ANDA 217650

ANDA TENTATIVE APPROVAL

Teva Pharmaceuticals, Inc.
Attention: Alberto Rivalta
Senior Director, Regulatory Affairs

Dear Alberto Rivalta:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 3, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Elagolix, Estradiol, and Norethindrone Acetate Capsules; Elagolix Capsules, 300 mg/1 mg/0.5 mg; 300 mg co-packaged.

Reference is also made to the complete response letter issued by this office on December 11, 2023, 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. We have determined your Elagolix, Estradiol, and Norethindrone Acetate Capsules; Elagolix Capsules, 300 mg/1 mg/0.5 mg; 300 mg co-packaged to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Oriahnn Capsules, 300 mg/1mg/0.5mg; 300 mg, of AbbVie Inc. (AbbVie), NDA - 213388.

However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the Agency at this time (e.g., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C Act.

The RLD upon which you have based your ANDA, AbbVie's Oriahnn Capsules, 300 mg/1mg/0.5mg; 300 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
7,419,983 (the '983 patent)	July 6, 2029
10,881,659 (the '659 patent)	March 14, 2034
11,045,470 (the '470 patent)	March 14, 2034
11,459,305 (the '305 patent)	November 7, 2028
11,542,239 (the '239 patent)	July 23, 2039
11,690,845 (the '845 patent)	August 27, 2040
12,083,227 (the '227 patent)	August 20, 2038

With respect to the '983 and '305 patents, your ANDA contains paragraph III certifications to each of the patents under section 505(j)(2)(A)(vii)(III) of the FD&C Act stating that Teva Pharmaceuticals, Inc. (Teva) will not market Elagolix, Estradiol, and Norethindrone Acetate Capsules; Elagolix Capsules, 300 mg/1 mg/0.5 mg; 300 mg co-packaged prior to the expiration of the patents. Therefore, final approval of your ANDA may not be granted pursuant to section 505(j)(5)(B)(ii) of the FD&C Act until the '983 and '305 patents have expired, currently July 6, 2029.

Your ANDA contains paragraph IV certifications to the '659, '470, '239, '845 and '227 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 Elagolix, Estradiol, and Norethindrone Acetate Capsules; Elagolix Capsules, 300 mg/1 mg/0.5 mg; 300 mg co-packaged, under this ANDA. You have notified the Agency that Teva Pharmaceuticals, Inc. 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 Teva for infringement of the '659 and '470 patents in the United States District Court for the District of Delaware [Abbvie Inc. v. Teva Pharmaceutical Inc., and Teva Pharmaceutical Industries LTD., Civil Action No. 23-00133]. You have also notified the Agency that this case was dismissed.

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, if your ANDA receives final approval, it 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.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Uzoma Nnebe, Regulatory Project Manager, at (240) 402 - 5828.

Sincerely yours,

{See appended electronic signature page}

For Malik Imam, PharmD, MBA
CDR, United States Public Health Service
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Paul
Levine

Digitally signed by Paul Levine
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