



NDA 50006/S-091  
NDA 50007/S-033  
NDA 50480/S-057  
NDA 50533/S-046

**SUPPLEMENT APPROVAL**

Pfizer, Inc  
Attention: Michele Burtness  
Senior Manager, Pfizer Essential Health Global Regulatory Affairs Brands  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Burtness:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 17, 2018, received May 17, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Drug Product	Supplement Number
50006	Vibramycin (doxycycline monohydrate) Powder for Suspension	S-091
50007	Vibramycin (doxycycline Hyclate) Oral Capsule	S-033
50480	Vibramycin (doxycycline Calcium) for Oral Suspension	S-057
50533	Vibra-tabs (doxycycline hyclate) Film Coated Oral	S-046

These Prior Approval supplemental new drug applications provide for changes to the addition in the **DOSAGE and ADMINISTRATION** section for the treatment of Rocky Mountain spotted fever in adults and children and revisions in the **ADVERSE REACTIONS** section to provide for the addition of Jarisch-Herxheimer reaction and skin hyperpigmentation.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. 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 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 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 Carmen DeBellas, Chief Regulatory Project Manager, at 301-796-1203.

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

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**ENCLOSURE:**

Content of Labeling  
Prescribing Information

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**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.**  
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/s/  
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DMITRI IARIKOV  
12/03/2018