submitted **3.2.P.5.3 Validation of Analytical Procedures** Samples - Statement of Availability and Identification of: 1. Finished Dosage Form 2. Same lot numbers *3. Please submit a samples statement of availability for the finished drug product* **3.2.P.5.4 Batch Analysis** Certificate of Analysis for Finished Dosage Form submitted Batch EC10123 **3.2.P.5.5 Characterization of Impurities** **3.2.P.5.6 Justification of Specifications submitted**	☐
3.2.P.7	**Container Closure System** 1. Summary of Container/Closure System (if new resin, provide data) submitted 2. Components Specification and Test Data 3. Packaging Configuration and Sizes submitted 4. Container/Closure Testing submitted 5. Source of supply and suppliers address submitted *4. Please submit an engineering diagram for the* (b) (4)	☐
3.2.P.8	**3.2.P.8.1 Stability (Finished Dosage Form)** 1. Stability Protocol submitted submitted 2. Expiration Dating Period 24 months **3.2.P.8.2 Post-approval Stability and Conclusion** Post Approval Stability Protocol and Commitments submitted **3.2.P.8.3 Stability Data** 1. 3 month accelerated stability data submitted 2. Batch numbers on stability records the same as the test batch **yes**	☒

MODULE 3

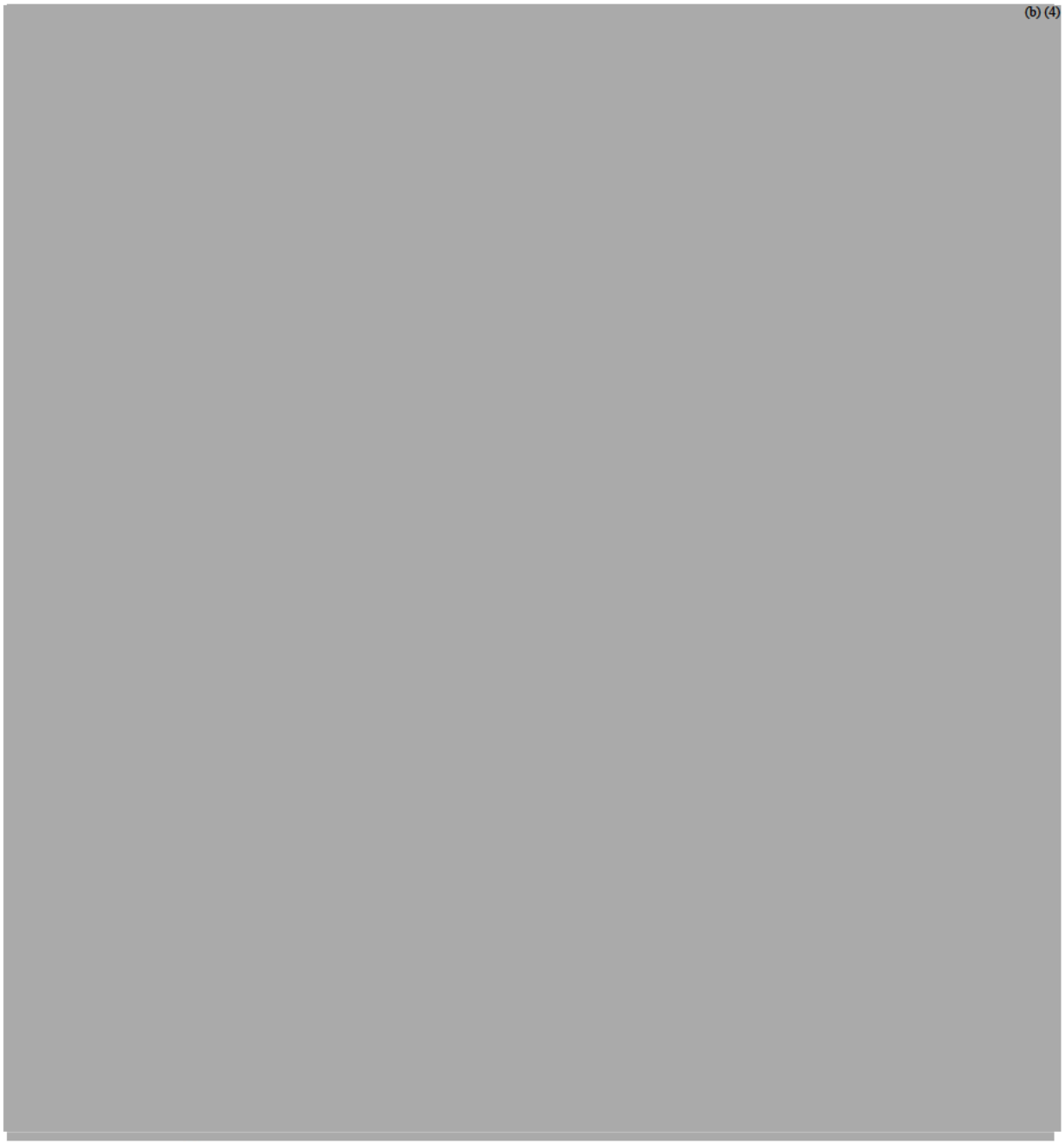
3.2.R Regional Information

ACCEPTABLE

3.2.R (Drug Substance)	**3.2.R.1.S Executed Batch Records for drug substance (if available)** **3.2.R.2.S Comparability Protocols** **3.2.R.3.S Methods Validation Package** Methods Validation Package (3 copies) (Mult Copies N/A for E-Submissions) (Required for Non-USP drugs)	☐

3.2.R (Drug Product)	**3.2.R.1.P.1** **Executed Batch Records** Copy of Executed Batch Record with Equipment Specified, including Packaging Records (Packaging and Labeling Procedures) Batch Reconciliation and Label Reconciliation Theoretical Yield Actual Yield Packaged Yield Sponsor has relied on (b) (4) to fulfill their minimum (b) (4) packaging requirement; however, they have not provided accelerated stability studies for the (b) (4) They have only provided 3 months CRT data. *5. You have used (b) (4) to fulfill the requirement of minimum (b) (4) packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product (b) (4) Alternatively, you may (b) (4) for which you have provided the accelerated stability data to total a minimum of (b) (4)* **3.2.R.1.P.2 Information on Components** **3.2.R.2.P Comparability Protocols** **3.2.R.3.P Methods Validation Package** Methods Validation Package (3 copies) (Mult Copies N/A for E-Submissions) (Required for Non-USP drugs)	☐

Summary of Batch Reconciliation Data



MODULE 5

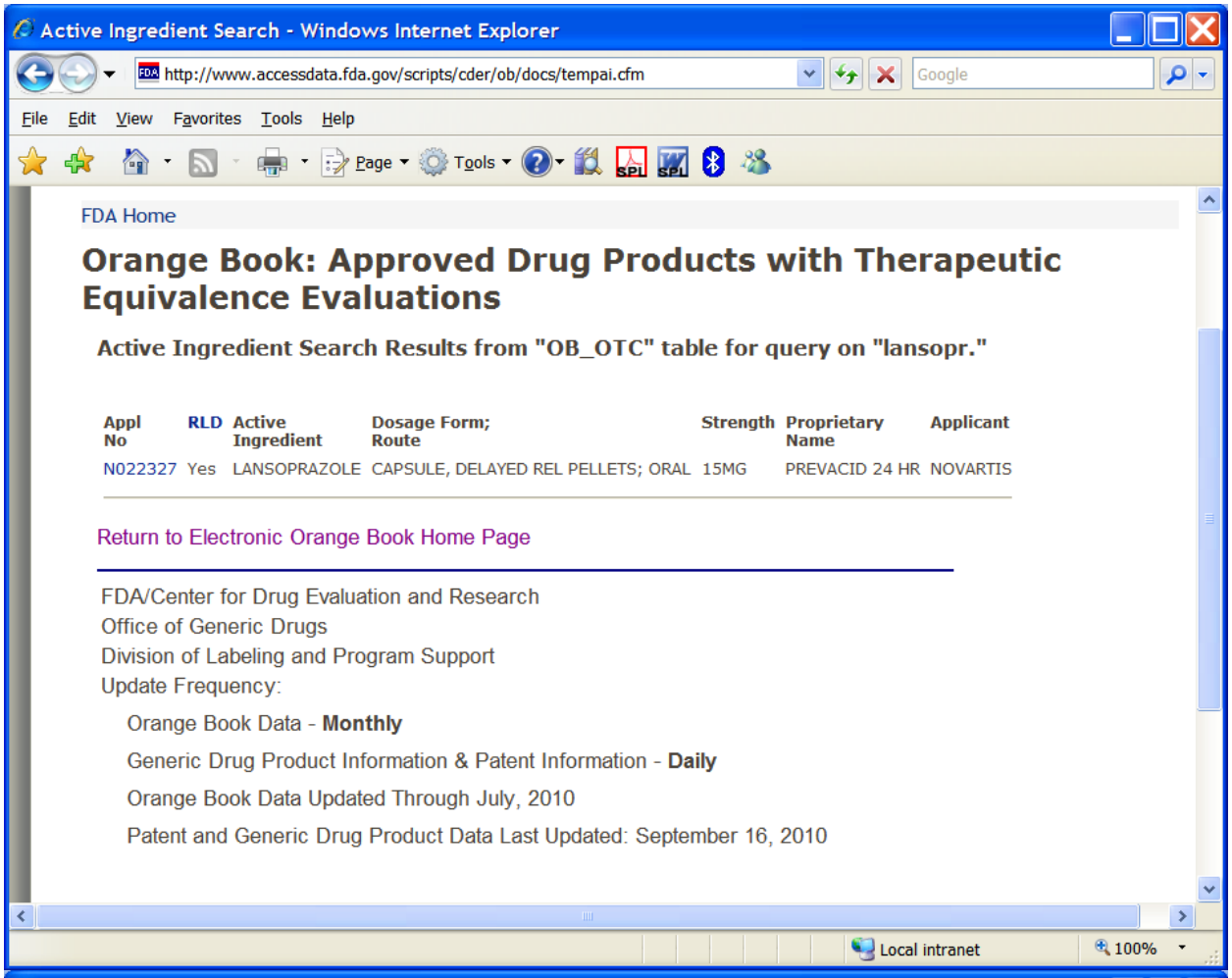
CLINICAL STUDY REPORTS ACCEPTABLE

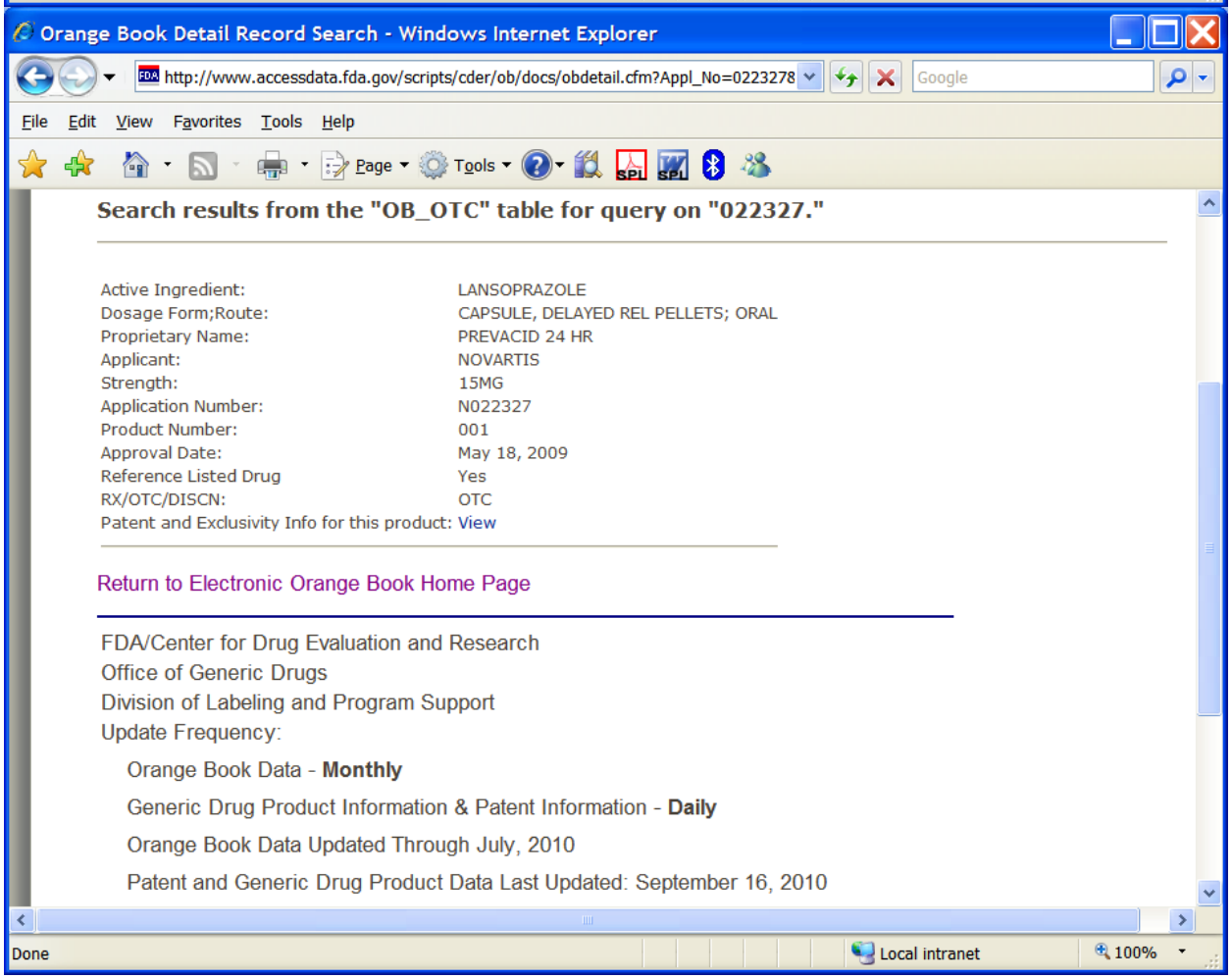
5.2	**Tabular Listing of Clinical Studies**	☐
5.3.1 (complete study data)	**Bioavailability/Bioequivalence** **1. Formulation data same?** a. Comparison of all Strengths (check proportionality of multiple strengths) b. Parenterals, Ophthalmics, Otics and Topicals per 21 CFR 314.94 (a)(9)(iii)-(v) **2. Lot Numbers of Products used in BE Study(ies):** **3. Study Type: IN-VIVO PK STUDY(IES)** (Continue with the appropriate study type box below)	☐

	5.3.1.2 Comparative BA/BE Study Reports 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) 2. Summary Bioequivalence tables: Table 10. Study Information Table 12. Dropout Information Table 13. Protocol Deviations **5.3.1.3** **In Vitro-In-Vivo Correlation Study Reports** 1. Summary Bioequivalence tables: Table 11. Product Information Table 16. Composition of Meal Used in Fed Bioequivalence Study **5.3.1.4** **Reports of Bioanalytical and Analytical Methods for Human Studies** 1. Summary Bioequivalence table: Table 9. Reanalysis of Study Samples Table 14. Summary of Standard Curve and QC Data for Bioequivalence Sample Analyses Table 15. SOPs Dealing with Bioanalytical Repeats of Study Samples **5.3.7** **Case Report Forms and Individual Patient Listing**	☐
5.4	**Literature References**	☐
	Possible Study Types:	
Study Type	**IN-VIVO BE STUDY(IES) with PK ENDPOINTS** (i.e., fasting/fed/sprinkle) NA 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) 2. EDR Email: Data Files Submitted: NA 3. In-Vitro Dissolution: NO	☐
Study Type	**IN-VIVO BE STUDY with CLINICAL ENDPOINTS** NO 1. Properly defined BE endpoints (eval. by Clinical Team) 2. Summary results meet BE criteria: 90% CI of the proportional difference in success rate between test and reference must be within (-0.20, +0.20) for a binary/dichotomous endpoint. For a continuous endpoint, the test/reference ratio of the mean result must be within (0.80, 1.25). 3. Summary results indicate superiority of active treatments (test & reference) over vehicle/placebo ($p<0.05$) (eval. by Clinical Team) 4. EDR Email: Data Files Submitted	☐
Study Type	**IN-VITRO BE STUDY(IES)** (i.e., in vitro binding assays) NO 1. Study(ies) meets BE criteria (90% CI of 80-125) 2. EDR Email: Data Files Submitted: 3. In-Vitro Dissolution:	☐

Study Type	**NASALLY ADMINISTERED DRUG PRODUCTS** 1. Solutions (Q1/Q2 sameness): a. In-Vitro Studies (Dose/Spray Content Uniformity, Droplet/Drug Particle Size Distrib., Spray Pattern, Plume Geometry, Priming & Repriming) 2. Suspensions (Q1/Q2 sameness): a. In-Vivo PK Study 1. Study(ies) meets BE Criteria (90% CI of 80-125, C max, AUC) 2. EDR Email: Data Files Submitted b. In-Vivo BE Study with Clinical End Points 1. Properly defined BE endpoints (eval. by Clinical Team) 2. Summary results meet BE criteria (90% CI within +/- 20% of 80-125) 3. Summary results indicate superiority of active treatments (test & reference) over vehicle/placebo ($p<0.05$) (eval. by Clinical Team) 4. EDR Email: Data Files Submitted c. In-Vitro Studies (Dose/Spray Content Uniformity, Droplet/Drug Particle Size Distrib., Spray Pattern, Plume Geometry, Priming & Repriming)	☐
Study Type	**IN-VIVO BE STUDY(IES) with PD ENDPOINTS** (e.g., topical corticosteroid vasoconstrictor studies) 1. Pilot Study (determination of ED50) 2. Pivotal Study (study meets BE criteria 90%CI of 80-125)	☐
Study Type	**TRANSDERMAL DELIVERY SYSTEMS** 1. In-Vivo PK Study 1. Study(ies) meet BE Criteria (90% CI of 80-125, C max, AUC) 2. In-Vitro Dissolution 3. EDR Email: Data Files Submitted 2. Adhesion Study 3. Skin Irritation/Sensitization Study	☐

Updated 10/19/2009


Active Ingredient Search - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm
File Edit View Favorites Tools Help
Page Tools
FDA Home
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Active Ingredient Search Results from "OB_OTC" table for query on "lansopr."
Appl No | RLD | Active Ingredient | Dosage Form; Route | Strength | Proprietary Name | Applicant
N022327 | Yes | LANSOPRAZOLE | CAPSULE, DELAYED REL PELLETS; ORAL | 15MG | PREVACID 24 HR | NOVARTIS
Return to Electronic Orange Book Home Page
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - Monthly
Generic Drug Product Information & Patent Information - Daily
Orange Book Data Updated Through July, 2010
Patent and Generic Drug Product Data Last Updated: September 16, 2010
Local intranet
100%


Orange Book Detail Record Search - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=0223278
File Edit View Favorites Tools Help
Page Tools
Search results from the "OB_OTC" table for query on "022327."
Active Ingredient: LANSOPRAZOLE
Dosage Form;Route: CAPSULE, DELAYED REL PELLETS; ORAL
Proprietary Name: PREVACID 24 HR
Applicant: NOVARTIS
Strength: 15MG
Application Number: N022327
Product Number: 001
Approval Date: May 18, 2009
Reference Listed Drug Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: View
Return to Electronic Orange Book Home Page
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - Monthly
Generic Drug Product Information & Patent Information - Daily
Orange Book Data Updated Through July, 2010
Patent and Generic Drug Product Data Last Updated: September 16, 2010
Done
Local intranet
100%


Patent and Exclusivity Search Results - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=0223
File Edit View Favorites Tools Help
U.S. Department of Health & Human Services
www.hhs.gov
U.S. Food and Drug Administration
A-Z Index
Search
Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products
FDA Home
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Patent and Exclusivity Search Results from query on Appl No 022327 Product 001 in the OB_OTC list.
There are no unexpired patents for this product in the Orange Book Database.
Appl No Prod No Exclusivity Code Exclusivity Expiration
N022327 001 NP May 18, 2012
View a list of all patent use codes
Done
Local intranet
100%

Date: AUGUST 25, 2009

Industry: Dr Reddy's Lab

Contact: Reena Zade

Control Number: 09-0440

Re: Submission of Lansoprazole Delayed-release Capsules 15 mg from RX to OTC.

