NDA 050824/S-011
NDA 050824/S-012

SUPPLEMENT APPROVAL

Cumberland Pharmaceuticals Inc.
Attention: Chris Lewis
Associate Director, Regulatory Affairs
1600 West End Avenue, Suite 1300
Nashville, Tennessee 37203

Dear Chris Lewis:

Please refer to your supplemental new drug applications (sNDAs) dated and received May 03, 2023 (supplement 011) and May 30, 2023 (supplement 012), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Omeclamox-Pak (omeprazole delayed-release capsules, clarithromycin tablets and amoxicillin capsules, 20 mg/500 mg/500 mg).

We also refer to our safety labeling change notification letters dated April 14, 2023, and May 03, 2023, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we have determined should be included in the labeling for Omeclamox-Pak. This information pertains to the risk of erectile dysfunction associated with omeprazole, a component of your drug product (April 14, 2023 letter) and the risk of drug interaction with clarithromycin, a component of your drug product, and lurasdone, an antipsychotic drug that is contraindicated to be taken concomitantly with strong CYP3A4 inducers and inhibitors (May 03, 2023 letter).

sNDA S-011 provides for revisions to the labeling, consistent with our April 14, 2023 letter, regarding the risk of erectile dysfunction associated with omeprazole, a component of Omeclamox.

sNDA S-012 provides for revisions to the labeling, consistent with our May 03, 2023 letter, regarding the risk of drug interaction with clarithromycin, a component of Omeclamox, and lurasdone, an antipsychotic drug that is contraindicated to be taken concomitantly with strong CYP3A4 inducers and inhibitors.

APPROVAL & LABELING

We have completed our review of these applications. They are 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. 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 these supplemental applications, 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).

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[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.

314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Kristine Park, PhD, RAC, Senior Regulatory Health Project Manager, at (301) 796-0471.

Sincerely,

{See appended electronic signature page}

Mukil Natarajan, MD
Deputy Director for Safety
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

MUKILAN NATARAJAN
08/16/2023 09:17:42 AM