



NDA 50-006/S-085
NDA 50-007/S-026
NDA 50-480/S-051
NDA 50-533/S-041

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Shai Srulovich, RPh, PharmD
Senior Manager, Worldwide Safety & Regulatory
235 East 42nd Street
New York, NY 10017

Dear Dr. Srulovich:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 24, 2013, received May 24, 2013, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug Name	NDA #/Supplement
Vibramycin Monohydrate (doxycycline monohydrate) for Oral Suspension	NDA 50-006/S-085
Vibramycin Hyclate (doxycycline hyclate capsules, USP) Capsules	NDA 50-007/S-026
Vibramycin Calcium (doxycycline calcium oral suspension) Syrup	NDA 50-480/S-051
Vibra-Tabs (doxycycline hyclate tablets, USP) Film Coated Tablets	NDA 50-533/S-041

We acknowledge receipt of your amendments dated August 23, 2013.

These “Changes Being Effected” supplemental new drug applications provide for the addition of Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) to the **ADVERSE REACTIONS** section, Immune subsection, of the package insert.

In addition, the following changes were made to the package insert:

- Revisions to the language related to benign intracranial hypertension in the **PRECAUTIONS** section, **General** subsection, and
- Editorial revisions in various sections of the package insert.

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 text.

We note that your August 23, 2013, submissions include final printed labeling (FPL) for your package inserts. We have not reviewed these FPLs. 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 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 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).

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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
Acting 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
09/04/2013