On August 11, 2009 Ms. Reena Zade contacted me via email to request some information regarding the submission of OTC Lansoprazole Delayed-release Capsules, 15 mg. She stated that Dr. Reddy's Rx version of this drug product was submitted and currently under the Agency's review. Please see attached email received from Ms. Zade.

Research of key topics to her question, please see below the conclusion:

1.) The use of tamper indicating technology is required for OTC capsules at initial time of submission. Therefore, the firm will not be able to submit the unbanded product at initial time of submission and then send an amendment for the banded product.

2.) Dissolution and stability data of the banded product must be submitted at time of initial submission.

3.) DBE has remarked that if the formulation of the firm's product is the same from RX to OTC, then the firm will not be required to submit separate bio studies.

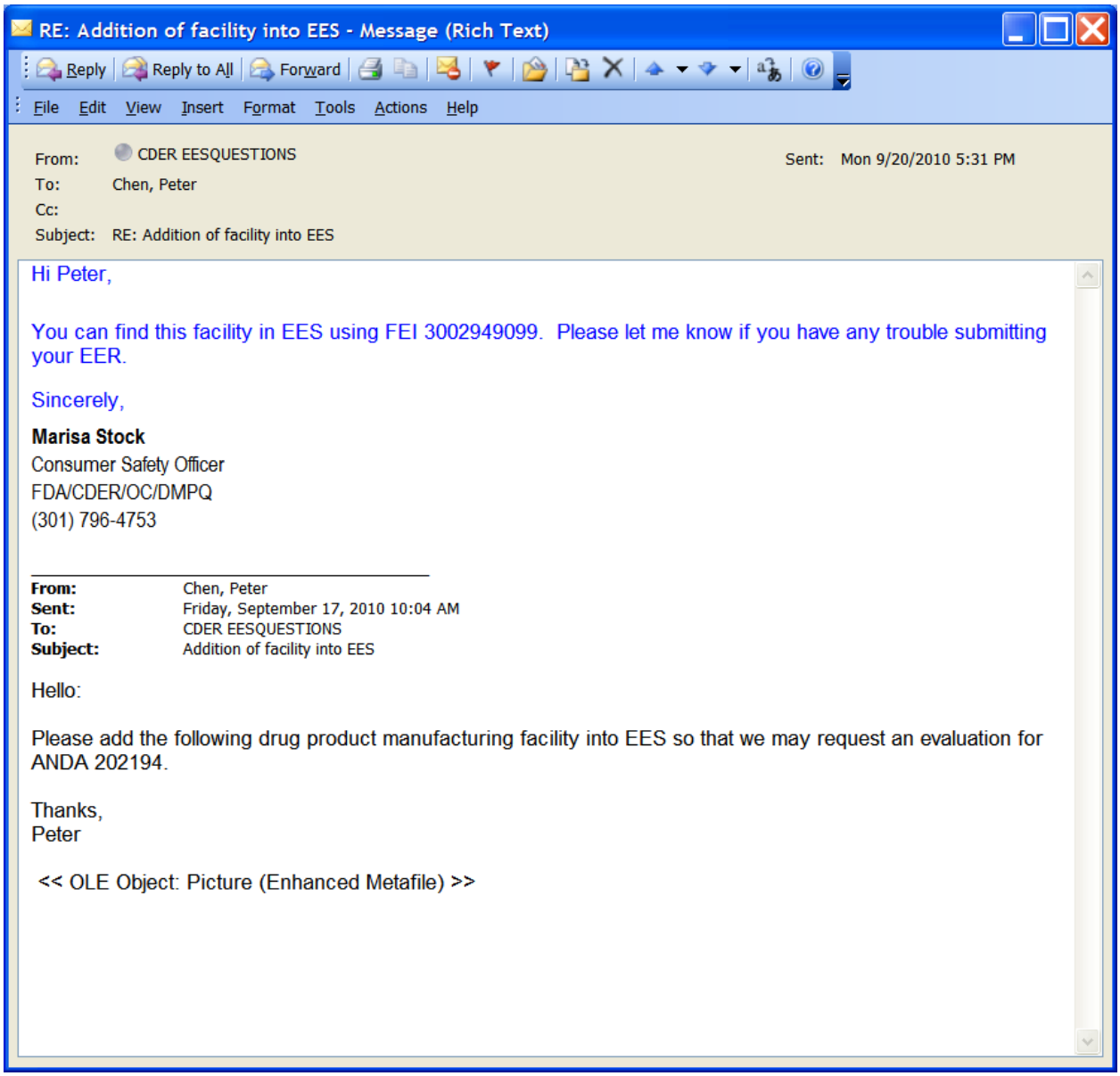
I requested the firm submit copies of the bio studies performed for the RX product in their OTC submission for ease of review.

The above was communicated to Ms. Zade on August 24, 2009.

Lisa Tan

ii) Quantitative Composition of Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)

Sno.	Component	Quantity per unit (mg)	% (w/w)	Pharmaceutical Function
Drug Layering				
1	Lansoprazole USP	15.000	8.13	Active Ingredient
				(b) (4)



RE: Addition of facility into EES - Message (Rich Text)

Reply | Reply to All | Forward

File Edit View Insert Format Tools Actions Help

From: CDER EESQUESTIONS
Sent: Mon 9/20/2010 5:31 PM
To: Chen, Peter
Cc:
Subject: RE: Addition of facility into EES

Hi Peter,

You can find this facility in EES using FEI 3002949099. Please let me know if you have any trouble submitting your EER.

Sincerely,

Marisa Stock
Consumer Safety Officer
FDA/CDER/OC/DMPQ
(301) 796-4753

From: Chen, Peter
Sent: Friday, September 17, 2010 10:04 AM
To: CDER EESQUESTIONS
Subject: Addition of facility into EES

Hello:

Please add the following drug product manufacturing facility into EES so that we may request an evaluation for ANDA 202194.

Thanks,
Peter

<< OLE Object: Picture (Enhanced Metafile) >>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

PETER CHEN
10/12/2010

MARTIN H Shimer
10/14/2010

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI.

DR. REDDY'S

October 22, 2010

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

Re: ANDA # 202194; eCTD Sequence No.:0001
Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)
Response to Screening information request dated October 14, 2010
Submitted via Electronic submission Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC), Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a screening information request. This is in response to the refuse to receive letter dated Oct 14, 2010, which is provided along with the cover letter. Please note that the original submission was dated August 09, 2010 and not September 09, 2010 as indicated on the refuse to receive letter.

Since the comments listed in the letter are minor in nature which can be easily corrected within 10 days of receiving the communication, we request the agency to reconsider the refuse to receive decision and accept this ANDA as on the original date of submission i.e. August 09, 2010.

A. Deficiencies:

FDA Comment

You have used (b) (4) *to fulfill the requirement of minimum* (b) (4) *packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product* (b) (4) *Alternatively, you may* (b) (4) (b) (4) *for which you have provided the accelerated stability data to total a minimum of* (b) (4)

Response:

(b) (4)

[redacted]

FDA Comment

You should submit module 2.3 QOS in an MS Word file.

Response:

We acknowledge the agency's comment. The QOS in MS word file was already provided in **Module 2.3**. However the same document has been provided again in **Module 2.3** for agency's ready reference.

FDA Comment

You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Technical Operations-II. State whether this facility will provide testing for commercial operation. If so, you should provide the full address, contact name, telephone and fax numbers.

Response:

We acknowledge the agency's comment. We confirm that the facility at Dr. Reddy's Laboratories Limited, Chemical Technical Operations-II will provide the testing of XRD parameter for the drug substance for all the commercial batches. As requested, the details of the facility have been provided in **Module 3.2.S.2.1.**

FDA Comment

You should submit a samples statement of availability for the finished drug product.

Response:

We would like to inform agency that the samples statement of availability for the finished drug product was already provided in **Module 3.2.R**. However the same details have been provided again in **Module 3.2.R** and also in **Module 3.2.P.5.3.1** for agency's ready reference.

FDA Comment

You should submit an engineering diagram for the (b) (4)

Response:

We acknowledge the agency's comment. As requested, the engineering diagram for the (b) (4) (b) (4) has been provided in **Module 3.2.P.7.**

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of October 22, 2010.

Please contact the undersigned at 908-203-4937 by phone or at 908-203-4980 by fax or by email at ksekar@drreddys.com if you have any questions regarding this submission.

Sincerely,

DR. REDDY'S LABORATORIES, INC.

Kumara Sekar Ph.D.,
Sr. Director, Global Regulatory Affairs

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI.

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

November 03, 2010

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

Re: ANDA # 202194; eCTD Sequence No.:0002
Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)
Telephone amendment
Submitted via Electronic submission Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC), Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a telephone amendment. This is in response to the refuse to receive letter dated Oct 14, 2010 and subsequent email communications received from Mr. Peter Chen and Mr. Martin Shimer.

Reference is made to our amendment dated October 22, 2010 in which a complete response to the comments listed in the refuse to receive letter dated October 14, 2010 was provided.

A. Deficiencies:

FDA Comment

You have used (b) (4) *to fulfill the requirement of minimum* (b) (4) *packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product* (b) (4) *Alternatively, you may* (b) (4) (b) (4) *for which you have provided the accelerated stability data to total a minimum of* (b) (4)

Your response dated October 22, 2010 for the above comment is not acceptable. Please provide the required stability data (b) (4).

RESPONSE:

We acknowledge the agency's comment. We would like to revise the proposed (b) (4) to 3 months. This 3 months (b) (4) is supported by the

Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)
ANDA # 202194

3 month stability data at CRT which was provided in the original ANDA submission. The revised expiration dating period statement is provided in **Module 3.2.P.8.**

Based on the above information, we request the agency to accept the ANDA for review.

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of November 03, 2010.

Please contact the undersigned at 908-203-4937 by phone or at 908-203-4980 by fax or by email at ksekar@drreddys.com if you have any questions regarding this submission.

Sincerely,

DR. REDDY'S LABORATORIES, INC.

A Jayalakshmi.

Kumara Sekar Ph.D.,
Sr. Director, Global Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202194

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

Please refer to your abbreviated new drug application (ANDA) dated September 9, 2010, submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Lansoprazole Delayed-release Capsules USP, 15 mg.

Reference is made to our "Refuse to Receive" letter dated October 14, 2010 and your amendment dated October 22, 2010. Further reference is made to your correspondence dated November 3, 2010.

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to receive this ANDA under 21 CFR 314.101(d)(3) for the following reasons:

> You have failed to provide at a minimum of either 3 months accelerated stability data or 6 months CRT data for the drug product [redacted] (b) (4) you must provide either 3 months accelerated or minimum 6 months CRT stability data.

Thus, it will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Upon receipt of this communication, you may either amend your application to correct the deficiencies or withdraw your application under 21 CFR 314.99. If you have any questions please call:

Peter Chen
Project Manager
240-276-8977

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARTIN H Shimer
01/07/2011
Signing for Wm Peter Rickman

Check 2

ANDA CHECKLIST FOR CTD or eCTD FORMAT
FOR COMPLETENESS and ACCEPTABILITY of an APPLICATION FOR FILING

For More Information on Submission of an ANDA in Electronic Common Technical Document (eCTD) Format please go to: http://www fda.gov/cder/regulatory/ersr/ectd.htm
***For a Comprehensive Table of Contents Headings and Hierarchy please go to:**
http://www fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf
**** For more** CTD and eCTD informational links **see the final page of the ANDA Checklist**
***** A model Quality Overall Summary for an immediate release tablet and an extended release capsule can be found on the OGD webpage** http://www.fda.gov/cder/ogd/ *****

ANDA #: 202194 **FIRM NAME**: DR. REDDY'S LABORATORIES LTD

PIV: NO **Electronic or Paper Submission:** ELECTRONIC (GATEWAY)

RELATED APPLICATION(S): NA

First Generic Product Received? NO

DRUG NAME: LANSOPRAZOLE

DOSAGE FORM: DELAYED-RELEASE CAPSULES USP, 15 MG

Review Team: (Bolded/Italicized & Checked indicate Assignment or DARRTS designation)

Quality Team: DC2 Team 21 ☒ ***Activity***	***Bio Team 7: Jiang Xiaojian*** ☒ ***Activity***
ANDA/Quality RPM:Frank Nice ☒ ***FYI***	Bio PM: Chitra Mahadevan ☐ ***FYI***
Quality Team Leader: Rajagopalan, Radhika No assignment needed in DARRTS	***Clinical Endpoint Team Assignment: (No)*** ☐ ***Activity***
Labeling Reviewer: Sarah Park ☒ ***Activity***	***Micro Review (No)*** ☐ ***Activity***

*****Document Room Note: for New Strength amendments and supplements, if specific reviewer(s) have already been assigned for the original, please assign to those reviewer(s) instead of the default random team(s). *****

Letter Date: AUGUST 9, 2010 **Received Date**: AUGUST 9, 2010

Comments: EC - 1 YES **On Cards:** YES
Therapeutic Code: 8019000 MISCELLANEOUS ULCER AGENT

Archival copy: ELECTRONIC (GATEWAY) **Sections** I
Review copy: NA E-Media Disposition: NA
Not applicable to electronic sections

PART 3 Combination Product Category N Not a Part3 Combo Product
(Must be completed for ALL Original Applications) Refer to the Part 3 Combination Algorithm

Reviewing CSO/CST Peter Chen **Date 12/10/2010**	**Recommendation:** ☐ **FILE** ☒ **REFUSE to RECEIVE**
Supervisory Concurrence/Date: ____	**Date:** ____

1. Edit Application Property Type in DARRTS where applicable for
   a. First Generic Received
      ☐ Yes ☒ No
   b. Market Availability
      ☒ Rx ☐ OTC
   c. Pepfar
      ☐ Yes ☒ No
   d. Product Type
      ☐ Small Molecule Drug (usually for most ANDAs except protein drug products)
   e. USP Drug Product (at time of filing review)
      ☐ Yes ☒ No
2. Edit Submission Patent Records
   ☒ Yes
3. Edit Contacts Database with Bioequivalence Recordation where applicable
   ☐ Yes
4. Requested EER
   ☐ Yes

ADDITIONAL COMMENTS REGARDING THE ANDA:

November 3, 2010 Correspondence: RTR

The sponsor has revised [redacted]

Per Martin Shimer the sponsor still must provide a minimum 6 months CRT [redacted] or 3 months ACC stability data.

You have failed to provide at a minimum of either 3 months accelerated stability data or 6 months CRT data for the drug product [redacted] you must provide either 3 months accelerated or minimum 6 months CRT stability data.

October 22, 2010 Amendment: RTR

Per 10/22/2010 Amendment sponsor indicates ACC stability data is not necessary for containers [redacted] and CRT data is being generated for 6 months which will be supplied as soon as it is available.

Not acceptable for filing

August 9, 2010 Original: RTR

5. You have used [redacted] to fulfill the requirement of minimum [redacted] packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product [redacted] Alternatively, you may [redacted] for which you have provided the accelerated stability data to total a minimum of [redacted]

Per 10/22/2010 Amendment sponsor indicates ACC stability data is not necessary for containers [redacted] and CRT data is being generated for 6 months which will be supplied as soon as it is available.

Per 11/3/2010 Correspondence they have [redacted] 3 months.

