DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-006/S-087
NDA 50-007/S-030
NDA 50-442/S-018
NDA 50-480/S-054
NDA 50-533/S-043

SUPPLEMENT APPROVAL

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

Dear Ms. Burtness:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 11, 2015, received September 11, 2015, 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
NDA 50-006	Vibramycin Monohydrate (doxycycline monohydrate) for Oral Suspension	S-087
NDA 50-007	Vibramycin Hyclate (doxycycline hyclate capsules, USP) Capsules	S-030
NDA 50-442	Vibramycin Hyclate (doxycycline hyclate for injection) intravenous	S-018
NDA 50-480	Vibramycin Calcium (doxycycline calcium oral suspension, USP) Oral Suspension Syrup	S-054
NDA 50-533	Vibra-Tabs (doxycycline hyclate tablets, USP) Film Coated Tablets	S-043

These supplemental applications propose an update to the **WARNINGS** section of labeling (b) (4) (b) (4) As the proposed change is not

acceptable, the **WARNINGS** section has not been revised [redacted] (b) (4)

In addition, new information for pediatric patients 8 years of age or less with severe or life-threatening conditions (e.g., anthrax, Rocky Mountain spotted fever) was added to the **WARNINGS, DOSAGE AND ADMINISTRATION** sections, and **PRECAUTIONS, Pediatric Use** subsection of the labeling.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling.

We note that your March 22, 2016, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 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 includes 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 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 any questions, call Carmen DeBellas Regulatory 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
03/31/2016