NDA 208623/S-001

SUPPLEMENT APPROVAL

Amicus Therapeutics U.S., Inc.
Attention: Dunni Odumosu, MS
Director, Global Regulatory Affairs
1 Cedar Brook Drive
Cranbury, NJ 08512

Dear Ms. Odumosu:

Please refer to your supplemental new drug application (sNDA) dated June 6, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Galafold ® (migalastat).

This "Changes Being Effected" supplemental new drug application provides for the following:

- Update the Patient Package Insert (PPI) to be consistent with the approved indication statement in the Prescribing Information (PI).

- Update the PI, PPI and Instructions for Use (IFU), as well as the carton labeling (outer sleeve) and container label (inner sleeve) with the registered trademark ®.

APPROVAL & LABELING

We completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

We note that your June 6, 2019, submission includes final printed labeling (FPL) for the following labeling: PI, PPI and IFU. We have not reviewed the FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the PI, PPI and IFU), with the addition of any labeling changes in pending "Changes Being

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

We acknowledge your June 6, 2019, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, contact LCDR Hong Vu, Regulatory Project Manager, at (301) 796-7401.

Sincerely,

{See appended electronic signature page}

Dragos G. Roman, MD
Acting Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DRAGOS G ROMAN
08/22/2019 06:05:21 PM