Not acceptable for filing

1. Please submit module 2.3 QOS in an MS Word file.

Adequate for filing per 10/22/2010 amendment

2. You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Technical Operations-II. Please state whether this facility will provide testing for commercial operation. If so, please provide the full address, contact person, telephone and fax numbers.

Adequate for filing per 10/22/2010 amendment - facility will be used for commercial batches and facility information provided

3. Please submit a samples statement of availability for the finished drug product

Adequate for filing per 10/22/2010 amendment - sponsor stated the information was already provided in module 3.2.R

4. Please submit an engineering diagram for the [redacted]

Adequate for filing per 10/22/2010 amendment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Dr. Reddy's Laboratories Limited	09/08/2010

TELEPHONE NO. *(Include Area Code)*	FACSIMILE *(FAX)* Number *(Include Area Code)*
0091-40-23045206	0091-40-23045238

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
Dr. Reddy's Laboratories Limited Bachepally -502 325 INDIA	Kumara Sekar Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd, 7th Floor, Bridgewater, NJ 0880,Tel: 908-203-4937, Fax: 908-203-4980

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)*: 202194

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Lansoprazole	None

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
See Attachment-1	None

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Delayed-Release Capsules	15 mg	Oral

(PROPOSED) INDICATION(S) FOR USE: Indicated for the treatment of frequent heart burn

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☑ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug: PREVACID®24 HOUR Holder of Approved Application: NOVARTIS

TYPE OF SUBMISSION *(check one)*
☑ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION: Original ANDA Submission-Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

PROPOSED MARKETING STATUS *(check one)* ☐ PRESCRIPTION PRODUCT (Rx) ☑ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: 1 THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☑ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attachment 2 and 3

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See Attachment 4

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☑	2. Labeling *(check one)* ☑ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☑	4. Chemistry section
☑	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☑	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☑	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☑	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☑	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☐	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.
The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
Sign	Kumara Sekar, Ph.D., Sr. Director, Global Regulatory Affairs	09/08/2010

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
200 Somerset Corporate Blvd, Floor 7, Bridgewater NJ 08807	908-203-4937

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

MODULE 1
ADMINISTRATIVE

ACCEPTABLE

1.1	**1.1.2 Signed and Completed Application Form (356h) (original signature)** (Check Rx/OTC Status) OTC YES	☒
1.2	**Cover Letter** Dated: AUGUST 9, 2010	☒

1.2.1	**Form FDA 3674 (PDF) YES**	☒
*	**Table of Contents (paper submission only)** YES	☒
1.3.2	**Field Copy Certification (original signature)** NA **(N/A for E-Submissions)**	☒
1.3.3	**Debarment Certification-GDEA (Generic Drug Enforcement Act)/Other:** 1. Debarment Certification (original signature) YES 2. List of Convictions statement (original signature) SAME	☒
1.3.4	**Financial Certifications** Bioavailability/Bioequivalence Financial Certification (Form FDA 3454) NA Disclosure Statement (Form FDA 3455, submit copy to Regulatory Branch Chief) NA	☒
1.3.5	**1.3.5.1 Patent Information** Patents listed for the RLD in the Electronic Orange Book Approved Drug Products with Therapeutic Equivalence Evaluations **1.3.5.2 Patent Certification** 1. Patent number(s) No Relevant patents certification 2. Paragraph: (Check all certifications that apply) MOU ☐ PI ☐ PII ☒ PIII ☐ PIV ☐ (Statement of Notification) ☐ 3. Expiration of Patent(s): NA a. Pediatric exclusivity submitted? b. Expiration of Pediatric Exclusivity? 4. Exclusivity Statement: YES	☒
1.4.1	**References** Letters of Authorization 1. DMF letters of authorization a. Type II DMF authorization letter(s) or synthesis for Active Pharmaceutical Ingredient submitted Type II DMF No. 21426 b. Type III DMF authorization letter(s) for container closure submitted 2. US Agent Letter of Authorization (U.S. Agent [if needed, countersignature on 356h]) submitted	☒
1.12.11	**Basis for Submission** NDA# : 22-327 Ref Listed Drug: PREVACID 24 Hours Firm: NOVARTIS ANDA suitability petition required? NA If Yes, then is change subject to PREA (change in dosage form, route or active ingredient) see section 1.9.1	☒

MODULE 1 (Continued)
ADMINISTRATIVE

ACCEPTABLE

1.12.12	**Comparison between Generic Drug and RLD-505(j)(2)(A)** 1. Conditions of use Same as RLD 2. Active ingredients Same as RLD 3. Inactive ingredients submitted 4. Route of administration Same as RLD 5. Dosage Form Same as RLD 6. Strength Same as RLD	☒
1.12.14	**Environmental Impact Analysis Statement** YES	☒
1.12.15	**Request for Waiver** Request for Waiver of In-Vivo BA/BE Study(ies): YES ON 15 MG -See control 09-0440 -Sponsor states formulation is dose proportional to formulation in ANDA 91-269 -Biostudy performed in ANDA 91-269 is acceptable	☒
1.14.1	**Draft Labeling (Mult Copies N/A for E-Submissions)** **1.14.1.1** 4 copies of draft (each strength and container) submitted **1.14.1.2** 1 side by side labeling comparison of containers and carton with all differences annotated and explained submitted **1.14.1.3** 1 package insert (content of labeling) submitted electronically submitted ***Was a proprietary name request submitted? no (If yes, send email to Labeling Reviewer indicating such.)	☒
1.14.3	**Listed Drug Labeling** **1.14.3.1** 1 side by side labeling (package and patient insert) comparison with all differences annotated and explained submitted **1.14.3.3** 1 RLD label and 1 RLD container label submitted	☒

How Lansoprazole Delayed-Release Capsule is sold

Lansoprazole delayed-release capsules are available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

MODULE 2
SUMMARIES ACCEPTABLE

2.3	**Quality Overall Summary (QOS)** **E-Submission: PDF** submitted **Word Processed e.g., MS Word** *1. Please submit module 2.3 QOS in an MS Word file.* A model Quality Overall Summary for an immediate release tablet and an extended release capsule can be found on the OGD webpage http://www fda.gov/cder/ogd/ **Question based Review (QbR)** **2.3.S** **Drug Substance (Active Pharmaceutical Ingredient)** **2.3.S.1 General Information** **2.3.S.2 Manufacture** **2.3.S.3 Characterization** **2.3.S.4 Control of Drug Substance** **2.3.S.5 Reference Standards or Materials** **2.3.S.6 Container Closure System** **2.3.S.7 Stability** **2.3.P** **Drug Product** **2.3.P.1 Description and Composition of the Drug Product** **2.3.P.2 Pharmaceutical Development** **2.3.P.2.1 Components of the Drug Product** **2.3.P.2.1.1 Drug Substance** **2.3.P.2.1.2 Excipients** **2.3.P.2.2 Drug Product** **2.3.P.2.3 Manufacturing Process Development** **2.3.P.2.4 Container Closure System** **2.3.P.3 Manufacture** **2.3.P.4 Control of Excipients** **2.3.P.5 Control of Drug Product** **2.3.P.6 Reference Standards or Materials** **2.3.P.7 Container Closure System** **2.3.P.8 Stability**	☐
2.7	**Clinical Summary (Bioequivalence)** **Model Bioequivalence Data Summary Tables** **E-Submission: PDF** **Word Processed e.g., MS Word** **2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods** **2.7.1.1 Background and Overview** Table 1. Submission Summary Table 4. Bioanalytical Method Validation Table 6. Formulation Data **2.7.1.2 Summary of Results of Individual Studies** Table 5. Summary of In Vitro Dissolution **2.7.1.3 Comparison and Analyses of Results Across Studies** Table 2. Summary of Bioavailability (BA) Studies Table 3. Statistical Summary of the Comparative BA Data **2.7.1.4 Appendix** **2.7.4.1.3 Demographic and Other Characteristics of Study Population** Table 7. Demographic Profile of Subjects Completing the Bioequivalence Study **2.7.4.2.1.1 Common Adverse Events** Table 8. Incidence of Adverse Events in Individual Studies	☐

MODULE 3

3.2.S DRUG SUBSTANCE ACCEPTABLE

<table>
<tr><td>3.2.S.1</td><td>General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties</td><td>☒</td></tr>
<tr><td>3.2.S.2</td><td>Manufacturer
3.2.S.2.1
Manufacturer(s) (This section includes contract manufacturers and testing labs)
Drug Substance (Active Pharmaceutical Ingredient)
1. Name and Full Address(es)of the Facility(ies) submitted
2. Function or Responsibility submitted
3. Type II DMF number for API submitted
4. CFN or FEI numbers submitted
2. You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Technical Operations-II. Please state whether this facility will provide testing for commercial operation. If so, please provide the full address, contact person, telephone and fax numbers.</td><td>☐</td></tr>
<tr><td>3.2.S.3</td><td>Characterization submitted</td><td>☒</td></tr>
<tr><td>3.2.S.4</td><td>Control of Drug Substance (Active Pharmaceutical Ingredient)
3.2.S.4.1 Specification
Testing specifications and data from drug substance manufacturer(s) submitted
3.2.S.4.2 Analytical Procedures submitted
3.2.S.4.3 Validation of Analytical Procedures
1. Spectra and chromatograms for reference standards and test samples submitted
2. Samples-Statement of Availability and Identification of:
a. Drug Substance submitted
b. Same lot number(s) A.R. Nos.: 80000132469,80000143926 and 80000131939
<u>Drug substance used in the Exhibit batch:</u>
<table><tr><th>SNO</th><th>Applicant analytical report number for the drug substance used in Exhibit batch</th><th>Manufacturer Certificate of analysis batch number</th></tr><tr><td>1</td><td>80000143926</td><td>AFCA0349</td></tr><tr><td>2</td><td>80000131939</td><td>AFCA0268</td></tr><tr><td>3</td><td>80000132469</td><td>AFCA0282</td></tr></table>3.2.S.4.4 Batch Analysis
1. COA(s) specifications and test results from drug substance mfgr(s) submitted
2. Applicant certificate of analysis submitted
3.2.S.4.5 Justification of Specification
submitted</td><td>☒</td></tr>
<tr><td>3.2.S.5</td><td>Reference Standards or Materials submitted</td><td>☒</td></tr>
<tr><td>3.2.S.6</td><td>Container Closure Systems submitted</td><td>☒</td></tr>
<tr><td>3.2.S.7</td><td>Stability submitted</td><td>☒</td></tr>
</table>

MODULE 3

3.2.P DRUG PRODUCT ACCEPTABLE

3.2.P.1	**Description and Composition of the Drug Product** 1. Unit composition submitted 2. Inactive ingredients and amounts are appropriate per IIG yes	☒
3.2.P.2	**Pharmaceutical Development** Pharmaceutical Development Report submitted	☒
3.2.P.3	**Manufacture** **3.2.P.3.1 Manufacture(s)** (Finished Dosage Manufacturer and Outside Contract Testing Laboratories) 1. Name and Full Address(es)of the Facility(ies) submitted 2. CGMP Certification: YES 3. Function or Responsibility submitted 4. CFN or FEI numbers **3.2.P.3.2 Batch Formula** submitted Exhibit Commercial (b) (4) **3.2.P.3.3 Description of Manufacturing Process and Process Controls** 1. Description of the Manufacturing Process submitted 2. Master Production Batch Record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified submitted 3. If sterile product: Aseptic fill / Terminal sterilization na 4. Reprocessing Statement submitted **3.2.P.3.4 Controls of Critical Steps and Intermediates submitted** **3.2.P.3.5 Process Validation and/or Evaluation** 1. Microbiological sterilization validation na 2. Filter validation (if aseptic fill) na	☒
3.2.P.4	**Controls of Excipients (Inactive Ingredients)** Source of inactive ingredients identified submitted **3.2.P.4.1 Specifications** 1. Testing specifications (including identification and characterization) submitted 2. Suppliers' COA (specifications and test results) submitted **3.2.P.4.2 Analytical Proceduressubmitted** **3.2.P.4.3 Validation of Analytical Procedures** **3.2.P.4.4 Justification of Specifications** Applicant COA submitted	☒

MODULE 3
3.2.P DRUG PRODUCT

ACCEPTABLE

3.2.P.5	**Controls of Drug Product** **3.2.P.5.1 Specification(s)** submitted **3.2.P.5.2 Analytical Procedures** submitted **3.2.P.5.3 Validation of Analytical Procedures** Samples - Statement of Availability and Identification of: 1. Finished Dosage Form 2. Same lot numbers *3. Please submit a samples statement of availability for the finished drug product* **3.2.P.5.4 Batch Analysis** Certificate of Analysis for Finished Dosage Form submitted Batch EC10123 **3.2.P.5.5 Characterization of Impurities** **3.2.P.5.6 Justification of Specifications submitted**	☐
3.2.P.7	**Container Closure System** 1. Summary of Container/Closure System (if new resin, provide data) submitted 2. Components Specification and Test Data 3. Packaging Configuration and Sizes submitted 4. Container/Closure Testing submitted 5. Source of supply and suppliers address submitted *4. Please submit an engineering diagram for the* (b) (4)	☐
3.2.P.8	**3.2.P.8.1 Stability (Finished Dosage Form)** 1. Stability Protocol submitted submitted 2. Expiration Dating Period 24 months **3.2.P.8.2 Post-approval Stability and Conclusion** Post Approval Stability Protocol and Commitments submitted **3.2.P.8.3 Stability Data** 1. 3 month accelerated stability data submitted 2. Batch numbers on stability records the same as the test batch **yes**	☒

MODULE 3

3.2.R Regional Information

ACCEPTABLE

3.2.R (Drug Substance)	**3.2.R.1.S Executed Batch Records for drug substance (if available)** **3.2.R.2.S Comparability Protocols** **3.2.R.3.S Methods Validation Package** Methods Validation Package (3 copies) (Mult Copies N/A for E-Submissions) (Required for Non-USP drugs)	☐

3.2.R (Drug Product)	**3.2.R.1.P.1** **Executed Batch Records** Copy of Executed Batch Record with Equipment Specified, including Packaging Records (Packaging and Labeling Procedures) Batch Reconciliation and Label Reconciliation Theoretical Yield Actual Yield Packaged Yield Sponsor has relied on [redacted] (b) (4) to fulfill their minimum [redacted] (b) (4) packaging requirement; however, they have not provided accelerated stability studies for the [redacted] (b) (4) They have only provided 3 months CRT data. *5. You have used [redacted] (b) (4) to fulfill the requirement of minimum [redacted] (b) (4) packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product [redacted] (b) (4) Alternatively, you may [redacted] (b) (4) into containers for which you have provided the accelerated stability data to total a minimum of [redacted] (b) (4).* **3.2.R.1.P.2 Information on Components** **3.2.R.2.P Comparability Protocols** **3.2.R.3.P Methods Validation Package** Methods Validation Package (3 copies) (Mult Copies N/A for E-Submissions) (Required for Non-USP drugs)	☐

Summary of Batch Reconciliation Data

(b) (4)

