



NDA 018764/S-042

SUPPLEMENT APPROVAL

Watson Labs, Inc.
an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.
Attention: Scott D. Tomsky
Vice President, Regulatory Affairs, Generics, North America
425 Privet Road
Horsham, PA 19044

Dear Mr. Tomsky:

Please refer to your Supplemental New Drug Application (sNDA) dated April 26, 2018, received April 26, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Metronidazole Tablets, USP, 250 mg and 500 mg.

This “Changes Being Effected” supplemental new drug application provides for the removal of the susceptibility test interpretive criteria and related information from the labeling as requested in the Agency’s letter of March 12, 2018. Additionally, the labeling has been updated to be in alignment with the recent changes made to the labeling of the reference listed drug (RLD).

APPROVAL & LABELING

We have completed our review of this supplemental application. 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, except with the revisions indicated, 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 with the revisions indicated above 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).

If you have questions, call Deborah Wang, PharmD, Regulatory Project Manager, at (301) 796-9053.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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
10/17/2018