



NDA 212801/S-007

SUPPLEMENT APPROVAL

Recordati Rare Diseases Inc
Attention: Priscilla Costa
Director, Regulatory Affairs - CMC
440 Route 22 East Suite 205
Bridgewater, NJ 08807

Dear Priscilla Costa:

Please refer to your Supplemental New Drug Application (sNDA) dated May 23, 2025, received May 23, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ISTURISA (osilodrostat) tablets.

We also refer to our approval letter dated November 4, 2025, which contained the following error: Secondary packaging components were inadvertently included in the approval letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain November 4, 2025, the date of the original approval letter.

This “Changes Being Effected” supplemental new drug application provides for the removal of the Isturisa® Wallet (Blister Card of 20) and Isturisa® Sleeve for Blister Pack of 20 which are secondary packaging components from the carton.

APPROVAL & LABELING

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

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

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.

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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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 LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. *Please submit these labels electronically according to the guidance for industry Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.* For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 212801/S-007.**” Approval of this submission by FDA is not required before the labeling is used.

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, call Dahlia A. Walters, Regulatory Business Process Manager, at (301) 796 - 8427.

Sincerely,

{See appended electronic signature page}

Sherita McLamore, Ph.D.
Supervisor
Division of Product Quality Assessment I
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

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Enclosure(s):

Content of Labeling



Sherita
McLamore

Digitally signed by Sherita McLamore

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