



NDA 50542/S-030
NDA 50754/S-020
NDA 50760/S-020
NDA 50761/S-017

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 November 6 (NDA 50760/S-20, NDA 50761/S-017) and November 9 (NDA 50542/S-030, NDA 50754/S-20), 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50542/S-030	AMOXIL (amoxicillin) Chewable Tablets, 125 mg, 250 mg
NDA 50754/S-020	AMOXIL (amoxicillin) Tablets-BID, 500 mg, 875 mg
NDA 50760/S-020	AMOXIL (amoxicillin) Oral Suspension-BID, 200 mg/5 mL, 400 mg/5mL
NDA 50761/S-017	AMOXIL (amoxicillin) Chewable Tablets-BID, 200 mg, 400 mg

These "Changes Being Effected" supplemental new drug applications correct the inadvertent omission of the sentence "If an allergic reaction occurs, AMOXIL should be discontinued and appropriate therapy instituted" from the WARNINGS AND PRECAUTIONS section, Anaphylactic Reactions subsection (5.1).

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:

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<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 include 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}

Joseph Toerner, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: 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/

JOSEPH G TOERNER
12/03/2015