



NDA 50006/S-088  
NDA 50007/S-031  
NDA 50442/S-019  
NDA 50480/S-055  
NDA 50533/S-044

**SUPPLEMENT APPROVAL**

Pfizer, Inc.  
Attention: Michele Burtness  
Senior Manager, Worldwide Safety and Regulatory  
235 East 42nd Street  
New York, NY 10017-5755

Dear Ms. Burtness:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 29, 2016, received January 29, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

<b>NDA Number</b>	<b>Drug Product</b>	<b>Supplement Number</b>
NDA 50006	Vibramcyin Monohydrate (doxycycline monohydrate) for Oral Suspension	S-088
NDA 50007	Vibramycin Hyclate (doxycycline hyclate capsules, USP) Capsules	S-031
NDA 50442	Vibramycin (doxycycline hyclate) Injection	S-019
NDA 50480	Vibramcyin Calcium (doxycycline calcium oral suspension) Syrup	S-055
NDA 50533	Vibra-Tabs (doxycycline hyclate, USP) Film Coated Tablets	S-044

These Prior Approval supplemental new drug applications propose to add Pancreatitis to the **ADVERSE REACTIONS** section of the label.

In addition, the Clinical Pharmacology, Microbiology subsection of the labeling was updated.

## **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 package insert, 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 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 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 MS Word format, that includes the changes approved in these supplemental applications, 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).

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If you have any questions, call Carmen DeBellas, Chief Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH  
Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
12/21/2016