ANDA 206921

ANDA APPROVAL

Sandoz Inc.
100 College Road West
Princeton, NJ 08540
Attention: Anthony Maffia III
Regulatory Affairs, Vice President

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 14, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Glatopa (Glatiramer Acetate) Injection, 40 mg/mL, 1 mL prefilled syringes.

Reference is also made to the complete response letter issued by this office on January 25, 2017, 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 is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Glatopa (Glatiramer Acetate) Injection, 40 mg/mL, 1 mL prefilled syringes, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Copaxone (Glatiramer Acetate) Injection, 40 mg/mL, 1 mL prefilled syringes, of Teva Pharmaceuticals USA (Teva).

The RLD upon which you have based your ANDA, Teva's Copaxone (Glatiramer Acetate) Injection, 40 mg/mL, 1 mL prefilled syringes, 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
8,232,250 (the '250 patent)	August 19, 2030
8,399,413 (the '413 patent)	August 19, 2030
8,969,302 (the '302 patent)	August 19, 2030
9,155,776 (the '776 patent)	August 19, 2030
9,402,874 (the '874 patent)	August 19, 2030

Your ANDA contains paragraph IV certifications to each of the patents,[1] 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 Glatopa (Glatiramer Acetate) Injection, 40 mg/mL, 1 mL prefilled syringes, under this ANDA. You have notified the Agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that litigation was initiated within the statutory 45-day period against Sandoz for infringement of the

'250, '413, '302, and '776 patents in the United States District Court for the District of Delaware [Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co. Ltd. v. Sandoz, Inc. and Momenta Pharmaceuticals, Inc., Civil Action No. 14-1171 (consolidated)], and for infringement of the '250 and '413 patents in the United States District Court for the District of New Jersey [Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co. Ltd. v. Doctor Reddy's Laboratories, Ltd., Doctor Reddy's Laboratories, Inc., Sandoz, Inc., and Momenta Pharmaceuticals, Civil Action No. 14-5672]. You have also notified the Agency that on January 30, 2017 the court rendered a decision in Civil Action No. 14-1171 finding that claims 1, 5, and 13-17 of the '250 patent are invalid as obvious, claims 1, 7, 15, and 20 of the '413 patent are invalid as obvious, claims 1, 10, and 11 of the '302 patent are invalid as obvious, and claims 1, 2, 5, 6, 9, 12, 16, and 17 of the '776 patent are invalid as obvious. You have further notified the Agency that litigation was initiated outside of the statutory 45-day period against Sandoz for infringement of the '874 patent in the United States District Court for the District of Delaware [Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co. Ltd. v. Sandoz, Inc. and Momenta Pharmaceuticals, Inc, et al., Civil Action No. 16-1267].

With respect to 180-day generic drug exclusivity, we note that Sandoz was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Glatiramer Acetate Injection, 40 mg/mL, prefilled syringes. Therefore, with this approval, Sandoz may be eligible for 180 days of generic drug exclusivity for Glatopa (Glatiramer Acetate) Injection, 40 mg/mL, 1 mL prefilled syringes. 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). The Agency notes that Sandoz 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 Sandoz's eligibility for 180-day exclusivity. It will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after a first applicant begins commercial marketing of Glatiramer Acetate Injection, 40 mg/mL prefilled syringes, or (b) at any time prior to the expiration of the '250 and '413 patents if a first applicant 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).

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in

writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[2] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts.

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products

misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

Sincerely yours,

{See appended electronic signature page}

For Vincent Sansone, Pharm.D.
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] The Agency notes that the '250, '413, '302, '776, and '874 patents were submitted to the Agency after submission of your ANDA.

[2] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Sarah Kurtz

Digitally signed by Sarah Kurtz
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