ANDA 216431

ANDA TENTATIVE APPROVAL

Sandoz Inc.
100 College Road West
Princeton, NJ 08540
Attention: Gregory Seitz
Executive Director, Regulatory Affairs

Dear Gregory Seitz:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 14, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Apalutamide Tablets, 60 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

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 Apalutamide Tablets, 60 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Erleada Tablets, 60 mg, of Janssen Biotech, Inc. (Janssen).

However, we are unable to grant final approval to your ANDA at this time because of the patent/exclusivity 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, Janssen's Erleada Tablets, 60 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
8,445,507 (the '507 patent)	September 15, 2030

8,802,689 (the '689 patent)	March 27, 2027
9,388,159 (the '159 patent)	March 27, 2027
9,481,663 (the '663 patent)	June 4, 2033
9,884,054 (the '054 patent)	September 23, 2033
9,987,261 (the '261 patent)	March 27, 2027
10,052,314 (the '314 patent)	September 23, 2033
10,702,508 (the '508 patent)	April 30, 2038
10,849,888 (the '888 patent)	September 23, 2033
RE49,353 (the '353 patent)	September 23, 2033

With respect to: 1) the '054, '314, '508, '888, and '353; and 2) the '507, '689, and '663 patents (including those portions pertaining to (b) (4) your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim any indication or other conditions of use (b) (4)

With respect to: 1) the '159 and '261 patents; and 2) the '507, '689, and '663 patents (excluding those portions pertaining to (b) (4) your ANDA contains paragraph IV certifications 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 Apalutamide Tablets, 60 mg, under this ANDA. You have notified the Agency that Sandoz Inc. (Sandoz) 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 Sandoz for infringement of the '507, '689, '159, '663, and '261 patents in the United States District Court for the District of New Jersey [Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., The Regents of the University of California, and Sloan-Kettering Institute for Cancer Research v. Sandoz Inc., Civil Action No. 22-03044].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 7.5-year period provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act,

   b. the date the court decides[1] that the '507, '689, '159, '663, and '261 patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the FD&C Act), or

c. the '507, '689, '159, '663, and '261 patents have expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

With respect to the '663 patent insofar as it pertains to the (b) (4) the Agency has determined that information on this use code for the '663 patent was submitted to the Agency by the new drug application (NDA) holder (a) after the date of the submission of your ANDA, and (b) more than 30 days after the description of the approved method(s) of use claimed by the patent was required to be submitted under 21 CFR 314.53. Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the submission of the description of the approved method(s) of use claimed by the '663 patent was required to submit an amended patent certification to address the (b) (4) to the '663 patent. You elected not to submit an amended patent certification with respect to this use code for the '663 patent.

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 Tram Nguyen, Regulatory Project Manager, at (240) 402-1028.

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] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

Catherine Poole

Digitally signed by Catherine Poole
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