MODULE 5

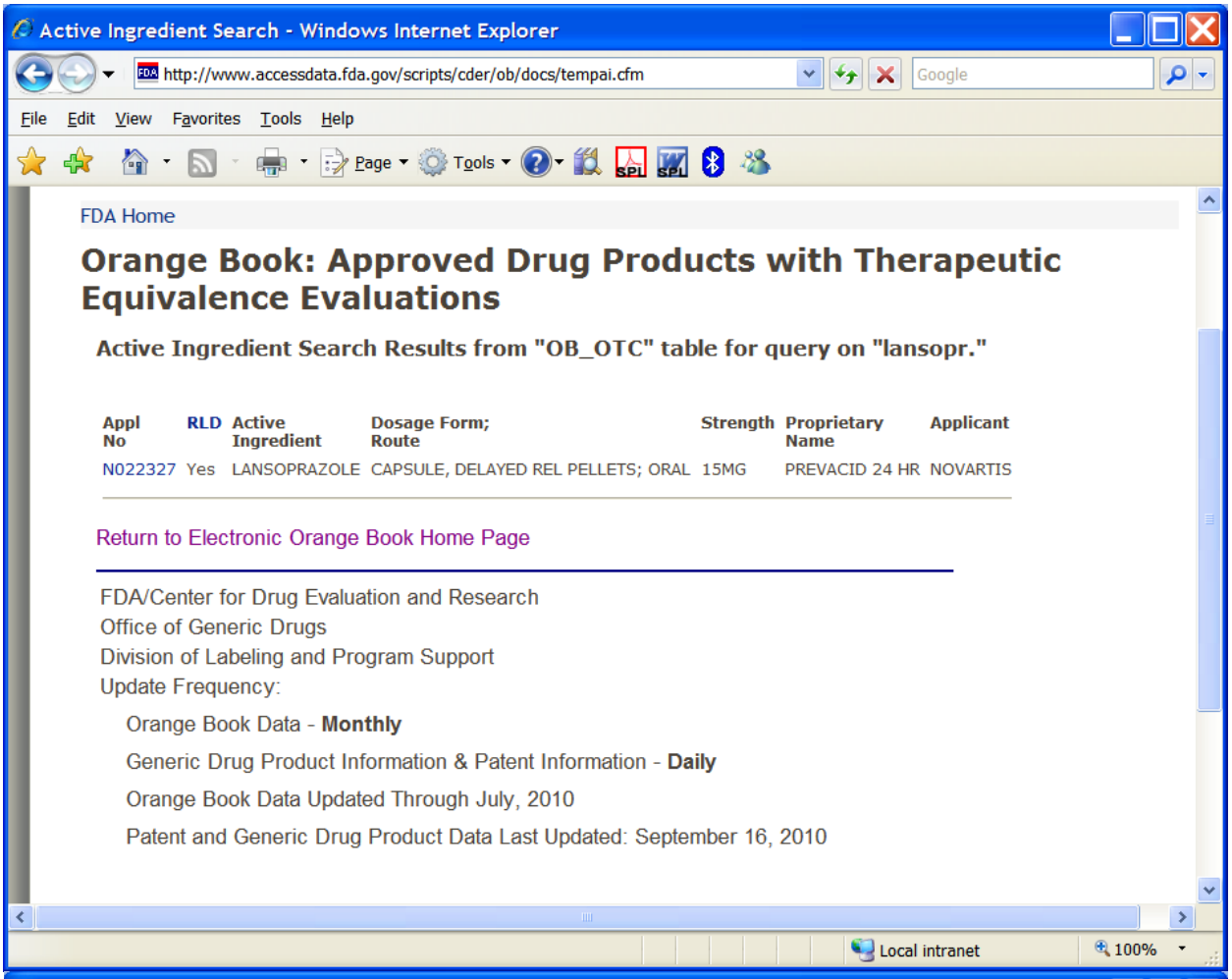
CLINICAL STUDY REPORTS ACCEPTABLE

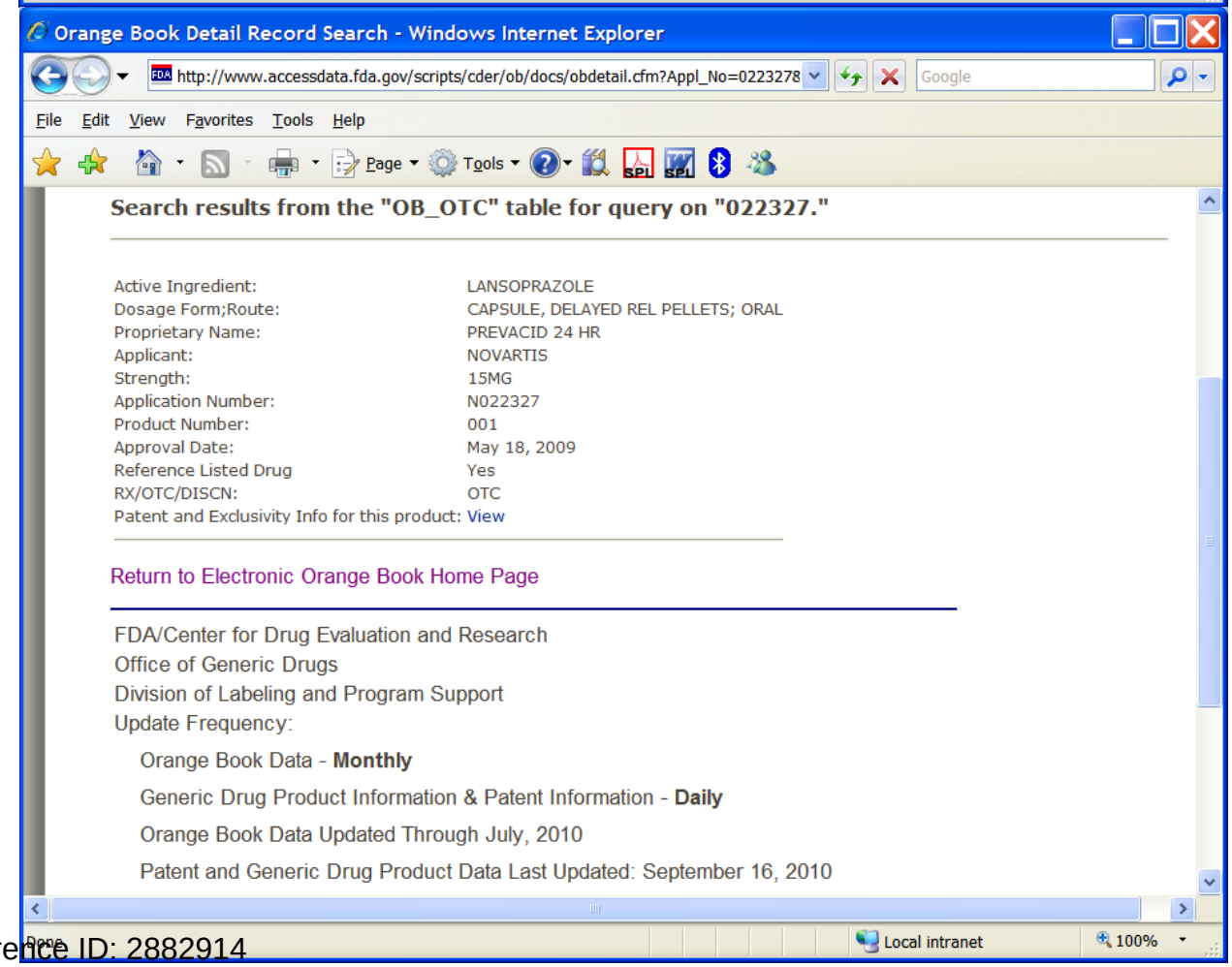
5.2	**Tabular Listing of Clinical Studies**	☐
5.3.1 (complete study data)	**Bioavailability/Bioequivalence** **1. Formulation data same?** a. Comparison of all Strengths (check proportionality of multiple strengths) b. Parenterals, Ophthalmics, Otics and Topicals per 21 CFR 314.94 (a)(9)(iii)-(v) **2. Lot Numbers of Products used in BE Study(ies):** **3. Study Type: IN-VIVO PK STUDY(IES)** (Continue with the appropriate study type box below)	☐

	5.3.1.2 Comparative BA/BE Study Reports 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) 2. Summary Bioequivalence tables: Table 10. Study Information Table 12. Dropout Information Table 13. Protocol Deviations **5.3.1.3** **In Vitro-In-Vivo Correlation Study Reports** 1. Summary Bioequivalence tables: Table 11. Product Information Table 16. Composition of Meal Used in Fed Bioequivalence Study **5.3.1.4** **Reports of Bioanalytical and Analytical Methods for Human Studies** 1. Summary Bioequivalence table: Table 9. Reanalysis of Study Samples Table 14. Summary of Standard Curve and QC Data for Bioequivalence Sample Analyses Table 15. SOPs Dealing with Bioanalytical Repeats of Study Samples **5.3.7** **Case Report Forms and Individual Patient Listing**	☐
5.4	**Literature References**	☐
	Possible Study Types:	
Study Type	**IN-VIVO BE STUDY(IES) with PK ENDPOINTS** (i.e., fasting/fed/sprinkle) NA 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) 2. EDR Email: Data Files Submitted: NA 3. In-Vitro Dissolution: NO	☐
Study Type	**IN-VIVO BE STUDY with CLINICAL ENDPOINTS** NO 1. Properly defined BE endpoints (eval. by Clinical Team) 2. Summary results meet BE criteria: 90% CI of the proportional difference in success rate between test and reference must be within (-0.20, +0.20) for a binary/dichotomous endpoint. For a continuous endpoint, the test/reference ratio of the mean result must be within (0.80, 1.25). 3. Summary results indicate superiority of active treatments (test & reference) over vehicle/placebo ($p<0.05$) (eval. by Clinical Team) 4. EDR Email: Data Files Submitted	☐
Study Type	**IN-VITRO BE STUDY(IES)** (i.e., in vitro binding assays) NO 1. Study(ies) meets BE criteria (90% CI of 80-125) 2. EDR Email: Data Files Submitted: 3. In-Vitro Dissolution:	☐

Study Type	**NASALLY ADMINISTERED DRUG PRODUCTS** 1. Solutions (Q1/Q2 sameness): a. In-Vitro Studies (Dose/Spray Content Uniformity, Droplet/Drug Particle Size Distrib., Spray Pattern, Plume Geometry, Priming & Repriming) 2. Suspensions (Q1/Q2 sameness): a. In-Vivo PK Study 1. Study(ies) meets BE Criteria (90% CI of 80-125, C max, AUC) 2. EDR Email: Data Files Submitted b. In-Vivo BE Study with Clinical End Points 1. Properly defined BE endpoints (eval. by Clinical Team) 2. Summary results meet BE criteria (90% CI within +/- 20% of 80-125) 3. Summary results indicate superiority of active treatments (test & reference) over vehicle/placebo ($p<0.05$) (eval. by Clinical Team) 4. EDR Email: Data Files Submitted c. In-Vitro Studies (Dose/Spray Content Uniformity, Droplet/Drug Particle Size Distrib., Spray Pattern, Plume Geometry, Priming & Repriming)	☐
Study Type	**IN-VIVO BE STUDY(IES) with PD ENDPOINTS** (e.g., topical corticosteroid vasoconstrictor studies) 1. Pilot Study (determination of ED50) 2. Pivotal Study (study meets BE criteria 90%CI of 80-125)	☐
Study Type	**TRANSDERMAL DELIVERY SYSTEMS** 1. In-Vivo PK Study 1. Study(ies) meet BE Criteria (90% CI of 80-125, C max, AUC) 2. In-Vitro Dissolution 3. EDR Email: Data Files Submitted 2. Adhesion Study 3. Skin Irritation/Sensitization Study	☐

Updated 10/19/2009


Active Ingredient Search - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm
File Edit View Favorites Tools Help
FDA Home
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Active Ingredient Search Results from "OB_OTC" table for query on "lansopr."
Appl No | RLD | Active Ingredient | Dosage Form; Route | Strength | Proprietary Name | Applicant
N022327 | Yes | LANSOPRAZOLE | CAPSULE, DELAYED REL PELLETS; ORAL | 15MG | PREVACID 24 HR | NOVARTIS
Return to Electronic Orange Book Home Page
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - Monthly
Generic Drug Product Information & Patent Information - Daily
Orange Book Data Updated Through July, 2010
Patent and Generic Drug Product Data Last Updated: September 16, 2010
Local intranet
100%


Orange Book Detail Record Search - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=0223278
File Edit View Favorites Tools Help
Search results from the "OB_OTC" table for query on "022327."
Active Ingredient: LANSOPRAZOLE
Dosage Form;Route: CAPSULE, DELAYED REL PELLETS; ORAL
Proprietary Name: PREVACID 24 HR
Applicant: NOVARTIS
Strength: 15MG
Application Number: N022327
Product Number: 001
Approval Date: May 18, 2009
Reference Listed Drug Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: View
Return to Electronic Orange Book Home Page
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - Monthly
Generic Drug Product Information & Patent Information - Daily
Orange Book Data Updated Through July, 2010
Patent and Generic Drug Product Data Last Updated: September 16, 2010
Done
Local intranet
100%


Patent and Exclusivity Search Results - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=0223
File Edit View Favorites Tools Help
U.S. Department of Health & Human Services
www.hhs.gov
U.S. Food and Drug Administration
A-Z Index
Search
Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products
FDA Home
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Patent and Exclusivity Search Results from query on Appl No 022327 Product 001 in the OB_OTC list.
There are no unexpired patents for this product in the Orange Book Database.
Appl No Prod No Exclusivity Code Exclusivity Expiration
N022327 001 NP May 18, 2012
View a list of all patent use codes
Done
Local intranet
100%

Date: AUGUST 25, 2009

Industry: Dr Reddy's Lab

Contact: Reena Zade

Control Number: 09-0440

Re: Submission of Lansoprazole Delayed-release Capsules 15 mg from RX to OTC.

On August 11, 2009 Ms. Reena Zade contacted me via email to request some information regarding the submission of OTC Lansoprazole Delayed-release Capsules, 15 mg. She stated that Dr. Reddy's Rx version of this drug product was submitted and currently under the Agency's review. Please see attached email received from Ms. Zade.

Research of key topics to her question, please see below the conclusion:

1.) The use of tamper indicating technology is required for OTC capsules at initial time of submission. Therefore, the firm will not be able to submit the unbanded product at initial time of submission and then send an amendment for the banded product.

2.) Dissolution and stability data of the banded product must be submitted at time of initial submission.

3.) DBE has remarked that if the formulation of the firm's product is the same from RX to OTC, then the firm will not be required to submit separate bio studies.

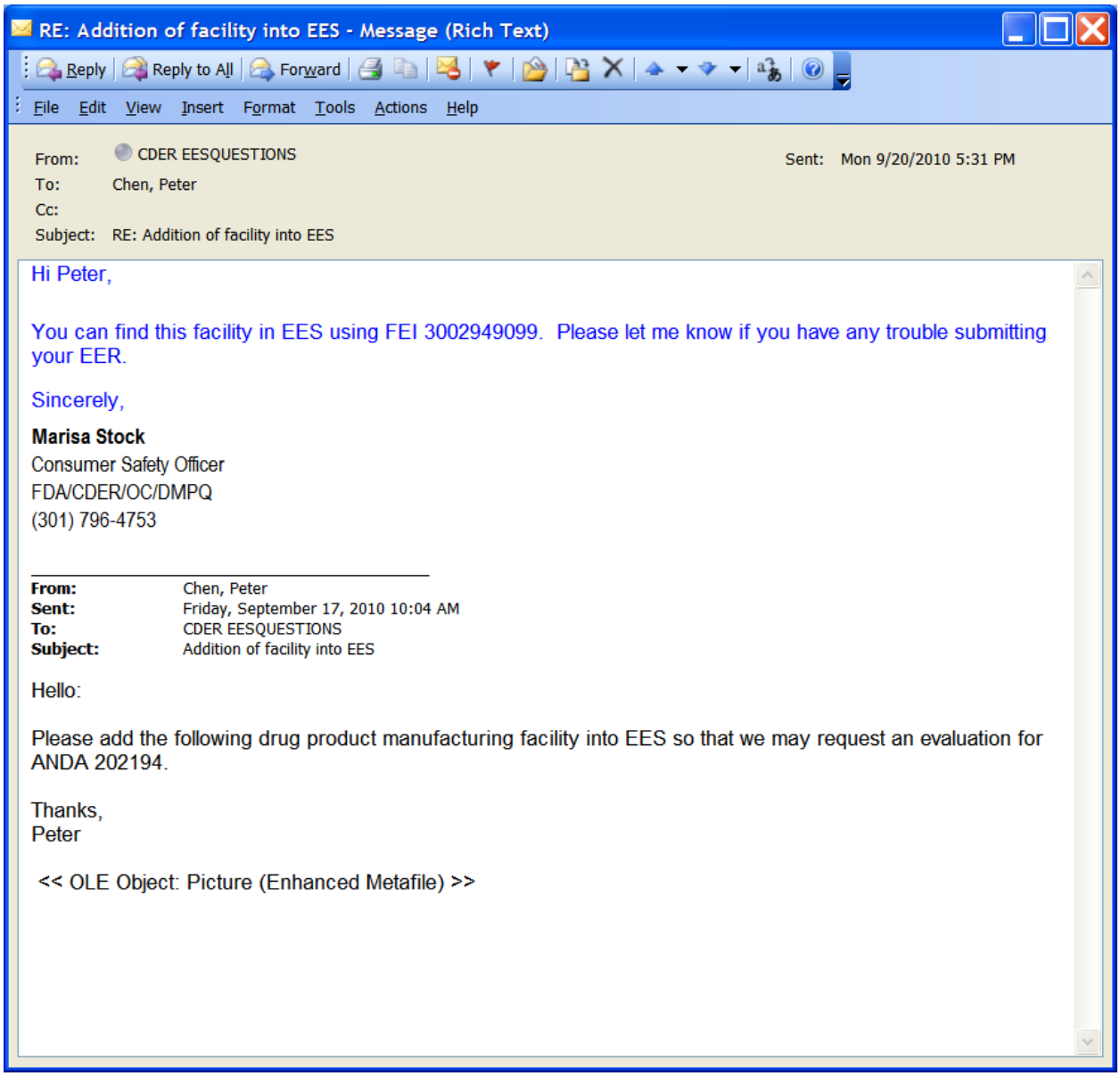
I requested the firm submit copies of the bio studies performed for the RX product in their OTC submission for ease of review.

The above was communicated to Ms. Zade on August 24, 2009.

Lisa Tan

ii) Quantitative Composition of Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)

Sno.	Component	Quantity per unit (mg)	% (w/w)	Pharmaceutical Function
Drug Layering				
1	Lansoprazole USP	15.000	8.13	Active Ingredient
				(b) (4)



RE: Addition of facility into EES - Message (Rich Text)

Reply | Reply to All | Forward

File Edit View Insert Format Tools Actions Help

From: CDER EESQUESTIONS
Sent: Mon 9/20/2010 5:31 PM
To: Chen, Peter
Cc:
Subject: RE: Addition of facility into EES

Hi Peter,

You can find this facility in EES using FEI 3002949099. Please let me know if you have any trouble submitting your EER.

Sincerely,

Marisa Stock
Consumer Safety Officer
FDA/CDER/OC/DMPQ
(301) 796-4753

From: Chen, Peter
Sent: Friday, September 17, 2010 10:04 AM
To: CDER EESQUESTIONS
Subject: Addition of facility into EES

Hello:

Please add the following drug product manufacturing facility into EES so that we may request an evaluation for ANDA 202194.

Thanks,
Peter

<< OLE Object: Picture (Enhanced Metafile) >>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

PETER CHEN
12/23/2010

MARTIN H Shimer
01/07/2011

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI.

DR. REDDY'S

January 14, 2011

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

Re: ANDA # 202194; eCTD Sequence No.:0003
Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)
Telephone amendment
Submitted via Electronic submission Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC), Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a telephone amendment. This is in response to the email request received from Mr. Peter Chen on January 13, 2011.

FDA Comment

- *We will accept 3 months CRT for the* (b) (4) *provided that you commit to test and submit the additional 3 months CRT.*

RESPONSE:

We acknowledge the agency's comment. We would like to confirm that the 6M stability data at CRT for the (b) (4) is available and is provided in Module **3.2.P.8.**

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of January 14, 2011.

