DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050564/S-052
NDA 050720/S-025

SUPPLEMENT APPROVAL

Dr. Reddy's Laboratories, Inc.
Attention: Kumara Sekar, Ph.D.
Senior Director, Global Regulatory Affairs and Compliance
200 Somerset Corporate Boulevard, 7th Floor
Bridgewater, NJ 08807

Dear Dr. Sekar:

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-052	October 8, 2008	October 8, 2008
050720	AUGMENTIN (amoxicillin/clavulanate potassium) Tablets, 875mg/125 mg	S-025	October 8, 2008	October 8, 2008

We acknowledge receipt of your amendments dated September 22, 2011, and your communication dated September 28, 2011.

These "Prior Approval" supplemental applications provide for a response to the Agency's request to review the interpretive criteria and the quality control parameters for *in vitro* susceptibility testing of the organisms listed in the label.

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 September 22, 2011, with the additional changes agreed to in your communication dated September 28, 2011.

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
09/29/2011