



ANDA 078560

APPROVAL

Glenmark Pharmaceuticals, Inc., USA
U.S. Agent for: Glenmark Pharmaceuticals Limited
750 Corporate Drive
Mahwah, NJ 07430
Attention: Kalpana Vanam
Vice President, Head of Regulatory Affairs, North America

Dear Sir or Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 25, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Ezetimibe Tablets, 10 mg.

Reference is also made to the tentative approval letter issued by this office on April 24, 2009, the complete response letter issued by this office on March 21, 2013, and to your amendments dated May 31 and June 3, 2013; May 13, September 12, October 10, and October 29, 2014; and June 5, 2015.

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 use as recommended in the submitted labeling. Accordingly the **ANDA is approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Ezetimibe Tablets, 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zetia (Ezetimibe), Tablets 10 mg, of MSD International GmbH (MSD). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, MSD's Zetia (Ezetimibe) Tablets, 10 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are 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>
7,030,106 (the '106 patent)	July 25, 2022
7,612,058 (the '058 patent)	April 30, 2026
RE37,721 (the '721 patent)	April 25, 2017
RE42,461 (the '461 patent)	April 25, 2017

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ezetimibe Tablets, 10 mg, under this ANDA.¹ You have notified the agency that Glenmark Pharmaceuticals Limited (Glenmark) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation for infringement of the ‘721 patent was brought against Glenmark in the United States District Court for the New Jersey [Schering Corporation and MSP Singapore Company LLC v. Glenmark Pharmaceuticals, Inc., USA and Glenmark Pharmaceuticals LTD, Civil Action No. 07-1334]. You have also notified the agency that the complaint was dismissed on May 10, 2010 and no action for infringement of the ‘106 patent was brought against Glenmark; therefore, under section 505(j)(5)(B)(iii) of the FD&C Act your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Glenmark was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Glenmark is eligible for 180 days of generic drug exclusivity for Ezetimibe Tablets, 10 mg. 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 correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

¹ The agency notes that the ‘058 and ‘461 patents were not listed in the Orange Book at the time your ANDA was submitted, and therefore litigation, if any, with respect to them creates no statutory stay of approval.

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions 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 1 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.

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,

**William P.
Rickman -S**

For Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS,
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