Please contact the undersigned at 908-203-4937 by phone or at 908-203-4980 by fax or by email at ksekar@drreddys.com if you have any questions regarding this submission.

Sincerely,

DR. REDDY'S LABORATORIES, INC.

A. Jayalakshmi

Kumara Sekar Ph.D.,
Sr. Director, Global Regulatory Affairs

March 10, 2011

This Rescind Refuse to Receive communication contains an incorrect Date of Application as September 9, 2010 instead of the correct date August 9, 2010. The communication function has been changed to Advice. Since this letter was mailed to the firm it is being maintained in the DARRTS archive in accordance with CDER DARRTS policy. A new corrected letter will be sent to the firm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202194

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

After careful review, the Office of Generic Drugs has decided to rescind our "Refuse to Receive" letter dated January 7, 2011. Accordingly, the application is acceptable for filing.

Reference is made to to your correspondence dated November 3, 2010 and January 17, 2011.

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Lansoprazole Delayed-release Capsules USP, 15 mg

DATE OF APPLICATION: September 9, 2010

DATE (RECEIVED) ACCEPTABLE FOR FILING: November 3, 2010

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Frank Nice
Project Manager
240-276-8555

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARTIN H Shimer
02/24/2011
Signing for Wm Peter Rickman

Check 2

ANDA CHECKLIST FOR CTD or eCTD FORMAT
FOR COMPLETENESS and ACCEPTABILITY of an APPLICATION FOR FILING

For More Information on Submission of an ANDA in Electronic Common Technical Document (eCTD) Format please go to: http://www fda.gov/cder/regulatory/ersr/ectd.htm
***For a Comprehensive Table of Contents Headings and Hierarchy please go to:**
http://www fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf
**** For more** CTD and eCTD informational links **see the final page of the ANDA Checklist**
***** A model Quality Overall Summary for an immediate release tablet and an extended release capsule can be found on the OGD webpage** http://www.fda.gov/cder/ogd/ *****

ANDA #: 202194 **FIRM NAME**: DR. REDDY'S LABORATORIES LTD

PIV: NO **Electronic or Paper Submission:** ELECTRONIC (GATEWAY)

RELATED APPLICATION(S): NA

First Generic Product Received? NO

DRUG NAME: LANSOPRAZOLE

DOSAGE FORM: DELAYED-RELEASE CAPSULES USP, 15 MG

Review Team: (Bolded/Italicized & Checked indicate Assignment or DARRTS designation)

Quality Team: DC2 Team 21 ☒***Activity***	***Bio Team 7: Jiang Xiaojian*** ☒***Activity***
ANDA/Quality RPM:Frank Nice ☒ ***FYI***	Bio PM: Chitra Mahadevan ☐ ***FYI***
Quality Team Leader: Rajagopalan, Radhika No assignment needed in DARRTS	***Clinical Endpoint Team Assignment: (No)*** ☐***Activity***
Labeling Reviewer: Sarah Park ☒***Activity***	***Micro Review (No)*** ☐***Activity***

*****Document Room Note: for New Strength amendments and supplements, if specific reviewer(s) have already been assigned for the original, please assign to those reviewer(s) instead of the default random team(s). *****

Letter Date: AUGUST 9, 2010 **Received Date**: AUGUST 9, 2010

Comments: EC - 1 YES **On Cards:** YES
Therapeutic Code: 8019000 MISCELLANEOUS ULCER AGENT

Archival copy: ELECTRONIC (GATEWAY) **Sections** I
Review copy: NA E-Media Disposition: NA
Not applicable to electronic sections

PART 3 Combination Product Category N Not a Part3 Combo Product
(Must be completed for ALL Original Applications) Refer to the Part 3 Combination Algorithm

Reviewing CSO/CST Peter Chen **Date 1/28/2011**	**Recommendation:** ☒ **FILE** ☐ **REFUSE to RECEIVE**
Supervisory Concurrence/Date: ____	**Date:** ____

1. Edit Application Property Type in DARRTS where applicable for
   a. First Generic Received
      ☐ Yes ☒ No
   b. Market Availability
      ☐ Rx ☒ OTC
   c. Pepfar
      ☐ Yes ☒ No
   d. Product Type
      ☒ Small Molecule Drug (usually for most ANDAs except protein drug products)
   e. USP Drug Product (at time of filing review)
      ☒ Yes ☐ No
2. Edit Submission Patent Records
   ☒ Yes
3. Edit Contacts Database with Bioequivalence Recordation where applicable
   ☒ Yes
4. Requested EER
   ☒ Yes

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Dr. Reddy's Laboratories Limited	09/08/2010
TELEPHONE NO. *(Include Area Code)* 0091-40-23045206	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)* 0091-40-23045238

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*

Dr. Reddy's Laboratories Limited
Bachepally -502 325
INDIA

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

Kumara Sekar

Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd,
7th Floor, Bridgewater, NJ 0880,Tel: 908-203-4937, Fax: 908-203-4980

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)*: 202194

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Lansoprazole	None

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
See Attachment-1	None

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Delayed-Release Capsules	15 mg	Oral

(PROPOSED) INDICATION(S) FOR USE: Indicated for the treatment of frequent heart burn

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☑ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug: PREVACID®24 HOUR Holder of Approved Application: NOVARTIS

TYPE OF SUBMISSION *(check one)*
☑ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION: Original ANDA Submission-Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)

PROPOSED MARKETING STATUS *(check one)* ☐ PRESCRIPTION PRODUCT (Rx) ☑ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: 1 THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☑ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attachment 2 and 3

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See Attachment 4

This application contains the following items: *(Check all that apply)*

☐	1. Index
☑	2. Labeling *(check one)* ☑ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☑	4. Chemistry section
☑	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☑	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☑	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☑	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☑	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☐	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.
The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
Sign	Kumara Sekar, Ph.D., Sr. Director, Global Regulatory Affairs	09/08/2010

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
200 Somerset Corporate Blvd, Floor 7, Bridgewater NJ 08807	908-203-4937

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

MODULE 1
ADMINISTRATIVE

ACCEPTABLE

1.1	**1.1.2 Signed and Completed Application Form (356h) (original signature)** (Check Rx/OTC Status) OTC YES	☒
1.2	**Cover Letter** Dated: AUGUST 9, 2010	☒

1.2.1	**Form FDA 3674 (PDF) YES**	☒
*	**Table of Contents (paper submission only)** YES	☒
1.3.2	**Field Copy Certification (original signature)** NA **(N/A for E-Submissions)**	☒
1.3.3	**Debarment Certification-GDEA (Generic Drug Enforcement Act)/Other:** 1. Debarment Certification (original signature) YES 2. List of Convictions statement (original signature) SAME	☒
1.3.4	**Financial Certifications** Bioavailability/Bioequivalence Financial Certification (Form FDA 3454) NA Disclosure Statement (Form FDA 3455, submit copy to Regulatory Branch Chief) NA	☒
1.3.5	**1.3.5.1 Patent Information** Patents listed for the RLD in the Electronic Orange Book Approved Drug Products with Therapeutic Equivalence Evaluations **1.3.5.2 Patent Certification** 1. Patent number(s) No Relevant patents certification 2. Paragraph: (Check all certifications that apply) MOU ☐ PI ☐ PII ☒ PIII ☐ PIV ☐ (Statement of Notification) ☐ 3. Expiration of Patent(s): NA a. Pediatric exclusivity submitted? b. Expiration of Pediatric Exclusivity? 4. Exclusivity Statement: YES	☒
1.4.1	**References** Letters of Authorization 1. DMF letters of authorization a. Type II DMF authorization letter(s) or synthesis for Active Pharmaceutical Ingredient submitted Type II DMF No. 21426 b. Type III DMF authorization letter(s) for container closure submitted 2. US Agent Letter of Authorization (U.S. Agent [if needed, countersignature on 356h]) submitted	☒
1.12.11	**Basis for Submission** NDA# : 22-327 Ref Listed Drug: PREVACID 24 Hours Firm: NOVARTIS ANDA suitability petition required? NA If Yes, then is change subject to PREA (change in dosage form, route or active ingredient) see section 1.9.1	☒

MODULE 1 (Continued)
ADMINISTRATIVE

ACCEPTABLE

1.12.12	**Comparison between Generic Drug and RLD-505(j)(2)(A)** 1. Conditions of use Same as RLD 2. Active ingredients Same as RLD 3. Inactive ingredients submitted 4. Route of administration Same as RLD 5. Dosage Form Same as RLD 6. Strength Same as RLD	☒
1.12.14	**Environmental Impact Analysis Statement** YES	☒
1.12.15	**Request for Waiver** Request for Waiver of In-Vivo BA/BE Study(ies): YES ON 15 MG -See control 09-0440 -Sponsor states formulation is dose proportional to formulation in ANDA 91-269 -Biostudy performed in ANDA 91-269 is acceptable	☒
1.14.1	**Draft Labeling (Mult Copies N/A for E-Submissions)** **1.14.1.1** 4 copies of draft (each strength and container) submitted **1.14.1.2** 1 side by side labeling comparison of containers and carton with all differences annotated and explained submitted **1.14.1.3** 1 package insert (content of labeling) submitted electronically submitted ***Was a proprietary name request submitted? no (If yes, send email to Labeling Reviewer indicating such.)	☒
1.14.3	**Listed Drug Labeling** **1.14.3.1** 1 side by side labeling (package and patient insert) comparison with all differences annotated and explained submitted **1.14.3.3** 1 RLD label and 1 RLD container label submitted	☒

How Lansoprazole Delayed-Release Capsule is sold

Lansoprazole delayed-release capsules are available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

2.3	**Quality Overall Summary (QOS)** **E-Submission: PDF** submitted **Word Processed e.g., MS Word** *1. Please submit module 2.3 QOS in an MS Word file.* Adequate for filing per 10/22/2010 amendment A model Quality Overall Summary for an immediate release tablet and an extended release capsule can be found on the OGD webpage http://www fda.gov/cder/ogd/ **Question based Review (QbR)** **2.3.S** **Drug Substance (Active Pharmaceutical Ingredient)** **2.3.S.1 General Information** **2.3.S.2 Manufacture** **2.3.S.3 Characterization** **2.3.S.4 Control of Drug Substance** **2.3.S.5 Reference Standards or Materials** **2.3.S.6 Container Closure System** **2.3.S.7 Stability** **2.3.P** **Drug Product** **2.3.P.1 Description and Composition of the Drug Product** **2.3.P.2 Pharmaceutical Development** **2.3.P.2.1 Components of the Drug Product** **2.3.P.2.1.1 Drug Substance** **2.3.P.2.1.2 Excipients** **2.3.P.2.2 Drug Product** **2.3.P.2.3 Manufacturing Process Development** **2.3.P.2.4 Container Closure System** **2.3.P.3 Manufacture** **2.3.P.4 Control of Excipients** **2.3.P.5 Control of Drug Product** **2.3.P.6 Reference Standards or Materials** **2.3.P.7 Container Closure System** **2.3.P.8 Stability**	☒
2.7	**Clinical Summary (Bioequivalence)** **Model Bioequivalence Data Summary Tables** **E-Submission: PDF** **Word Processed e.g., MS Word** **2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods** **2.7.1.1 Background and Overview** Table 1. Submission Summary Table 4. Bioanalytical Method Validation Table 6. Formulation Data **2.7.1.2 Summary of Results of Individual Studies** Table 5. Summary of In Vitro Dissolution **2.7.1.3 Comparison and Analyses of Results Across Studies** Table 2. Summary of Bioavailability (BA) Studies Table 3. Statistical Summary of the Comparative BA Data **2.7.1.4 Appendix** **2.7.4.1.3 Demographic and Other Characteristics of Study Population** Table 7. Demographic Profile of Subjects Completing the Bioequivalence Study **2.7.4.2.1.1 Common Adverse Events** Table 8. Incidence of Adverse Events in Individual Studies	☐

MODULE 3

3.2.S DRUG SUBSTANCE ACCEPTABLE

<table>
<tr><td>3.2.S.1</td><td>General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties</td><td>☒</td></tr>
<tr><td>3.2.S.2</td><td>Manufacturer
3.2.S.2.1
Manufacturer(s) (This section includes contract manufacturers and testing labs)
Drug Substance (Active Pharmaceutical Ingredient)
1. Name and Full Address(es)of the Facility(ies) submitted
2. Function or Responsibility submitted
3. Type II DMF number for API submitted
4. CFN or FEI numbers submitted
2. You stated that XRD for the drug substance has been performed at Dr. Reddy's Laboratories, Chemical Technical Operations-II. Please state whether this facility will provide testing for commercial operation. If so, please provide the full address, contact person, telephone and fax numbers.
Adequate for filing per 10/22/2010 amendment</td><td>☒</td></tr>
<tr><td>3.2.S.3</td><td>Characterization submitted</td><td>☒</td></tr>
<tr><td>3.2.S.4</td><td>Control of Drug Substance (Active Pharmaceutical Ingredient)
3.2.S.4.1 Specification
Testing specifications and data from drug substance manufacturer(s) submitted
3.2.S.4.2 Analytical Procedures submitted
3.2.S.4.3 Validation of Analytical Procedures
1. Spectra and chromatograms for reference standards and test samples submitted
2. Samples-Statement of Availability and Identification of:
a. Drug Substance submitted
b. Same lot number(s) A.R. Nos.: 80000132469,80000143926 and 80000131939
<u>Drug substance used in the Exhibit batch:</u>
<table><tr><th>SNO</th><th>Applicant analytical report number for the drug substance used in Exhibit batch</th><th>Manufacturer Certificate of analysis batch number</th></tr><tr><td>1</td><td>80000143926</td><td>AFCA0349</td></tr><tr><td>2</td><td>80000131939</td><td>AFCA0268</td></tr><tr><td>3</td><td>80000132469</td><td>AFCA0282</td></tr></table>3.2.S.4.4 Batch Analysis
1. COA(s) specifications and test results from drug substance mfgr(s) submitted
2. Applicant certificate of analysis submitted
3.2.S.4.5 Justification of Specification
submitted</td><td>☒</td></tr>
<tr><td>3.2.S.5</td><td>Reference Standards or Materials submitted</td><td>☒</td></tr>
<tr><td>3.2.S.6</td><td>Container Closure Systems submitted</td><td>☒</td></tr>
<tr><td>3.2.S.7</td><td>Stability submitted</td><td>☒</td></tr>
</table>

MODULE 3

3.2.P DRUG PRODUCT ACCEPTABLE

3.2.P.1	**Description and Composition of the Drug Product** 1. Unit composition submitted 2. Inactive ingredients and amounts are appropriate per IIG yes	☒
3.2.P.2	**Pharmaceutical Development** Pharmaceutical Development Report submitted	☒
3.2.P.3	**Manufacture** **3.2.P.3.1 Manufacture(s)** (Finished Dosage Manufacturer and Outside Contract Testing Laboratories) 1. Name and Full Address(es)of the Facility(ies) submitted 2. CGMP Certification: YES 3. Function or Responsibility submitted 4. CFN or FEI numbers **3.2.P.3.2 Batch Formula** submitted Exhibit Commercial (b) (4) **3.2.P.3.3 Description of Manufacturing Process and Process Controls** 1. Description of the Manufacturing Process submitted 2. Master Production Batch Record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified submitted 3. If sterile product: Aseptic fill / Terminal sterilization na 4. Reprocessing Statement submitted **3.2.P.3.4 Controls of Critical Steps and Intermediates submitted** **3.2.P.3.5 Process Validation and/or Evaluation** 1. Microbiological sterilization validation na 2. Filter validation (if aseptic fill) na	☒
3.2.P.4	**Controls of Excipients (Inactive Ingredients)** Source of inactive ingredients identified submitted **3.2.P.4.1 Specifications** 1. Testing specifications (including identification and characterization) submitted 2. Suppliers' COA (specifications and test results) submitted **3.2.P.4.2 Analytical Proceduressubmitted** **3.2.P.4.3 Validation of Analytical Procedures** **3.2.P.4.4 Justification of Specifications** Applicant COA submitted	☒

MODULE 3
3.2.P DRUG PRODUCT

ACCEPTABLE

3.2.P.5	**Controls of Drug Product** **3.2.P.5.1 Specification(s)** submitted **3.2.P.5.2 Analytical Procedures** submitted **3.2.P.5.3 Validation of Analytical Procedures** Samples - Statement of Availability and Identification of: 1. Finished Dosage Form 2. Same lot numbers *3. Please submit a samples statement of availability for the finished drug product* Adequate for filing per 10/22/2010 amendment **3.2.P.5.4 Batch Analysis** Certificate of Analysis for Finished Dosage Form submitted Batch EC10123 **3.2.P.5.5 Characterization of Impurities** **3.2.P.5.6 Justification of Specifications submitted**	☒
3.2.P.7	**Container Closure System** 1. Summary of Container/Closure System (if new resin, provide data) submitted 2. Components Specification and Test Data 3. Packaging Configuration and Sizes submitted 4. Container/Closure Testing submitted 5. Source of supply and suppliers address submitted *4. Please submit an engineering diagram for the* (b) (4) Adequate for filing per 10/22/2010 amendment	☒
3.2.P.8	**3.2.P.8.1 Stability (Finished Dosage Form)** 1. Stability Protocol submitted submitted 2. Expiration Dating Period 24 months **3.2.P.8.2 Post-approval Stability and Conclusion** Post Approval Stability Protocol and Commitments submitted **3.2.P.8.3 Stability Data** 1. 3 month accelerated stability data submitted 2. Batch numbers on stability records the same as the test batch **yes**	☒

