



ANDA 209253

ANDA APPROVAL

Actavis Laboratories FL, Inc.
2945 West Corporate Lakes Blvd., Suite B
Weston, FL 33331
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 May 10, 2016, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg.

Reference is also made to the complete response letter issued by this office on February 25, 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 Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Adzenys XR-ODT Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, and 18.8 mg, of Neos Therapeutics Brands, LLC (Neos).

The RLD upon which you have based your ANDA, Neos's Adzenys XR-ODT Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, and 18.8 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>U.S. Patent Number</u>	<u>Expiration Date</u>
8,709,491 (the '491 patent)	June 28, 2032
8,840,924 (the '924 patent)	April 9, 2026
9,017,731 (the '731 patent)	June 28, 2032

9,265,737 (the '737 patent)

June 28, 2032

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 Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg, under this ANDA. You have notified the Agency that Actavis Laboratories FL, Inc. (Actavis) 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 Actavis for infringement of the '491, '924, '731 and '737 patents in the United States District Court for the District of Delaware [Neos Therapeutics, Inc. and Neos Therapeutics, LP, v. Actavis Laboratories FL, Inc., Civil Action No. 16-00766]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Actavis was the first ANDA applicant for Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Actavis may be eligible for 180 days of generic drug exclusivity for Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg. 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 Actavis failed to obtain tentative approval of this 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 Actavis'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 Actavis begins commercial marketing of Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg, or (b) at any time prior to the expiration of the '491, '731, '924 and '737 patents if Actavis 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 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 Edward M. Sherwood
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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