ANDA 214862

ANDA APPROVAL

Apotex Corp.
U.S. Agent for Apotex Inc.
2400 North Commerce Parkway, Suite 400
Weston, FL 33326
Attention: Kiran Krishnan
Senior Vice President, Global Regulatory Affairs

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 27, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Obeticholic Acid Tablets, 5 mg and 10 mg.

Reference is also made to the tentative approval letter issued by this office on June 14, 2022, 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 meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Obeticholic Acid Tablets, 5 mg and 10 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Ocaliva Tablets, 5 mg and 10 mg, of Intercept Pharmaceuticals, Inc. (Intercept).

The RLD upon which you have based your ANDA, Intercept's Ocaliva Tablets, 5 mg and 10 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
9,238,673 (the '673 patent)	June 17, 2033
10,047,117 (the '117 patent)	September 6, 2033
10,052,337 (the '337 patent)	April 26, 2036
10,174,073 (the '073 patent)	June 17, 2033
10,751,349 (the '349 patent)	April 26, 2036

10,758,549 (the '549 patent)	April 26, 2036
RE48,286 (the '286 patent)	February 21, 2027

Your ANDA contains paragraph IV certifications to each of the patents[1], 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 Obeticholic Acid Tablets, 5 mg and 10 mg, under this ANDA. You have notified the Agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Apotex for infringement of the '673, '117, '337, and '073 patents in the United States District Court for the District of Delaware [Intercept Pharmaceuticals, Inc. and Intercept Pharma Europe Ltd. v. Apotex Inc. and Apotex Corp., Civil Action No. 20-01105 (consolidated]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Apotex was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Obeticholic Acid Tablets, 5 mg and 10 mg. Therefore, with this approval, Apotex is eligible for 180 days of shared generic drug exclusivity for Obeticholic Acid Tablets, 5 mg and 10 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). 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).

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

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] The Agency notes that the '349, '549 and '286 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Catherine Poole

Digitally signed by Catherine Poole
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