MODULE 3

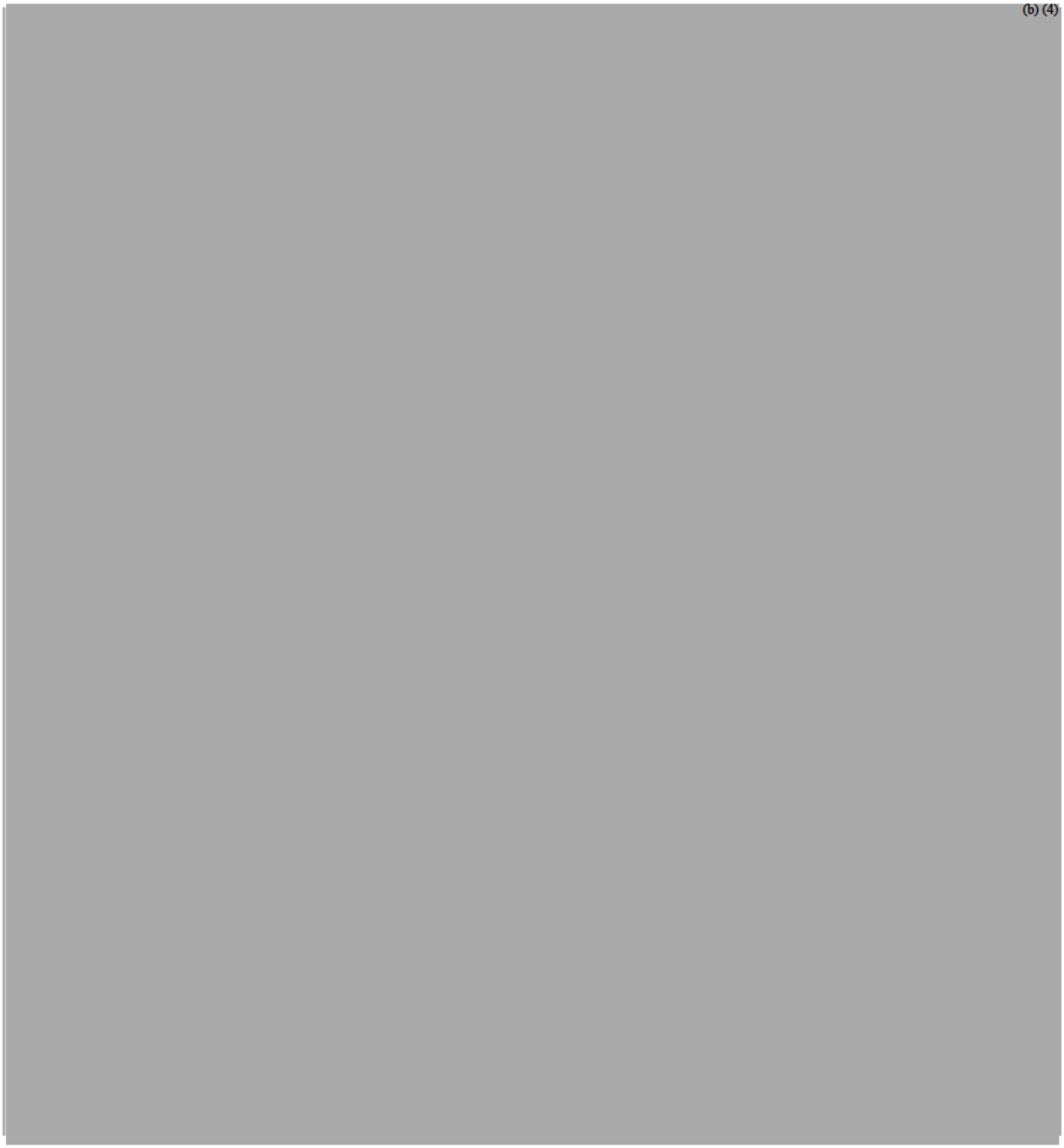
3.2.R Regional Information

ACCEPTABLE

3.2.R (Drug Substance)	**3.2.R.1.S Executed Batch Records for drug substance (if available)** **3.2.R.2.S Comparability Protocols** **3.2.R.3.S Methods Validation Package** Methods Validation Package (3 copies) (Mult Copies N/A for E-Submissions) (Required for Non-USP drugs)	☐

3.2.R (Drug Product)	**3.2.R.1.P.1** **Executed Batch Records** Copy of Executed Batch Record with Equipment Specified, including Packaging Records (Packaging and Labeling Procedures) Batch Reconciliation and Label Reconciliation Theoretical Yield Actual Yield Packaged Yield Sponsor has relied on (b) (4) packaging to fulfill their minimum (b) (4) packaging requirement; however, they have not provided accelerated stability studies for the (b) (4) They have only provided 3 months CRT data. *5. You have used (b) (4) containers to fulfill the requirement of minimum (b) (4) packaging. However the stability data you have provided is inadequate. Please provide 3 months accelerated stability data for the drug product (b) (4) Alternatively, you may (b) (4) into containers for which you have provided the accelerated stability data to total a minimum of (b) (4)* Adequate for filing based on November 3, 2010 correspondence **3.2.R.1.P.2 Information on Components** **3.2.R.2.P Comparability Protocols** **3.2.R.3.P Methods Validation Package** Methods Validation Package (3 copies) (Mult Copies N/A for E-Submissions) (Required for Non-USP drugs)	☒

Summary of Batch Reconciliation Data



MODULE 5

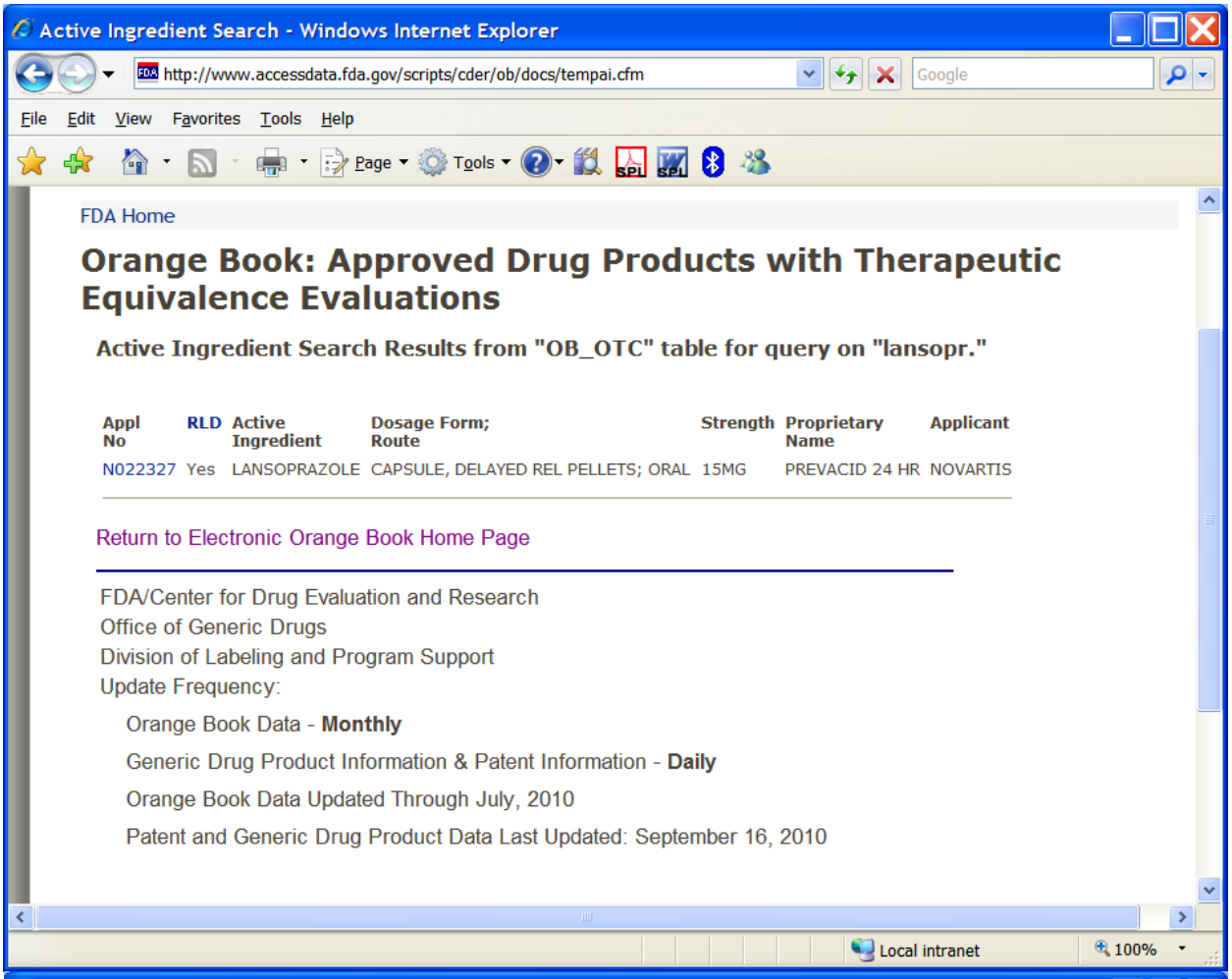
CLINICAL STUDY REPORTS ACCEPTABLE

5.2	**Tabular Listing of Clinical Studies**	☐
5.3.1 (complete study data)	**Bioavailability/Bioequivalence** **1. Formulation data same?** a. Comparison of all Strengths (check proportionality of multiple strengths) b. Parenterals, Ophthalmics, Otics and Topicals per 21 CFR 314.94 (a)(9)(iii)-(v) **2. Lot Numbers of Products used in BE Study(ies):** **3. Study Type: IN-VIVO PK STUDY(IES)** (Continue with the appropriate study type box below)	☐

	5.3.1.2 Comparative BA/BE Study Reports 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) 2. Summary Bioequivalence tables: Table 10. Study Information Table 12. Dropout Information Table 13. Protocol Deviations **5.3.1.3** **In Vitro-In-Vivo Correlation Study Reports** 1. Summary Bioequivalence tables: Table 11. Product Information Table 16. Composition of Meal Used in Fed Bioequivalence Study **5.3.1.4** **Reports of Bioanalytical and Analytical Methods for Human Studies** 1. Summary Bioequivalence table: Table 9. Reanalysis of Study Samples Table 14. Summary of Standard Curve and QC Data for Bioequivalence Sample Analyses Table 15. SOPs Dealing with Bioanalytical Repeats of Study Samples **5.3.7** **Case Report Forms and Individual Patient Listing**	☐
5.4	**Literature References**	☐
	Possible Study Types:	
Study Type	**IN-VIVO BE STUDY(IES) with PK ENDPOINTS** (i.e., fasting/fed/sprinkle) NA 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) 2. EDR Email: Data Files Submitted: NA 3. In-Vitro Dissolution: NO	☐
Study Type	**IN-VIVO BE STUDY with CLINICAL ENDPOINTS** NO 1. Properly defined BE endpoints (eval. by Clinical Team) 2. Summary results meet BE criteria: 90% CI of the proportional difference in success rate between test and reference must be within (-0.20, +0.20) for a binary/dichotomous endpoint. For a continuous endpoint, the test/reference ratio of the mean result must be within (0.80, 1.25). 3. Summary results indicate superiority of active treatments (test & reference) over vehicle/placebo ($p<0.05$) (eval. by Clinical Team) 4. EDR Email: Data Files Submitted	☐
Study Type	**IN-VITRO BE STUDY(IES)** (i.e., in vitro binding assays) NO 1. Study(ies) meets BE criteria (90% CI of 80-125) 2. EDR Email: Data Files Submitted: 3. In-Vitro Dissolution:	☐

Study Type	**NASALLY ADMINISTERED DRUG PRODUCTS** 1. Solutions (Q1/Q2 sameness): a. In-Vitro Studies (Dose/Spray Content Uniformity, Droplet/Drug Particle Size Distrib., Spray Pattern, Plume Geometry, Priming & Repriming) 2. Suspensions (Q1/Q2 sameness): a. In-Vivo PK Study 1. Study(ies) meets BE Criteria (90% CI of 80-125, C max, AUC) 2. EDR Email: Data Files Submitted b. In-Vivo BE Study with Clinical End Points 1. Properly defined BE endpoints (eval. by Clinical Team) 2. Summary results meet BE criteria (90% CI within +/- 20% of 80-125) 3. Summary results indicate superiority of active treatments (test & reference) over vehicle/placebo ($p<0.05$) (eval. by Clinical Team) 4. EDR Email: Data Files Submitted c. In-Vitro Studies (Dose/Spray Content Uniformity, Droplet/Drug Particle Size Distrib., Spray Pattern, Plume Geometry, Priming & Repriming)	☐
Study Type	**IN-VIVO BE STUDY(IES) with PD ENDPOINTS** (e.g., topical corticosteroid vasoconstrictor studies) 1. Pilot Study (determination of ED50) 2. Pivotal Study (study meets BE criteria 90%CI of 80-125)	☐
Study Type	**TRANSDERMAL DELIVERY SYSTEMS** 1. In-Vivo PK Study 1. Study(ies) meet BE Criteria (90% CI of 80-125, C max, AUC) 2. In-Vitro Dissolution 3. EDR Email: Data Files Submitted 2. Adhesion Study 3. Skin Irritation/Sensitization Study	☐

Updated 10/19/2009


Active Ingredient Search - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm
File Edit View Favorites Tools Help
FDA Home
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Active Ingredient Search Results from "OB_OTC" table for query on "lansopr."
Appl No | RLD | Active Ingredient | Dosage Form; Route | Strength | Proprietary Name | Applicant
N022327 | Yes | LANSOPRAZOLE | CAPSULE, DELAYED REL PELLETS; ORAL | 15MG | PREVACID 24 HR | NOVARTIS
Return to Electronic Orange Book Home Page
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - Monthly
Generic Drug Product Information & Patent Information - Daily
Orange Book Data Updated Through July, 2010
Patent and Generic Drug Product Data Last Updated: September 16, 2010
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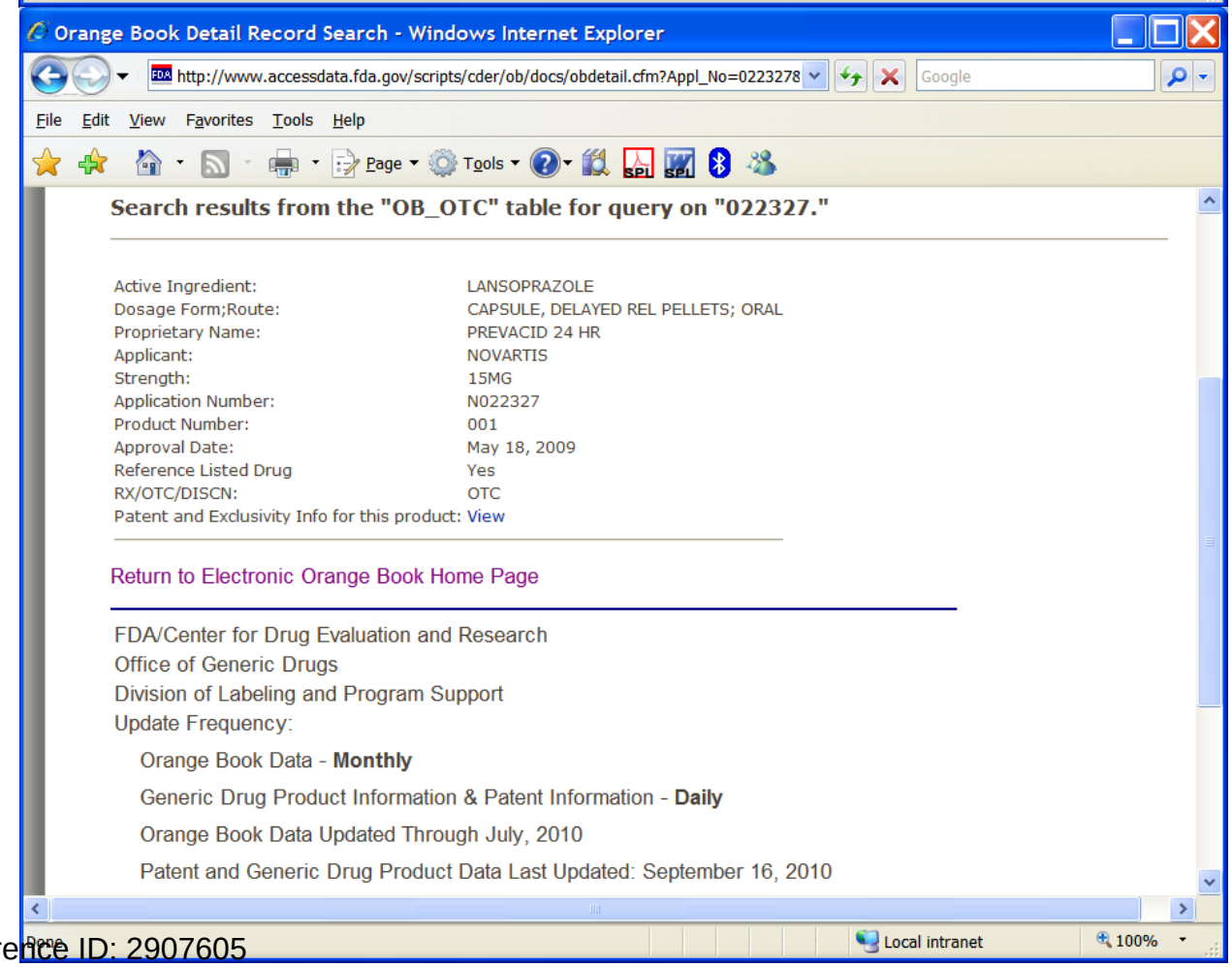
Orange Book Detail Record Search - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=0223278
File Edit View Favorites Tools Help
Search results from the "OB_OTC" table for query on "022327."
Active Ingredient: LANSOPRAZOLE
Dosage Form;Route: CAPSULE, DELAYED REL PELLETS; ORAL
Proprietary Name: PREVACID 24 HR
Applicant: NOVARTIS
Strength: 15MG
Application Number: N022327
Product Number: 001
Approval Date: May 18, 2009
Reference Listed Drug Yes
RX/OTC/DISCN: OTC
Patent and Exclusivity Info for this product: View
Return to Electronic Orange Book Home Page
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - Monthly
Generic Drug Product Information & Patent Information - Daily
Orange Book Data Updated Through July, 2010
Patent and Generic Drug Product Data Last Updated: September 16, 2010
Done
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Patent and Exclusivity Search Results - Windows Internet Explorer
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=0223
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FDA Home
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Patent and Exclusivity Search Results from query on Appl No 022327 Product 001 in the OB_OTC list.
There are no unexpired patents for this product in the Orange Book Database.
Appl No Prod No Exclusivity Code Exclusivity Expiration
N022327 001 NP May 18, 2012
View a list of all patent use codes
Done
Local intranet
100%

Date: AUGUST 25, 2009

Industry: Dr Reddy's Lab

Contact: Reena Zade

Control Number: 09-0440

Re: Submission of Lansoprazole Delayed-release Capsules 15 mg from RX to OTC.

