NDA 202292/S-009

SUPPLEMENT APPROVAL

Napo Pharmaceuticals Inc.
Attention: Mark Longer
Regulatory Affairs Consultant
200 Pine Street
Suite 400
San Francisco, CA 94104

Dear Mark Longer:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 6, 2023, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mytesi (crofelemer) 125 mg Tablets.

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

> Introduction of a professional sample presentation for Mytesi (crofelemer) 125 mg Tablets with associated labeling changes.

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.

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 202292/S-009.**" 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, contact Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@hhs.fda.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Supervisor, Division of Product Quality Assessment XI
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Container Labeling

David Lewis

Digitally signed by David Lewis
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