U.S. FOOD & DRUG ADMINISTRATION

ANDA 217793

ANDA TENTATIVE APPROVAL

Lupin Pharmaceuticals, Inc.
U.S. Agent for Lupin Limited
111 South Calvert Street
Harborplace Tower, 21st Floor
Baltimore, MD 21202
Attention: Debashis Mohanty
Associate Director -Regulatory Affairs

Dear Debashis Mohanty:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 10, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Migalastat Capsules, 123 mg.

Reference is also made to the complete response letter issued by this office on November 24, 2023, 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. We have determined your Migalastat Capsules, 123 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Galafold Capsules, 123 mg, of Amicus Therapeutics US LLC (Amicus).

However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the Agency at this time (e.g., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C Act.

The RLD upon which you have based your ANDA, Amicus's Galafold Capsules, 123 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
8,592,362 (the '362 patent)	February 12, 2029
9,000,011 (the '011 patent)	May 16, 2027
9,095,584 (the '584 patent)	February 12, 2029
9,480,682 (the '682 patent)	May 16, 2027
9,987,263 (the '263 patent)	May 16, 2027
9,999,618 (the '618 patent)	April 28, 2028
10,076,514 (the '514 patent)	March 15, 2037
10,251,873 (the '873 patent)	May 30, 2038
10,383,864 (the '864 patent)	May 16, 2027
10,406,143 (the '143 patent)	May 16, 2027
10,471,053 (the '053 patent)	May 30, 2038
10,525,045 (the '045 patent)	April 28, 2028
10,792,278 (the '278 patent)	May 30, 2038
10,792,279 (the '279 patent)	May 30, 2038
10,799,491 (the '491 patent)	May 30, 2038
10,806,727 (the '727 patent)	May 30, 2038
10,813,921 (the '921 patent)	February 12, 2029
10,849,889 (the '889 patent)	May 30, 2038
10,849,890 (the '890 patent)	May 30, 2038
10,857,141 (the '141 patent)	May 30, 2038
10,857,142 (the '142 patent)	May 30, 2038
10,874,655 (the '655 patent)	May 30, 2038

10,874,656 (the '656 patent)	May 30, 2038
10,874,657 (the '657 patent)	May 30, 2038
10,925,866 (the '866 patent)	April 28, 2028
11,033,538 (the '538 patent)	April 28, 2028
11,234,972 (the '972 patent)	March 15, 2037
11,241,422 (the '422 patent)	May 16, 2027
11,278,536 (the '536 patent)	May 30, 2038
11,278,537 (the '537 patent)	May 30, 2038
11,278,538 (the '538 patent)	May 30, 2038
11,278,539 (the '539 patent)	May 30, 2038
11,278,540 (the '540 patent)	May 30, 2038
11,357,761 (the '761 patent)	May 30, 2038
11,357,762 (the '762 patent)	May 30, 2038
11,357,763 (the '763 patent)	May 30, 2038
11,357,784 (the '784 patent)	February 6, 2039
11,389,436 (the '436 patent)	May 30, 2038
11,389,437 (the '437 patent)	May 30, 2038
11,458,128 (the '128 patent)	May 30, 2038
11,633,388 (the '388 patent)	March 25, 2039
11,642,334 (the '334 patent)	February 20, 2039
11,666,564 (the '564 patent)	May 30, 2038
11,813,255 (the '255 patent)	May 30, 2038
11,833,164 (the '164 patent)	January 11, 2042

RE48,608 (the '608 patent)	February 12, 2029
11,304,940 (the '940 patent)	May 30, 2038
11,357,764 (the '764 patent)	May 30, 2038
11,357,765 (the '765 patent)	May 30, 2038
11,376,244 (the '244 patent)	May 30, 2038
11,426,396 (the '396 patent)	May 30, 2038
11,612,593 (the '593 patent)	May 30, 2038
11,612,594 (the '594 patent)	May 30, 2038
11,622,962 (the '962 patent)	March 17, 2039
11,633,387 (the '387 patent)	May 30, 2038
11,786,516 (the '516 patent)	May 30, 2038
11,826,360 (the '360 patent)	February 16, 2039
11,903,938 (the '938 patent)	August 17, 2038

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 Migalastat Capsules, 123 mg, under this ANDA. You have notified the Agency that Lupin Limited (Lupin) 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 Lupin for infringement of the ’279, ’727, ’889, ’890, ’655, ’536, ’537, ’538, ’539, ’540, ’761, ’762, ’763, ’436, ’437, ’940, ’764, ’765, ’244, ’657, ’784 patents in the United States District Court for the District of Delaware [Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc., v. Lupin Ltd., Lupin Pharmaceuticals, Inc., and Springcare USA LLC, Civil Action No. 22-01465] and for infringement of the '011, '263, '864, '143, '921, '866, and '608 patents in the United States District Court for the District of Delaware [Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc., Civil Action No. 23-00964].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 7.5-year and 30-month periods provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act,

   b. the date the court decides[2] that the '011, '263, '864, '143, '279, '727, '921, '889, '890, '655, '657, '866, '536, '537, '538, '539, '540, '761, '762, '763, '784, '436, '437, '608, '940, '764, '765, and '244 patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the FD&C Act), or

   c. the '011, '263, '864, '143, '279, '727, '921, '889, '890, '655, '657, '866, '536, '537, '538, '539, '540, '761, '762, '763, '784, '436, '437, '608, '940, '764, '765, and '244 patent have expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

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.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, if your ANDA receives final approval, it 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.

RESUBMISSION

To request final approval, please submit an amendment titled “FINAL APPROVAL REQUESTED” with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities’ compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available Agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including

changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a “FINAL APPROVAL REQUESTED.”

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Diane Smith, PharmD, RPh, Regulatory Project Manager, at (301) 796 - 3652.

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

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[1] The Agency notes that the '128, '388, '334, '564, '255, '164, '396, '593, '594, '962, '387, '516, '360, and '938 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

Sarah Kurtz

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