NDA 202292/S-007

SUPPLEMENT APPROVAL

Napo Pharmaceuticals, Inc.
Attention: Pravin R. Chaturvedi, Ph.D.
Chairman, Scientific Advisory Board
201 Mission Street, Suite 2375
San Francisco, CA 94105

Dear Dr. Chaturvedi:

Please refer to your supplemental new drug application (sNDA), dated and received on June 27, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mytesi (crofelemer) delayed-release tablets.

This Prior Approval sNDA provides for updates to the Prescribing Information to comply with the Pregnancy and Lactation Labeling Rule (PLLR) and to add data corresponding to the fulfilled

- postmarketing requirements (1975-2 and 1975-3) to Section 13.1 'Carcinogenesis, Mutagenesis, Impairment of Fertility', and
- postmarketing commitments (1975-4 and 1975-5) to Section 12.3 'Pharmacokinetics'.

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.

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 (MS) 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 MS 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, call Benjamin Vali, Regulatory Project Manager, at 301-796-4261 or Benjamin.vali@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling:
Prescribing Information

[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/

JOYCE A KORVICK
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