

NDA 022562/S-011

SUPPLEMENT APPROVAL

Recordati Rare Diseases
c/o Intertek Surveying Services
Attn: Jennifer Tillman
16441 Space Center Blvd, Suite D-10
Houston, TX 77058

Dear Ms. Tillman:

Please refer to your supplemental new drug application (sNDA) dated June 28, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Carbaglu (carglumic acid) tablets for oral suspension.

This Prior Approval supplemental new drug application provides for updates to the Prescribing Information to reflect Pregnancy and Lactation Labeling Final Rule (PLLR) format.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

- Update the revision date at the end of Highlights in the Prescribing Information to the approval date.
- Revert the issued date at the end of the Instructions for Use to November 2017, the date of the last approved changes.

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 Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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).

REPORTING REQUIREMENTS

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

If you have any questions, contact Nicolas Kong, Regulatory Project Manager at Nicolas.Kong@fda.hhs.gov or 240-402-0269.

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

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Instructions for Use

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>.

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/

NICOLAS KONG
12/23/2019 10:41:07 AM

DRAGOS G ROMAN
12/23/2019 11:01:32 AM