ANDA 207891

ANDA APPROVAL

Sun Pharmaceutical Industries, Inc.
U.S. Agent for Sun Pharmaceutical Industries Limited
2 Independence Way
Princeton, NJ 08540
Attention: Mr. Ronak Patel
Regulatory Affairs Manager

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 18, 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 complete response letter issued by this office on May 25, 2016, 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, of Dexcel Pharma Technologies Limited (Dexcel).

The RLD upon which you have based your ANDA, Dexcel's Omeprazole Delayed Release Tablets, 20 mg, 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.S. Patent Number	Expiration Date
9,023,391 (the '391 patent)	August 16, 2025

Your ANDA contains a paragraph IV certification to the '391 patent[1] 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 Sun Pharmaceutical Industries Limited (Sun) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that litigation was initiated against Sun 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. Sun Pharma Global FZE, et al., Civil Action No. 15-08017]. You have also notified the Agency that on August 6, 2018, the court entered a Consent Judgment finding that Sun's ANDA product does not infringe any claim of the '391 patent.

With respect to 180-day generic drug exclusivity, we note that Sun was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Omeprazole Delayed-Release Tablets, 20 mg (OTC). Therefore, with this approval, Sun is eligible for 180 days of generic drug exclusivity for Omeprazole Delayed-Release Tablets, 20 mg (OTC). It is noted that this ANDA was not tentatively approved within 30-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the Agency has determined that Sun has not forfeited its eligibility for 180-day generic drug exclusivity.[2] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing. Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

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[3] 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, Pharm.D.
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] 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.
[2] ANDA 207891 was received on June 18, 2014. This ANDA was never tentatively approved and therefore was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the Agency has determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed.
[3] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Heidi Lee

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