On August 11, 2009 Ms. Reena Zade contacted me via email to request some information regarding the submission of OTC Lansoprazole Delayed-release Capsules, 15 mg. She stated that Dr. Reddy's Rx version of this drug product was submitted and currently under the Agency's review. Please see attached email received from Ms. Zade.

Research of key topics to her question, please see below the conclusion:

1.) The use of tamper indicating technology is required for OTC capsules at initial time of submission. Therefore, the firm will not be able to submit the unbanded product at initial time of submission and then send an amendment for the banded product.

2.) Dissolution and stability data of the banded product must be submitted at time of initial submission.

3.) DBE has remarked that if the formulation of the firm's product is the same from RX to OTC, then the firm will not be required to submit separate bio studies.

I requested the firm submit copies of the bio studies performed for the RX product in their OTC submission for ease of review.

The above was communicated to Ms. Zade on August 24, 2009.

Lisa Tan

ii) Quantitative Composition of Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)

Sno.	Component	Quantity per unit (mg)	% (w/w)	Pharmaceutical Function
Drug Layering				
1	Lansoprazole USP (b) (4)	15.000	8.13	Active Ingredient
				(b) (4)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

PETER CHEN
02/18/2011

MARTIN H Shimer
02/24/2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202194

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

After careful review, the Office of Generic Drugs has decided to rescind our "Refuse to Receive" letter dated January 7, 2011. Accordingly, the application is acceptable for filing.

Reference is made to to your correspondence dated November 3, 2010 and January 17, 2011.

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Lansoprazole Delayed-release Capsules USP, 15 mg

DATE OF APPLICATION: August 9, 2010

DATE (RECEIVED) ACCEPTABLE FOR FILING: November 3, 2010

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Frank Nice
Project Manager
240-276-8555

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

PETER CHEN
03/14/2011

MARTIN H Shimer
03/21/2011
Signing for Wm Peter Rickman

Electronic Log Book

Electronic Log Book ID	745
Contact:	Dr. Reddy's Laboratories Limited
Contact Person:	Kumara Sekar
Reason:	Outgoing, FDA Request for Information
Contact Type:	Phone
Category:	ANDA
ANDA/Control/Protocol #:	202194
FDA Contact:	Chitra Mahadevan
Contact Time and Date	4/29/2011 at 11:38:49 AM

Subject: Bioequivalence

Query
Bioequivalence Telephone Amendment Request for ANDA 202194, Lansoprazole Delayed-Release Capsules (OTC), 15 mg. Please submit the raw dissolution data for the acid stage. Please submit in electronic format as a Bioequivalence Response to Information Request amendment within ten business days (COB Friday, May 13, 2011).

Response
Left voicemail requesting above information.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHITRA MAHADEVAN
04/29/2011

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI.

DR. REDDY'S

May 3, 2011

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

Reference: ANDA # 202194 eCTD Seq no. 0004
Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)
Bioequivalence Amendment - Response to Information Request
Submitted Via Electronic Submission Gateway

Dear Sir/Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed Release Capsules USP, 15 mg (OTC), Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, is here with submits a Bioequivalence Amendment. This is in response to the telephonic request dated March 29, 2011 from Chitra Mahadevan of the agency.

FDA Comments:

Provide the raw dissolution data for the acid stage.

RESPONSE:

We acknowledge agency's comment.The information regarding the acid stage dissolution profile data was missed unintentionally in the ANDA.The relevant information regarding the acid stage dissolution profile has been provided in **Section 3.2.P.2.2.1**

This eCTD is submitted through electronic submission gateway. We also certify that all the files include in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of May 03, 2011.

Please contact the undersigned at 908-203-4937 or by fax at 908-203-4980 or email ksekar@drreddys.com if you have any questions regarding this submission.

Sincerely,
DR. REDDY'S LABORATORIES, INC.

Kumara Sekar Ph.D.,
Director, Global Regulatory Affairs

QUALITY DEFICIENCY - MINOR

ANDA 202194

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

APPLICANT: Dr. Reddy's Laboratories Limited TEL: 908-203-4937

ATTN: Kumara Sekar, Ph.D. FAX: 908-203-4980

FROM: Frank J. Nice FDA CONTACT PHONE: (240) 276-8555

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated August 9, 2010, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Lansoprazole Delayed Release Capsules USP, 15 mg (OTC).

Reference is also made to your amendments dated October 22 and November 3, 2010 and January 17, 2011.

The Division of Chemistry has completed its review of the submission(s) referenced above and has identified deficiencies which are presented on the attached ____ pages. This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

Your amendment should respond to all of the deficiencies listed. **Facsimiles or partial replies will not be considered for review**, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. Your cover letter should clearly indicate that the response is a ***QUALITY MINOR AMENDMENT / RESPONSE TO INFORMATION REQUEST*** and should appear prominently in your cover letter.

We also request that you include a copy of this communication with your response. Please direct any questions concerning this communication to the project manager identified above.

SPECIAL INSTRUCTIONS:

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents will be:*

Office of Generic Drugs, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

All ANDA documents will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

ANDA: 202194

APPLICANT: Dr. Reddy's Laboratories Ltd.

DRUG PRODUCT: Lansoprazole Delayed Release Capsules USP, 15 mg

The deficiencies presented below represent **MINOR** deficiencies.

Drug Substance

1. We recommend that you qualify [redacted] (b) (4)

Drug Product

2. [redacted] (b) (4)
3.
4.
5.
6.

Following this page, 1 page withheld in full (b)(4)

15. (b) (4)

16.

17.

18.

19.

20.

In addition to the deficiencies cited above we have following comments:

- Please clarify how you calculate the expiration date of your product (b) (4)

.

- Please provide the updated long term stability data.
- Please provide samples of the ANDA product along with the RLD. The samples should be sent to the attention of Dr. Frank J. Nice, HFD-645, FDA, CDER-OGD, 7500 Standish Place, Rockville, MD 20855

Sincerely yours,

{See appended electronic signature}

Glen J. Smith
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RADHIKA RAJAGOPALAN
08/08/2011
For Glen Smith,

This Letter Contains Confidential, Commercial and Trade Secret Information, Do Not Disclose Under FOI

DR. REDDY'S

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

December 02, 2011

Office of Generic Drugs,
Food and Drug Administration,
Document Control Room,
Metro Park North VII,
7620 Standish Place,
Rockville, Maryland 20855

Ref : ANDA # 202194, eCTD Seq No. 0005
Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)
Quality (CMC) Minor Amendment / Response to Information Request
Submitted via Electronic Submissions Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed Release Capsules USP, 15 mg (OTC) Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a Quality Minor Amendment. This is in response to the Agency's Quality minor deficiency letter dated August 09, 2011 which is provided along with the cover letter.

FDA Comment

1. *We recommend that you qualify* (b) (4) [redacted]

RESPONSE:

(b) (4) [redacted]

Following this page, 14 pages withheld in full (b)(4)

2. We also would like to inform the agency that we propose to use Empty Hard Gelatin capsules of Size '3' (Opaque Pink colored cap and Opaque green colored body, imprinted 'RDY' on cap and '398'on body with white ink) instead of [redacted (b) (4)]

   The revised specifications are provided in ***Module 3.2.P.5***

3. We intend to propose the batch size of pellets and filled capsules which is exactly same as that of approved Lansoprazole DR Capsule 15 mg Rx (ANDA # 091269). The proposed batch size for pellets is [redacted (b) (4)] instead of [redacted (b) (4)] and the batch size for filled capsules is [redacted (b) (4)] units instead of [redacted (b) (4)] units.

   The revised manufacturing records in ***Module 3.2.P.3***.

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of December, 2011.

Please contact the undersigned at 908-203-7022 by phone or by fax at 908-203-4980 by fax or email kernst@drreddys.com if you have any questions regarding this submission.

Sincerely,
DR. REDDY'S LABORATORIES, INC.

A Jayalakshmi.

Kimberly Ernst
Associate Director – Regulatory Affairs

This Letter Contains Confidential, Commercial and Trade Secret Information, Do Not Disclose Under FOI

DR. REDDY'S

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-4937
Fax: (908) 203-4980

www.drreddys.com

December 02, 2011

Office of Generic Drugs,
Food and Drug Administration,
Document Control Room,
Metro Park North VII,
7620 Standish Place,
Rockville, Maryland 20855

Ref : ANDA # 202194, eCTD Seq No. 0006
Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)
Gratuitous labeling amendment
Submitted via Electronic Submissions Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed Release Capsules USP, 15 mg (OTC) Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a gratuitous labeling amendment .

Reference is made to the quality minor amendment / response to information request dated December 02, 0211 (eCTD Seq 0005) in which the following change was proposed for the commercial batches.

- Usage Empty Hard Gelatin capsules of Size '3' (Opaque Pink colored cap and Opaque green colored body, imprinted 'RDY' on cap and '398'on body with white ink) instead of (b) (4)

The proposed labeling is revised to reflect the changes associated with the change in the (b) (4) (b) (4) The following labeling files are included in this submission

1. The Revised labels are provided in **Module 1 (1.14.2.1)**
2. SPL – **Module 1 (1.14.2.2)**
3. Side-by-side comparison with previously submitted labeling – **Module 1 (1.14.2.3)**

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of December 02, 2011.

Please contact the undersigned at 908-203-7022 by phone or by fax at 908-203-4980 by fax or email kernst@drreddys.com if you have any questions regarding this submission.

Sincerely,

DR. REDDY'S LABORATORIES, INC.

A Jayalakshmi.

Kimberly Ernst
Associate Director – Regulatory Affairs

QUALITY DEFICIENCY - MINOR

ANDA 202194

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

TO: Dr. Reddy's Laboratories Limited

TEL: 908-203-7022

ATTN: Kimberly Ernst

FAX: 908-203-4980

FROM: Frank J. Nice

FDA CONTACT PHONE: (240) 276-8555

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated August 9, 2010, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC).

Reference is also made to your amendment dated December 2 and December 13, 2011.

The Division of Chemistry has completed its review of the submission(s) referenced above and has identified deficiencies which are presented on the attached ____ pages. This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

Your amendment should respond to all of the deficiencies listed. **Facsimiles or partial replies will not be considered for review**, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. Your cover letter should clearly indicate that the response is a ***QUALITY MINOR AMENDMENT / RESPONSE TO INFORMATION REQUEST*** and should appear prominently in your cover letter.

We also request that you include a copy of this communication with your response. Please direct any questions concerning this communication to the project manager identified above.

SPECIAL INSTRUCTIONS:

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents will be:*

Office of Generic Drugs, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

All ANDA documents will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

ANDA: 202194

APPLICANT: Dr. Reddy's Laboratories Ltd.

DRUG PRODUCT: Lansoprazole Delayed Release Capsules USP, 15 mg

The deficiencies presented below represent **MINOR** deficiencies.

Drug Product

1. You have proposed to [redacted] (b) (4)

2. Your response indicating that [redacted] (b) (4)

3. Please justify [redacted] (b) (4) .

4. We recommend that you [redacted] (b) (4) .

5. You have indicated that microbial limit test at stability will be performed as per stability protocol. Please provide an updated stability protocol that includes in a tabular form the tests, criteria, and stability time points, including microbial limits. Please also provide the updated long term stability data with the microbial limit test results.

6. Please provide drug product analytical method transfer reports to your alternate site in [redacted] (b) (4) .

7. You have proposed [redacted] (b) (4)

Sincerely yours,

{See appended electronic signature}

Glen J. Smith
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RADHIKA RAJAGOPALAN
01/09/2012
For Glen Smith,

This Letter Contains Confidential, Commercial and Trade Secret Information, Do Not Disclose Under FOI

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-7022
Fax: (908) 203-4980

www.drreddys.com

January 24, 2012

Office of Generic Drugs,
Food and Drug Administration,
Document Control Room,
Metro Park North VII,
7620 Standish Place,
Rockville, Maryland 20855

Reference: ANDA # 202194, eCTD Seq No. 0007
Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)
Quality Minor Amendment / Response to Information Request
(Submitted via Electronic Submissions Gateway)

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed Release Capsules USP, 15 mg (OTC) Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a Quality Minor Amendment. This is in response to the Agency's Quality minor deficiency letter dated January 10, 2012 which is provided along with the cover letter.

FDA Comment

1. *You have proposed to* (b) (4)

RESPONSE:

(b) (4)

Following this page, 3 pages withheld in full (b)(4)

(b) (4)

[redacted]

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of January 24, 2012.

Please contact the undersigned at 908-203-4908 by phone or by fax at 908-203-4980 by fax or email rzade@drreddys.com if you have any questions regarding this submission.

Sincerely,
DR. REDDY'S LABORATORIES, INC.

Reena Zade
Senior Associate – Regulatory Affairs
Kimberly Ernst
Associate Director – Regulatory Affairs

** Please email me at chan.park@fda.hhs.gov to confirm that you have received this labeling comment.

Telephone Fax

ANDA 202194

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North I
7520 Standish Place
Rockville, MD 20855-2773
240-276-8951

TO: Dr. Reddys Laboratories Limited TEL: 908-203-4937

ATTN: Kumara Sekar FAX: 908-203-4980

FROM: Chan Park

This facsimile is in reference to your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Lansoprazole Delayed-Release Capsules USP, 15 mg.

Pages (including cover): 4

SPECIAL INSTRUCTIONS:

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents has become:*

Office of Generic Drugs
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

ANDAs will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 202194 Date of Submission: August 9, 2010

Applicant's Name: Dr. Reddys Laboratories Limited

Established Name: Lansoprazole Delayed-Release Capsules USP, 15 mg

Labeling Deficiencies:

1. CONTAINER – 14s (b) (4)

   a. Please confirm that your container/closure system employs a tamper-evident inner foil seal printed with "SEALED for YOUR PROTECTION".

   b. We recommend that you include the phone number for the Poison Control Center.

   c. (b) (4)

2. CARTON – 1 x 14s, 2 x 14s, and 3 x 14s

   a. See comments under CONTAINER, whichever applicable.

   b. We recommend that you increase the prominence of the text "xxx 14-DAY COURSE OF TREATMENT". Please ensure that this text be closely associated with the net quantity statement, the packaging of 42s in particular.

   c. We strongly recommend that you include the text "One Bottle Inside", "Two Bottles Inside" or "Three Bottles Inside" in a prominent manner for the packaging of 14s, 28s, and 42s, respectively. Please include this text in association with the net quantity statement.

   d. Inactive Ingredients:

      We recommend that you specify the botanical source for "Starch, *i.e.* Starch (Corn)".

3. (b) (4)

4.

(b) (4)

5. INSERT

Please delete the (b) (4) as it is not appearing in the updated labeling for the "Prevacid®24 Capsules.

Revise the labeling as described above and submit final printed labeling electronically. Please provide the labeling in the Structured Product Labeling (SPL) as well as pdf. format.

Prior to approval, it may be necessary to revise your labeling subsequent to approved changes for the reference listed drug. In order to keep ANDA labeling current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address - http://service.govdelivery.com/service/subscribe.html?code=USFDA_17

To facilitate review of your next submission please provide a side-by-side comparison of your proposed labeling with your last labeling submission with all differences annotated and explained.

If you have any questions, please call Chan Park at 240-276-8951 or send e-mail to chan.park@fda.hhs.gov

{See appended electronic signature page}

_____

William Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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/s/

CHAN H PARK
02/03/2012

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI.

DR. REDDY'S

February 09, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-7022
Fax: (908) 203-4980

www.drreddys.com

Re: ANDA # 202194, eCTD Seq No.: 0008
Lansoprazole Delayed-Release Capsules USP, 15 mg
Labeling Amendment – Response to deficiency letter
CMC amendment – (b) (4)
(b) (4)
Submitted Via Electronic Submission Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed-Release Capsules USP, 15 mg, Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a Labeling Amendment. This is in response to the deficiency dated February 06, 2012, which is provided along with the cover letter.

We would also like to inform the agency that Dr. Reddy's would like to (b) (4)

FDA Comment

1. ***CONTAINER - 14s*** (b) (4)

   a. *Please confirm that your container/closure system employs a tamper-evident inner foil seal printed with "SEALED for YOUR PROTECTION"*
   b. *We recommend that you include the phone number for the Poison Control Center.*
   c. (b) (4)

Response:

We acknowledge agency's comment. We confirm that the container/closure system employs a tamper-evident inner foil seal printed with "SEALED for YOUR PROTECTION". The Container label for 14s (b) (4) are revised to include the phone number for Poison Control Centre. (b) (4)

FDA Comment

2. ***CARTON -1 x 14s, 2 x 14s, and 3 x 14s***
   a. *See comments under CONTAINER, whichever applicable.*
   b. *We recommend that you increase the prominence of the text "xxx 14-DAY COURSE OF TREATMENT". Please ensure that this text be closely associated with the net quantity statement, the packaging of 42s In particular.*
   c. *We strongly recommend that you include the text "One Bottle Inside", "Two Bottles Inside" or "Three Bottles Inside" in a prominent manner for the packaging of 14s, 28s, and 42s, respectively. Please include this text in association with the net quantity statement.*
   d. *Inactive ingredients:*
   We recommend that you specify the botanical source for "Starch, i.e. Starch (Corn)".

