DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050542/S-026, S-027, S-028
NDA 050754/S-013, S-014, S-017
NDA 050760/S-012, S-013, S-015
NDA 050761/S-012, S-013, S-015

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
050542	AMOXIL (amoxicillin) Chewable Tablets	S-026 S-027 S-028	June 24, 2009 December 10, 2008 September 25, 2009	June 24, 2009 December 10, 2008 September 25, 2009
050754	AMOXIL (amoxicillin) Tablets-BID	S-013 S-014 S-017	June 24, 2009 December 10, 2008 September 25, 2009	June 24, 2009 December 10, 2008 September 25, 2009
050760	AMOXIL (amoxicillin) Oral Suspension-BID	S-012 S-013 S-015	June 24, 2009 December 10, 2008 September 25, 2009	June 24, 2009 December 10, 2008 September 25, 2009
050761	AMOXIL (amoxicillin) Chewable Tablets-BID	S-012 S-013 S-015	June 24, 2009 December 10, 2008 September 25, 2009	June 24, 2009 December 10, 2008 September 25, 2009

We acknowledge receipt of your amendments dated September 15 and November 15, 2011. The September 15, 2011 submissions constituted a complete response to our July 22, 2011 action letter.

The "Prior Approval" supplemental applications submitted on June 24, 2009, propose to revise the label as per the guidance on the Physician's Labeling Rule (PLR).

The "Prior Approval" supplemental applications submitted on December 10, 2008, provide for changes in the quality control ranges for *Staphylococcus aureus* and *Streptococcus pneumoniae.*

The "Changes Being Effected" supplemental applications submitted on September 25, 2009, provide for the addition of information regarding the prolongation of prothrombin time in patients receiving amoxicillin and oral anticoagulants to the PRECAUTIONS/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 text, submitted on November 15, 2011.

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 submission, 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

ENCLOSURES:
Content of Labeling

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
11/16/2011