NDA 211843/S-002

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Mission Pharmacal Company
Attention: Margaret E. Hurley, MD (U.S. Agent)
President, Hurley Consulting Associates Ltd.
25 DeForest Avenue
Summit, NJ 07901

Dear Ms. Hurley:

Please refer to your supplemental new drug application (sNDA) dated and received February 28, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Thiola EC (tiopronin) Enteric Coated Tablets.

This Prior Approval supplemental new drug application provides revision to the approved label to include information regarding crushing of Thiola tablets for administration. The following sections of labeling were revised: Highlights, Dosage and Administration, Use In Specific Populations, Clinical Pharmacology, and Patient Counseling Information.

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, Patient Package Insert, Instructions for Use, and Medication Guide), 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).

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated February 28, 2020 containing the final report for the following postmarketing commitment listed in the June 28, 2019 approval letter.

> 3633-1 Conduct a randomized, two-way, crossover, single oral dose study to evaluate the relative bioavailability of 300 mg of Thiola EC crushed, mixed in apple sauce compared to 300 mg Thiola EC intact tablet in healthy subjects to support providing dosing instructions to pediatric patients weighing less than 20 kg or who cannot swallow the tablet whole.

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our June 28, 2019, letter.

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, please call Lori Anne Wachter, RN, BSN, RAC, Regulatory Project Manager for Safety, at 301 796-3975.

[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.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

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/

MARY R SOUTHWORTH
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