



NDA 018900/S-038

SUPPLEMENT APPROVAL

B. Braun Medical, Inc.
Attention: Cindy Katsempris, MS, RAC
Director, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109-9341

Dear Ms. Katsempris:

Please refer to your supplemental new drug application (sNDA) dated and received January 27, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Metronidazole Injection USP in PAB® Container, 500 mg/100 mL (5 mg/mL).

This “Changes Being Effected” supplemental new drug application provides for revisions to the prescribing information (PI), **WARNINGS** section, **CENTRAL AND PERIPHERAL NERVOUS SYSTEM EFFECTS** subsection, and the **ADVERSE REACTIONS** section, **GASTROINTESTINAL, MOUTH, HEMATOPOIETIC, HEPATOBILIARY DISORDERS, SKIN AND SUBCUTANEOUS DISORDERS, CENTRAL NERVOUS SYSTEM, LABORATORY INVESTIGATIONS, HYPERSENSITIVITY**, and **OTHER** subsections. Minor editorial revisions have also been made throughout the labeling.

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.

We note that your March 29, 2021 submission includes final printed labeling (FPL) for your PI. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 SPL format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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).

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 Deborah Kim, PharmD, RAC, Regulatory Project Manager, at (301) 796-9053.

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

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>.

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
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