DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50542/S-029
NDA 50754/S-019
NDA 50760/S-019
NDA 50761/S-016

**SUPPLEMENT APPROVAL**

Dr. Reddy's Laboratories, Inc.
Attention: Lalitha Subramanian
Associate Director, Regulatory Affairs
107 College Road East
Princeton, NJ 08540

Dear Ms. Subramanian:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received July 8, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

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| NDA 50542/S-029 | AMOXIL (amoxicillin) Chewable Tablets,125 mg, 250 mg |
| NDA 50754/S-019 | AMOXIL (amoxicillin) Tablets-BID, 500 mg, 875 mg |
| NDA 50760/S-019 | AMOXIL (amoxicillin) Oral Suspension-BID, 200 mg/5 mL, 400 mg/5mL |
| NDA 50761/S-016 | AMOXIL (amoxicillin) Chewable Tablets-BID, 200 mg, 400 mg |

We acknowledge receipt of your amendments dated August 19 and 28, and September 17, 2015.

These "Prior Approval" supplemental applications provide for the following revisions to the package insert:

- Deletion of the following indication from the Indications and Usage section (1): Gonorrhea, acute uncomplicated (ano-genital and urethral infections in males and females) – due to *Neisseria gonorrhoeae*.

- Deletion of dosage information related to Gonorrhea acute, uncomplicated ano-genital and urethral infections in males and females in the DOSAGE AND ADMINISTRATION section, Dosage for Adult and Pediatric Patients > 3 Months of Age subsection (2.1).

- Updates to the Microbiology (12.4) subsection regarding susceptibility test interpretive criteria and deletion of language regarding *N. gonorrhoeae*.

- Editorial revisions to other sections of the package insert.

**APPROVAL & LABELING**

We have completed our review of these supplemental applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**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 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 that includes labeling changes 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 this supplemental application, 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, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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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.**

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/s/

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SUMATHI NAMBIAR
09/24/2015