



NDA 050606/S-039

SUPPLEMENT APPROVAL

ANI Pharmaceuticals, Inc.
Attention: Sheila Fish
Labeling Manager, Regulatory Affairs
210 Main Street West
Baudette, MN 56623

Dear Ms. Fish:

Please refer to your supplemental new drug application (sNDA) dated November 10, 2021, received November 10, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vancocin (vancomycin hydrochloride) Capsules, USP, equivalent to 125 mg base and equivalent to 250 mg base.

This Prior Approval sNDA proposes revisions to the prescribing information (PI) to replace the terms like "red man syndrome" or "red neck" with "vancomycin infusion reaction" to emphasize pathophysiology over the visual appearance of the skin. We note this Prior Approval sNDA has been submitted in response to our September 2, 2021, Supplement Request letter.

APPROVAL & LABELING

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with the minor editorial revisions listed below and reflected in the enclosed labeling.

- We enclosed the text "vancomycin infusion reaction" in quotation marks.

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](http://www.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 Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

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): 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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