Dear Dr. Aravapalli:

Please refer to your Supplemental New Drug Application (sNDA) dated October 30, 2017, received October 30, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BILTRICIDE (praziquantel) tablets, 600 mg.

This Prior Approval sNDA provides for the following revisions to the U.S. Prescribing Information (PI):

- Conversion of the previously approved PI to the Physician’s Labeling Rule (PLR) format, with relevant sections of the PLR format added or revised, including the requirements of the Pregnancy and Lactation Labeling Rule (PLLR) format.

- Revised pediatric use information to include pediatric patients aged 1 to < 4 years old in relevant sections of the PI including the INDICATIONS AND USAGE section (1), DOSAGE AND ADMINISTRATION section, Administration subsection (2.2), ADVERSE REACTIONS section (6), USE IN SPECIFIC POPULATIONS section, Pediatric Use subsection (8.4), and PATIENT COUNSELING INFORMATION section (17).

- Updated the WARNINGS AND PRECAUTIONS subsection (5.1) to include papilledema.

- Updated the ADVERSE REACTIONS section (6) to include the following postmarketing adverse reactions: tinnitus, visual disturbance, gait disturbance, hepatitis, allergic reaction, anaphylactic reaction, intention tremor, pneumonitis, dyspnea, wheezing, and Stevens-Johnson syndrome.
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 text.

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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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).

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 information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety 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) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, M.D., Ph.D.
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
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/

DMITRI IARIKOV
01/08/2019 09:43:10 PM