ANDA 202327

ANDA APPROVAL

Watson Laboratories Inc.
Attention: Mahendra Barot
Director, Regulatory Affairs

Dear Mahendra Barot:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on October 18, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Sitagliptin Tablets USP, 25 mg, 50 mg and 100 mg.

Reference is also made to the tentative approval letter issued by this office on April 15, 2014, 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 Sitagliptin Tablets USP, 25 mg, 50 mg and 100 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Januvia Tablets, 25 mg, 50 mg and 100 mg, of Merck Sharp & Dohme LLC (Merck Sharp & Dohme) NDA - 021995.

The RLD upon which you have based your ANDA, Merck Sharp & Dohme's Januvia Tablets, 25 mg, 50 mg and 100 mg, is subject to a period of patent protection. The following patent and expiration date (including attached pediatric exclusivity) is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
7,326,708 (the '708 patent)	May 24, 2027

Your ANDA contains a paragraph IV certification to the '708 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Sitagliptin Tablets USP, 25 mg, 50 mg and 100 mg, under this ANDA. You have notified the Agency that Watson Laboratories Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the

FD&C Act and that no action for infringement was brought against Watson within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Watson was one of the first ANDA applicants for Sitagliptin Tablets USP, 25 mg, 50 mg and 100 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Watson may be eligible for 180 days of shared generic drug exclusivity for Sitagliptin Tablets USP, 25 mg, 50 mg and 100 mg. The Agency notes that Watson failed to obtain tentative approval of its ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Watson's eligibility for 180-day generic drug exclusivity.

At least one first applicant remains eligible for 180-day generic drug exclusivity for Sitagliptin Tablets USP, 25 mg, 50 mg and 100 mg absent forfeiture under section 505(j)(5)(D) of the FD&C Act.[1] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, would begin 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.

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 at: https://www.uspnf.com/.

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 Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] See also draft guidance for industry on *180-Day Exclusivity: Questions and Answers*, Q. 42, at 26 (Jan. 2017).

Paul
Levine

Digitally signed by Paul Levine
Date: 12/30/2025 03:32:38PM
GUID: 56323ddc003554a87fad6698c2baa467