NDA 018714/S-020

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Sangeeta Patel, MBA, BSc
Associate Director, Regulatory Affairs
100 Bayer Boulevard, P.O. Box 915
Whippany, NJ 07981-0915

Dear Sangeeta Patel:

Please refer to your supplemental new drug application (sNDA) dated and received June 2, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Biltricide (praziquantel) tablets.

This Prior Approval sNDA provides for:

- Revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, and **FULL PRESCRIBING INFORMATION**. Specifically,
    - **Under the HIGHLIGHTS OF PRESCRIBING INFORMATION, the RECENT MAJOR CHANGES** section and **DRUG INTERACTIONS** section were updated to reflect changes made to subsequent sections 4, 5.6, 7.1 and 12.3.
    - Under the **FULL PRESCRIBING INFORMATION,** the following revisions were made:
        - Under section **5 WARNINGS AND PRECAUTIONS,** subsection **5.6 Concomitant Administration with Cytochrome P450 Enzyme Inducers** was changed from 4 weeks to “at least 2 weeks to 4 weeks”.
        - Under section **7 DRUG INTERACTIONS,** subsection **7.1 CYP3A Inducers** was modified to reduce redundancy and to be more general and specific with respect to Strong and Moderate CYP3A inducers.
        - Under section **12 CLINICAL PHARMACOLOGY**, subsection **12.3 Pharmacokinetics,** information regarding clinically significant interaction with Efavirenz was added.

- Under section **17 PATIENT COUNSELING INFORMATION,** information was updated to be consistent with sections **5 WARNINGS AND PRECAUTIONS** and **7 DRUG INTERACTIONS**.

- Minor editorial revisions where made throughout the prescribing 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, 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 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).

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

[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.

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 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, please contact Jennifer Grant, MSHS, Regulatory Project Manager, at jennifer.grant@fda.hhs.gov or (301) 796-0480.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
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
12/19/2023 10:34:20 AM