



ANDA 207740

**ANDA APPROVAL**

Dr. Reddy's Laboratories Inc.  
U.S. Agent for Dr. Reddy's Laboratories Limited  
107 College Road East, 2<sup>nd</sup> Floor  
Princeton, NJ 08540  
Attention: Srinivasa Rao  
Vice President and Head, Regulatory Affairs, North America

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 19, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Omeprazole Delayed-Release Tablets, 20 mg [OTC].

Reference is also made to the tentative approval letter issued by this office on July 27, 2018, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly, the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Omeprazole Delayed-Release Tablets, 20 mg [OTC], to be bioequivalent to the reference listed drug (RLD), Omeprazole Delayed-Release Tablets, 20 mg [OTC], of Dexcel Pharma Technologies Limited (Dexcel).

The RLD upon which you have based your ANDA, Dexcel's Omeprazole Delayed-Release Tablets, 20 mg [OTC], is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
9,023,391 (the '391 patent)	August 16, 2025

Your ANDA contains a paragraph IV certification to the '391 patent<sup>1</sup> under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Omeprazole Delayed-Release Tablets, 20 mg [OTC], under this ANDA. You have notified the Agency that Dr. Reddy's Laboratories Limited (Dr. Reddy's) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that litigation was initiated within the statutory 45-day period against Dr. Reddy's for infringement of the '391 patent in the United States District Court for the District of New Jersey [Dexcel Pharma Technologies Ltd. and Dexcel Ltd. v. Dr. Reddy's Laboratories, Ltd., et al., Civil Action No. 15-08017 (consolidated)]. You have also notified the Agency that on August 6, 2018, the court

entered a Consent Judgment finding that Dr. Reddy's ANDA product does not infringe any claim of the '391 patent.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

### **REPORTING REQUIREMENTS**

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

### **ANNUAL FACILITY FEES**

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions<sup>2</sup> with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts.

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

For Vincent Sansone, PharmD  
Deputy Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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<sup>1</sup> The Agency notes that the ‘391 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.  
<sup>2</sup> Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).



Priya  
Shah

Digitally signed by Priya Shah  
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