



ANDA 213195

ANDA APPROVAL

Teva Pharmaceuticals USA, Inc.
400 Interpace Pkwy
Morris Corporate Center III
Parsippany, NJ 07054
Attention: Narendra Racharla
Director, Regulatory Affairs, US Generics

Dear Narendra Racharla:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 18, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on September 26, 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 Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vivitrol for Extended-Release Injectable Suspension, 380 mg/vial of Alkermes, Inc. (Alkermes).

The RLD upon which you have based your ANDA, Alkermes's Vivitrol for Extended-Release Injectable Suspension, 380 mg/vial, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
7,919,499 (the '499 patent)	October 15, 2029

Your ANDA contains a paragraph IV certification to the '499 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 Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial, under this ANDA. You have notified the Agency that Teva Pharmaceuticals USA, Inc. (Teva) 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 '499 patent in the United States District Court for the District of New Jersey [Alkermes, Inc. and Alkermes Pharma Ireland Limited v. Teva Pharmaceutical Industries LTD. and Teva Pharmaceuticals USA, Inc., Civil Action No. 20-12470]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant for Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Teva may be eligible for 180 days of generic drug exclusivity for Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Teva failed to obtain tentative approval of this ANDA within 30 months after the date of 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 Teva's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Teva begins commercial marketing of Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial, or (b) at any time prior to the expiration of the '499 patent if Teva has not begun commercial marketing. 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 as <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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research



Catherine
Poole

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