DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020076/S-045

SUPPLEMENT APPROVAL

Dr. Reddy's Laboratories, Inc.
Attention: Srinivasa Rao, PharmD (US Agent)
Vice President and Head Regulatory Affairs-North America
107 College Road East, 2nd Floor
Princeton, NJ 08540

Dear Dr. Rao:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 23, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Habitrol (nicotine transdermal system) 7 mg, 14 mg, and 21 mg.

This "Prior Approval" supplemental new drug application provides for the following:

- Four new bonus count size configurations (21- and 28-count STEP 1, 21 mg; 14-count STEP 2, 14 mg; 14-count STEP 3, 7 mg)
- An adhesive (sticker) label which states 'TWIN PACK 2 x 14ct PATCHES'
- One $3.00 coupon (placed inside the carton with discount applied at subsequent purchase)
- Addition of 'See Coupon inside' flag on the principal display panel (PDP)
- Three $3.00 instantly redeemable coupons (IRCs)
- New carton labeling with a $3.00 IRC adhered to the PDP
- Revision to the net quantity statement to include the number of weeks of treatment, in addition to the already approved number of patches
- Addition of statement on all incomplete package sizes that informs the consumer of an incomplete course of treatment

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

- Change the comma to a semicolonin the incomplete package statements on all cartons. The statement on 7-count 14 mg (STEP 2) carton is used as an example and should read: "The full course of treatment for STEP 2 is 2 or 6 weeks (depending on how many cigarettes you smoke per day); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information."

- Add a period to the last sentence of the incomplete package statement on the principal display panel on the 7-count 7 mg (STEP 3) carton, so that it reads: "The full treatment course for STEP 3 is 14 patches (2 weeks); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information."

LABELING

Submit final printed labeling, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the labeling listed in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
21 mg, STEP 1	
1-count immediate container (pouch)	January 23, 2017
2-count carton (standard label)	July 17, 2017
2-count carton with 'See Coupon inside' flag	July 17, 2017
4-count carton (standard label)	July 17, 2017
4-count carton with 'See Coupon inside' flag	July 17, 2017
7-count carton (standard label)	July 14, 2017
7-count carton with 'See Coupon inside' flag	July 14, 2017
7-count carton with $3.00 IRC on the PDP	July 14, 2017
14-count carton (standard label)	July 14, 2017
14-count carton with 'See Coupon inside' flag	July 14, 2017
14-count carton with $3.00 IRC on the PDP	July 14, 2017
28-count carton with 'See Coupon inside' flag	July 14, 2017
28-count carton with $3.00 IRC on the PDP	July 17, 2017

21-count (14+7 BONUS PACK) carton	July 14, 2017
28-count (BONUS PACK 14+14) carton	July 14, 2017
'TWIN PACK 2 x 14ct PATCHES' adhesive (sticker) label	January 23, 2017
$3.00 Instantly Redeemable Coupon (IRC) corresponding with the 21 mg product	April 3, 2017
14 mg, STEP 2	
1-count immediate container (pouch)	January 23, 2017
2-count carton (standard label)	July 20, 2017
2-count carton with 'See Coupon inside' flag	July 20, 2017
4-count carton (standard label)	July 20, 2017
4-count carton with 'See Coupon inside' flag	July 20, 2017
7-count carton (standard label)	July 20, 2017
7-count carton with 'See Coupon inside' flag	July 20, 2017
7-count carton with $3.00 IRC on the PDP	July 20, 2017
14-count carton (standard label)	July 14, 2017
14-count carton with 'See Coupon inside' flag	July 14, 2017
14-count carton with $3.00 IRC on the PDP	July 20, 2017
14-count carton (BONUS PACK 7 + 7)	July 20, 2017
$3.00 IRC corresponding with the 14 mg product	April 3, 2017
7 mg, STEP 3	
1-count immediate container (pouch)	January 23, 2017
2-count carton (standard label)	July 17, 2017
2-count carton with 'See Coupon inside' flag	July 17, 2017
4-count carton (standard label)	July 17, 2017
4-count carton with 'See Coupon inside' flag	July 17, 2017
7-count carton (standard label)	July 14, 2017
7-count carton with 'See Coupon inside' flag	July 14, 2017
7-count carton with $3.00 IRC on the PDP	July 14, 2017
14-count carton (standard label)	July 14, 2017
14-count carton with 'See Coupon inside' flag	July 14, 2017

14-count carton with $3.00 IRC on the PDP	July 14, 2017
14-count carton (BONUS PACK 7 + 7)	July 14, 2017
$3.00 IRC corresponding with the 7 mg product	April 3, 2017
All strengths: 21 mg (STEP 1), 14 mg (STEP 2), or 7 mg (STEP 1)	
56-count Complete Kit carton	July 14, 2017
Self-help Guide (Consumer Information Leaflet), front	January 23, 2017
Self-help Guide (Consumer Information Leaflet), back	January 23, 2017
$3.00 Coupon	April 3, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020076/S-045**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

KAREN M MAHONEY
07/23/2017