



NDA 021497/S-017

SUPPLEMENT APPROVAL

Romark Laboratories, L.C.
Attention: Gladys Martin
Senior Manager, Regulatory Affairs
3000 Bayport Drive, Suite 200
Tampa, FL 33607

Dear Ms. Martin:

Please refer to your supplemental new drug application (sNDA) dated February 19, 2021, received February 19, 2021, and your amendments, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nitazoxanide tablets.

This Prior Approval sNDA provides new Prescribing Information for an Authorized Generic for Nitazoxanide tablets, 500mg.

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 prescribing information. We acknowledge your agreement to make the following changes to the container label and carton labeling at the next printing in 2023:

- Addition of *the degree and Centigrade symbols (°C) following the “15” and degree and Fahrenheit symbols (°F) following the “59” within the storage statement. Additionally, to provide further clarity, consider replacing the hyphens with their intended meaning “to”*
- Reorientation of the linear barcode to a vertical position
- Revision of the formatting of the expiration date for the container labels and carton labeling as per the formatting recommendations that FDA sent to you on July 30, 2021

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 Effectuated” (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 questions, call Sheel Shah, Pharm D, Regulatory Project Manager, at 240-402-3968.

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>.

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(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
12/16/2021 12:03:23 PM