DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17481/S-047

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
c/o Janssen Research & Development, LLC
Attention: Andrea F. Kollath, DVM
Director, Global Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Kollath:

Please refer to your Supplemental New Drug Application (sNDA) dated December 16, 2016, received December 16, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VERMOX™ (mebendazole) Tablets, 100 mg.

This Prior Approval supplemental new drug application provides for changes to the labeling to conform to the requirements of the Physician Labeling Rule (PLR) and to align with the labeling for VERMOX™ Chewable (mebendazole chewable tablets), 500 mg. Additionally, the following revisions have been made:

1. A pediatric age limit has been added to the **INDICATIONS AND USAGE (1)** and **DOSAGE AND ADMINISTRATION (2)** sections.
2. Identifying characteristics have been added to the **DOSAGE FORMS AND STRENGTHS (3)** section.
3. The **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3) subsection,** has been revised.
4. Revisions have been made to the **NONCLINICAL TOXICOLOGY (13)** section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection.
5. Information to facilitate identification of the dosage form has been added to the **HOW SUPPLIED/STORAGE AND HANDLING (16)** section.

Changes have also been made to the **PATIENT INFORMATION** to align with the updates to the Prescribing Information for this strength.

Additionally, minor editorial changes have been made throughout the labeling.

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 package insert, text for the patient package insert), 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/DrugsGuidanceComplianceRegulatoryInformation/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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DMITRI IARIKOV
06/13/2017