ANDA 217449

ANDA APPROVAL

Norwich Pharmaceuticals, Inc.
Attention: Archana Deodhar
Director, Regulatory Affairs

Dear Archana Deodhar:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on October 24, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Baloxavir Marboxil Tablets, 40 mg and 80 mg.

Reference is also made to the tentative approval letter issued by this office on September 13, 2023.

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 Baloxavir Marboxil Tablets, 40 mg and 80 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xofluza Tablets, 40 mg and 80 mg, of Genentech, Inc. (Genentech) NDA – 210854.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated November 29, 2022.

The RLD upon which you have based your ANDA, Genentech's Xofluza Tablets, 40 mg and 80 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
8,927,710 (the '710 patent)	May 5, 2031
8,987,441 (the '441 patent)	October 24, 2032
9,815,835 (the '835 patent)	June 14, 2030
10,392,406 (the '406 patent)	April 27, 2036

10,633,397 (the '397 patent)	April 27, 2036
10,759,814 (the '814 patent)	August 9, 2037
11,261,198 (the '198 patent)	September 25, 2038
11,306,106 (the '106 patent)	August 9, 2037
12,064,438 (the '438 patent)	October 9, 2039

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 Baloxavir Marboxil Tablets, 40 mg and 80 mg, under this ANDA. You have notified the Agency that Norwich Pharmaceuticals, Inc. (Norwich) 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 Norwich for infringement of the '710, '441, '835, '406, '397, '814, '198, and '106 patents in the United States District Court for the District Delaware [Shionogi & Co., Ltd., Hoffmann-La Roche Inc., and Genentech, Inc. v. Norwich Pharmaceuticals, Inc. et al.,, Civil Action No. 23-00161]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Norwich was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Baloxavir Marboxil Tablets, 40 mg and 80 mg. Therefore, with this approval, Norwich is eligible for 180 days of generic drug exclusivity for Baloxavir Marboxil Tablets, 40 mg and 80 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing 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).

We note that Norwich was granted a Competitive Generic Therapy (CGT) designation for Baloxavir Marboxil Tablets, 40 mg and 80 mg. However, as noted in the November 29, 2022, 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 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.
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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