NDA 18-620/S-021
NDA 18-740/S-039

SUPPLEMENT APPROVAL

Fosun Pharma USA Inc.
Attention: Kuo Jiao, MPH
Regulatory Affairs Specialist
104 Carnegie Center, Suite 204
Princeton, New Jersey 08540

Dear Mr. Jiao:

Please refer to your supplemental new drug applications (sNDAs) dated November 21, 2018, received November 21, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Metronidazole Tablets USP, 250 mg and 500 mg [NDA 18-620] and Metronidazole Tablets USP, 250 mg and 500 mg [NDA 18-740].

These "Changes Being Effected" supplemental new drug applications provide for the removal of the susceptibility test interpretive criteria (STIC) and related information from the approved labeling in accordance with the requirements of Section 3044 of the 21st Century Cures Act that added Section 511A(d)(1) of the FD&C Act. These supplements also provide for updated NDC numbers.

APPROVAL & LABELING

We have completed our review of these applications, as amended, and 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 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

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

enclosed labeling. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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 these NDAs, 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).

PROPRIETARY NAME

If you intend to have a proprietary name for these products, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

REPORTING REQUIREMENTS

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

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database

If you have any questions, call Maureen Dillon-Parker, MS, RAC, Chief, Regulatory Project Management Staff, at 301-796-0706.

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
- Package insert

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
04/27/2020 05:42:47 PM