ANDA 214085

ANDA APPROVAL/TENTATIVE APPROVAL

Zydus Pharmaceuticals (USA) Inc.
73-B, Route 31 North
Pennington, NJ 08534
Attention: Srinivas Gurram
Sr. VP and Head of Regulatory Affairs and CQA Lead- Americas

Dear Srinivas Gurram:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on October 23, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Darunavir Tablets, 75 mg, 150 mg, 600 mg and 800 mg.

Reference is also made to the tentative approval letter issued by this office on June 7, 2023, and to any amendments thereafter.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated December 2, 2019.

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 Darunavir Tablets, 75 mg, 150 mg, 600 mg and 800 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Prezista Tablets, 75 mg, 150 mg, 600 mg and 800 mg, of Janssen Products, LP (Janssen).

However, we are unable to grant final approval to your Darunavir Tablets, 75 mg and 150 mg, at this time because of the exclusivity issue noted below. Therefore, your ANDA is **approved** insofar as it pertains to Darunavir Tablets, 600 mg and 800 mg. Your Darunavir Tablets, 75 mg and 150 mg, are **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.

The reference listed drug (RLD) upon which you have based your ANDA, Prezista Tablets, 75 mg, 150 mg, 600 mg and 800 mg, of Janssen, 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.S. Patent Number	Expiration Date
7,700,645 (the '645 patent)	June 26, 2027
8,518,987 (the '987 patent)	August 16, 2024

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 Darunavir Tablets, 75 mg, 150 mg, 600 mg and 800 mg, under this ANDA. You have notified the Agency that Zydus Pharmaceuticals (USA) Inc. (Zydus) 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 Zydus for infringement of the '645 and '987 patents in the United States District Court for the District of New Jersey [Janssen Products, LP and Janssen Sciences Ireland Unlimited Company v. Zydus Pharmaceuticals (USA) Inc., Civil Action No. 20-00787]. You have also notified the Agency that this case was dismissed.

However, we are unable to grant final approval with respect to the 75 mg and 150 mg, strength product(s) at this time. Prior to the submission of your ANDA, another applicant or applicants submitted a substantially complete ANDA providing for Darunavir Tablets, 75 mg and 150 mg, and containing a paragraph IV certification. Your ANDA for these strengths will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

Upon the foregoing, your ANDA is **approved** insofar as it pertains to the 600 mg and 800 mg products. Your 75 mg and 150 mg products are **tentatively approved**.

I. Approval of Darunavir Tablets, 600 mg and 800 mg

We note that Zydus Pharmaceuticals (USA) Inc. (Zydus) was granted a Competitive Generic Therapy (CGT) designation for Darunavir Tablets, 800 mg. However, as noted in the December 2, 2019, CGT Designation – Grant Letter, your drug products are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

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.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

II. Tentative Approval of Darunavir Tablets, 75 mg and 150 mg

Our decision to tentatively approve your Darunavir Tablets, 75 mg and 150 mg, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

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.

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, i.e., 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 "MINOR/MAJOR AMENDMENT TO ORIGINAL #2 – 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.

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.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Paula Oriaku, PharmD, MS, Regulatory Project Manager, at (301) 796 - 1644.

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

John Ibrahim

Digitally signed by John Ibrahim
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