DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 050564/S-053, S-055
NDA 050575/S-040, S-042
NDA 050597/S-047, S-049
NDA 050720/ S-026, S-028
NDA 050725/S-028, S-030
NDA 050726/S-022, S-024

SUPPLEMENT APPROVAL

Dr. Reddy's Laboratories, Inc.
Attention: Shobha Reddy Chagam
Senior Manager, Regulatory Affairs
200 Somerset Corporate Boulevard
Building 11, 7th Floor
Bridgewater, NJ 08807-2862

Dear Ms. Chagam:

Please refer to your supplemental New Drug Applications (sNDA) for the following:

NDA Number	Drug Name	Supplement Number	Submission Date	Date Received
050564	AUGMENTIN (amoxicillin/clavulanate potassium) Tablets, 250 mg/125 mg and 500 mg/125 mg	S-053 S-055	June 25, 2009 October 30, 2009	June 25, 2009 October 30, 2009
050575	AUGMENTIN (amoxicillin/clavulanate potassium) Powder for Oral Suspension	S-040 S-042	June 29, 2009 October 30, 2009	June 29, 2009 October 30, 2009
050597	AUGMENTIN (amoxicillin/clavulanate potassium) Chewable Tablets	S-047 S-049	June 29, 2009 October 30, 2009	June 29, 2009 October 30, 2009
050720	AUGMENTIN (amoxicillin/clavulanate potassium) Tablets, 875mg/125 mg	S-026 S-028	June 25, 2009 October 30, 2009	June 25, 2009 October 30, 2009
050725	AUGMENTIN (amoxicillin/clavulanate potassium) Oral Suspension	S-028 S-030	June 29, 2009 November 3, 2009	June 29, 2009 November 3, 2009
050726	AUGMENTIN (amoxicillin/clavulanate potassium) Chewable Tablets	S-022 S-024	June 29, 2009 October 30, 2009	June 29, 2009 October 30, 2009

We acknowledge receipt of your amendments dated January 10, 2013.

The "Prior Approval" supplemental applications submitted on June 25 and June 29, 2009, provide for revisions to the labeling as per guidance on the Physician's Labeling Rule (PLR).

The "Changes Being Effected" supplemental applications submitted on October 30 and November 3, 2009, provide for the addition of information regarding the prolongation of prothrombin time in patients receiving amoxicillin and oral anticoagulants to the Drug Interactions section.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling, submitted on January 10, 2013, with the additional changes agreed to in your communication dated January 22, 2013.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. 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/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

SUMATHI NAMBIAR
01/22/2013