Response:

We acknowledge agency's comment. The carton labels are revised as per the FDAs comments. The phone number for Poison Control Centre has been added on carton labeling. Prominence of text 'xxx 14-day course of treatment' has been increased by moving the text (xx capsules & xxx-14-day course of treatment) on right side of panel, and making the text bold non-caps. For comment number c, the text has been revised to 1 BOTTLE INSIDE 14 CAPSULES TOTAL, 2 BOTTLES INSIDE 28 CAPSULES TOTAL AND 3 BOTTLES INSIDE 42 CAPSULES TOTAL to match the innovator. Botanical source for starch has been specified under inactive ingredients section as 'starch (corn)'.

FDA Comment

3. (b) (4)

4. (b) (4)

[redacted] (b) (4)

FDA Comment

5. INSERT

Please delete the [redacted] (b) (4) *section as it is not appearing in the updated labeling for the "Prevacid® 24 Capsules"*

Response:

We acknowledge agency's comment. The package inert has been revised as per the FDAs comment. Based on comments received for carton container labeling, the phone number for Poison Control Centre has also been added on the insert.

The following labeling is included in this submission:

1. Final labels – **Module 1 (1.14.2.1)**
2. Final package insert – **Module 1 (1.14.2.2)**
3. SPL – **Module 1 (1.14.2.2)**
3. Side-by-side comparison of previous and revised labeling – **Module 1 (1.14.2.3)**

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of February 09, 2012.

Please contact the undersigned by email at rzade@drreddys.com or by phone 908-203-4908 or by fax at 908-203-4980 if you have any questions regarding this submission.

Sincerely,
DR. REDDY'S LABORATORIES, INC.

Reena Zade
Sr Associate Regulatory Affairs as designee for
Kimberly Ernst
Director Regulatory Affairs

** Please email me at chan.park@fda.hhs.gov to confirm that you have received this labeling comment.

Telephone Fax

ANDA 202194

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North I
7520 Standish Place
Rockville, MD 20855-2773
240-276-8951

TO: Dr. Reddys Laboratories Ltd. TEL: 908-203-4937

ATTN: Kumara Sekar FAX: 908-203-4980

FROM: Chan Park

This facsimile is in reference to your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Lansoprazole Delayed-Release Capsules USP, 15 mg.

Pages (including cover): 3

SPECIAL INSTRUCTIONS:

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents has become:*

Office of Generic Drugs
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

ANDAs will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 202194 Date of Submission: February 9, 2012

Applicant's Name: Dr. Reddys Laboratories Limited

Established Name: Lansoprazole Delayed-Release Capsules USP, 15 mg

Labeling Deficiencies:

1. CONTAINER – 14s

   Satisfactory in FPL as of the 2/9/2012 submission

2. CARTON – 1 x 14s, 2 x 14s, and 3 x 14s

   We note that you included (b) (4) .

3. INSERT

   Satisfactory in FPL as of the 2/9/2012 submission

Revise the labeling as described above and submit final printed labeling electronically. Please provide the labeling in the Structured Product Labeling (SPL) as well as pdf. format.

Prior to approval, it may be necessary to revise your labeling subsequent to approved changes for the reference listed drug. In order to keep ANDA labeling current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address - http://service.govdelivery.com/service/subscribe.html?code=USFDA_17

To facilitate review of your next submission please provide a side-by-side comparison of your proposed labeling with your last labeling submission with all differences annotated and explained.

If you have any questions, please call Chan Park at 240-276-8951 or send e-mail to chan.park@fda.hhs.gov

{See appended electronic signature page}

William Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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/s/

CHAN H PARK
02/14/2012

This Letter Contains Confidential, Commercial and Trade Secret Information. Do Not Disclose Under FOI

DR. REDDY'S

February 20, 2012

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-7022
Fax: (908) 203-4980

www.drreddys.com

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

Re: ANDA # 202194, eCTD Seq No.: 0009
Lansoprazole Delayed-Release Capsules USP, 15 mg
Labeling Amendment
Submitted Via Electronic Submission Gateway

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed-Release Capsules USP, 15 mg, Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a Labeling Amendment. This is in response to the deficiency dated February 15, 2012, which is provided along with the cover letter. Reference is also made to the email communication with Mr. Chan Park dated February 16, 2012.

FDA Comment

1. CONTAINER - 14s
Satisfactory in FPL as of the 2/9/2012 submission

Response:

We acknowledge agency's comment. The container label 14s count is revised to change the term [redacted] (b) (4) to "24 Hour" to be in line with the carton labelling.

FDA Comment

2. CARTON -1 x 14s, 2 x 14s, and 3 x 14s

We note that you included [redacted] (b) (4)

Response:

We acknowledge agency's comment. [redacted] (b) (4)

FDA Comment

3. INSERT

Satisfactory in FPL as of the 2/9/2012 submission

Response:

We acknowledge agency's comment.

The following labeling is included in this submission:

1. Final labels – **Module 1 (1.14.2.1)**
2. SPL – **Module 1 (1.14.2.2)**
3. Side-by-side comparison of previous and revised labeling – **Module 1 (1.14.2.3)**

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of February 20, 2012.

Please contact the undersigned by email at rzade@drreddys.com or by phone 908-203-4908 or by fax at 908-203-4980 if you have any questions regarding this submission.

Sincerely,

DR. REDDY'S LABORATORIES, INC.

Reena Zade
Sr Associate Regulatory Affairs as designee for
Kimberly Ernst
Associate Director , Regulatory Affairs

Record of Telephone Conversation

The reviewer called the applicant to convey that the applicant's response about monitoring (b) (4) [redacted]. The applicant was told to submit a telephone amendment to revise the in-process specifications.

Date:
03/02/2012

ANDA Number:
202194

Product Name:
Lansoprazole Capsules OTC

Firm Name:
Dr. Reddy's Laboratories

Firm Representative:
Reena Zade

Phone Number:
908-203-4908

FDA Representative:
Bhagwant Rege

Signatures:
Bhagwant Rege

CC: ANDA

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BHAGWANT D REGE
03/02/2012

DR. REDDY'S

This Letter Contains Confidential, Commercial and Trade Secret Information, Do Not Disclose Under FOI

Dr. Reddy's Laboratories, Inc.
Regulatory Affairs

200 Somerset Corporate Boulevard
Building II, 7th Floor
Bridgewater, NJ 08807-2862

Tel: (908) 203-7022
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www.drreddys.com

March 05, 2012

Office of Generic Drugs,
Food and Drug Administration,
Document Control Room,
Metro Park North VII,
7620 Standish Place,
Rockville, Maryland 20855

Reference: ANDA # 202194, eCTD Seq No. 0010
Lansoprazole Delayed Release Capsules USP, 15 mg (OTC)
Telephonic Amendment
(Submitted via Electronic Submissions Gateway)

Dear Sir/ Madam:

With reference to ANDA # 202194 for Lansoprazole Delayed Release Capsules USP, 15 mg (OTC) Dr. Reddy's Laboratories Inc., U.S. agent for Dr. Reddy's Laboratories Limited, herewith submits a Telephonic Amendment. This is in response to the telephonic correspondence dated March 02, 2012 with Bhagwant Rege of the agency.

FDA Comment

1. Provide the side by side comparison of the batch record data (of Rx and OTC ANDA's) and also please provide side by side comparison of the in process specifications at commercial scale for the OTC capsules and the Rx capsules (approved under ANDA 091269). Please identify and justify the differences, if any.

RESPONSE: As recommended by the agency, the side by side comparison of the batch record data and in process specifications at commercial scale for the OTC capsules and the Rx capsules (approved under ANDA 091269) have been provided below for ready reference.

Following this page, 4 pages withheld in full (b)(4)

This submission is provided as an electronic copy only and is submitted through electronic submission gateway. We also certify that all the files included in this submission were checked and verified to be free of viruses using McAfee® VirusScan® Enterprise, program version 8.7i and scan engine 5400 with a virus definition date of March 05, 2012.

Please contact the undersigned at 908-203-4908 by phone or by fax at 908-203-4980 by fax or email rzade@drreddys.com if you have any questions regarding this submission.

Sincerely,
DR. REDDY'S LABORATORIES, INC.

Reena Zade
Senior Associate, Regulatory Affairs as designee for
Kimberly Ernst
Director, Regulatory Affairs

ROUTING SHEET

☒ **APPROVAL** ☐ **TENTATIVE APPROVAL** ☐ **SUPPLEMENTAL APPROVAL (NEW STRENGTH)** ☐ **CGMP**

Division: II	**Team: 7**	**PM: Frank Nice**

Electronic ANDA: Yes ☒ No ☐

ANDA #:202194
Firm Name:Dr. Reddy's Laboratories, Inc.
ANDA Name:Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC)
RLD Name:Prevacid 24 HR Delayed Release Pellets Capsules (OTC)

Electronic AP Routing Summary Located:
V:\Chemistry Division II\Team 7\Electronic AP Summaries

AP/TA Letter Located:
V:\Chemistry Division II\Team 7\Final Version For DARRTS\AP TA Letters

Project Manager Evaluation: **Date: 3/9/12 Initials:** fjn

☐ Previously reviewed and tentatively approved --- Date _____
☐ Previously reviewed and CGMP Complete Response issued -- Date _____

Original Rec'd date August 9, 2010	Date of Application August 9, 2010	Date Acceptable for Filing October 14, 2010
Patent Certification (type) PIII	Date Patent/Excl. expires n/a	Citizens' Petition/Legal Case? Yes☐ No ☒ (If YES, attach email from PM to CP coord)
First Generic Yes ☐ No ☒ **DMF#:** _____ (provide MF Jackets)	Priority Approval (Top 100, PEPFAR, etc.)? Yes ☐ No ☒ Comment: Prepared Draft Press Release sent to Cecelia Parise Yes ☐ No ☒ Date:	
☐ Suitability Petition/Pediatric Waiver	Pediatric Waiver Request: Accepted ☐ Rejected ☐ Pending ☐	

EER Status: ☐ Pending ☒ Acceptable ☐ OAI *EES Date Acceptable: 4/2/12* ☐ Warning Letter Issued; Date:
Has there been an amendment providing for a Major change in formulation since filling? Yes ☐ No ☒ Comment:
Date of Acceptable Quality (Chemistry) 3/8/12 Addendum Needed: Yes ☐ No ☒ Comment:
Date of Acceptable Bio 5/20/11 Bio reviews in DARRTS: Yes ☒ No ☐ (Volume location:)
Date of Acceptable Labeling 3/9/12 Attached labeling to Letter: Yes ☒ No ☐ Comment:
Date of Acceptable Sterility Assurance (Micro) n/a

Methods Val. Samples Pending: Yes ☐ No ☒**;** Commitment Rcvd. from Firm: Yes ☐ No ☐

Post Marketing Agreement (PMA): Yes ☐ No ☒ (If yes, email PM Coordinator) Comment:

Modified-release dosage form: Yes ☐ No ☒ (If yes, enter dissolution information in Letter)

Routing:
☒ Labeling Endorsement, Date emailed: 3/12/12 REMS Required: Yes ☐ No ☒ REMS Acceptable: Yes ☐ No ☐

☒ Regulatory Support

☒ Paragraph 4 Review (Dave Read, Susan Levine), Date emailed: n/a

☐ Division

☒ 1st Generic Review

☐ Bob West / Peter Rickman
☐ Keith Webber

☒Filed AP Routing Summary in DARRTs	☒Notified Firm and Faxed Copy of Approval Letter	☒ Sent Email to "CDER-OGDAPPROVALS" distribution list

OGD APPROVAL ROUTING SUMMARY

1. ***Regulatory Support Branch Evaluation***

Martin Shimer **Date: 3/14/2012**

Chief, Reg. Support Branch **Initials:** MHS

Contains GDEA certification: Yes ☒ No ☐	Determ. of Involvement? Yes ☐ No ☒
(required if sub after 6/1/92)	Pediatric Exclusivity System
	RLD = Prevacid 24 Hour NDA# 22-327 Date Checked 4/10/12 Nothing Submitted ☒ Written request issued ☐ Study Submitted ☐
Patent/Exclusivity Certification: Yes ☒ No ☐ If Para. IV Certification- did applicant: Notify patent holder/NDA holder Yes ☐ No ☐ Was applicant sued w/in 45 days:Yes ☐ No ☐ Has case been settled: Yes ☐ No ☐ Date settled: Is applicant eligible for 180 day	
Generic Drugs Exclusivity for each strength: Yes ☐ No ☒	
Date of latest Labeling Review/Approval Summary _____	
Any filing status changes requiring addition Labeling Review Yes ☐ No ☒	

Type of Letter:
☒ APPROVAL ☐ TENTATIVE APPROVAL ☐ SUPPLEMENTAL APPROVAL (NEW STRENGTH) ☐ CGMP
☐ OTHER:

Comments:ANDA submitted on 8/9/2010, BOS=Prevacid 24 hour NDA 22-327, no relevant patent statement provided, firm acknowledge that NP exclusivity expires on 5/18/2012. RTR issued on 10/24/2010. Second RTR issued on 1/7/2011. This second RTR was rescinded and the application was Accepted for Filing on 11/3/2010. There are no patents currently listed for the NDA but there is NP exclusivity which will expire on 5/18/2012.
ANDA is currently eligible for TA only due to unexpired NP Exclusivity.
Update 5/2/2012-As this ANDA was not TA'd by 4/30/2012 this ANDA will go to Full Approval on 5/18/2012 upon the expiration of the NP exclusivity.

2. ***Labeling Endorsement***

Reviewer, Chan Park:
Date3/12/1`2
Initialscp

Labeling Team Leader, Koung Lee:
Date3/12/12
Initialskl

REMS required?
☐Yes ☒No

REMS acceptable?
☐Yes ☐No ☒n/a

Comments:

Hi Frank,

Please endorse the APS for me. I could not locate the Team 7 under "Chem Div. II" folder, so I could not endorse in the electronic APS. Thanks,

Chan

Good morning gentlemen. I concur. Thanks.

Koung

3. ***Paragraph IV Evaluation*** **PIV's Only**

David Read — **Date 4/10/12**
OGD Regulatory Counsel — **Initials rlw/for**

Pre-MMA Language included ☐
Post-MMA Language Included ☐
Comments: N/A. There are no paragraph IV certifications associated with this ANDA.

4. ***Quality Division Director /Deputy Director Evaluation*** **Date 4/9/2012**

Chemistry Div. **II (Fang)** — **InitialsGJS**

Comments:CMC Acceptable.

5. ***First Generic Evaluation*** **First Generics Only**

Frank Holcombe — **Date 4/10/12**
Assoc. Dir. For Chemistry — **Initials rlw/for**

Comments: (First generic drug review)
N/A. Multiple ANDAs have been approved for the prescription only presentation of this drug product.

OGD Office Management Evaluation

6. Peter Rickman — **Date 4/10/12**

Director, DLPS — **Initials rlw/for**

Para.IV Patent Cert: Yes☐ No☐
Pending Legal Action: Yes ☐ No ☐
Petition: Yes☐ No☐

Comments: Bioequivalence waiver granted under 21 CFR 320.24(b)(6). Acceptable fasting, non-fasting and sprinkle studies were conducted by the applicant under ANDA 91-269 for the prescription-only version of this drug product. In-vitro dissolution testing under both ANDA 202194 and 91-269 were found acceptable. ANDA 91-269 was approved on 10/15/10. Office-level bio endorsed 5/20/11.

Final-printed labeling (FPL) found acceptable for approval 3/9/12, as endorsed 4/10/12 via email. No REMS is required.

CMC found acceptable for approval [Chemistry Review #3(a)] 4/9/12.

AND/OR

7. Robert L. West **Date 5/18/12**
Deputy Director, OGD **Initials RLWest**
Para.IV Patent Cert: Yes☐ No☒
Pending Legal Action: Yes☐ No☒
Petition: Yes☐ No☒
Press Release Acceptable ☐
Date PETS checked for first generic drug _____

Comments: Acceptable EES dated 4/2/12 (Verified 5/18/12). No "OAI" Alerts noted. Reevaluation date is 5/20/12.

The new product (NP) exclusivity currently listed in the "Orange Book" for this drug product will expire on May 18, 2012. There are no additional patents or exclusivity listed in the current "Orange book" for this drug product.

Note: A Citizen Petition (2011-P-0840) submitted by Perrigo Company has been before the agency. The C.P. has been classified as a 505(q) petition with a due date of May 16, 2012. The agency's has issued its response to this C.P.

With the expiration of the new product (NP) exclusivity, this ANDA is recommended for final approval.

8. ***OGD Director Evaluation***
Keith Webber

Deputy Director, OPS

Comments: RLWest for Keith Webber, Ph.D. 5/18/12
First Generic Approval ☐
PD or Clinical for BE ☐
Special Scientific or Reg.Issue ☐
Press Release Acceptable ☐

Comments:

9. Project Manager

Date 5-18-12
Initials lp

Check Communication and Routing Summary into DARRTS

Orange Book Report:

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

- 
-  [1]
-  [2]

- FDA Home[3]
- Drug Databases[4]
- Orange Book[5]

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Patent and Exclusivity Search Results from query on Appl No 022327 Product 001 in the OB_OTC list.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N022327	001	NP	May 18, 2012

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LINDA M PARK
05/22/2012