NDA 50006/S-092
NDA 50007/S-034
NDA 50480/S-058
NDA 50533/S-047

SUPPLEMENT APPROVAL

Pfizer, Inc
Pfizer Essential Health Global Regulatory Affairs Brand
Attention: Michele Burtness
Senior Manager
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Burtness:

Please refer to your supplemental new drug applications (sNDA) dated and received December 13, 2019, 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-092
50007	Vibramycin (doxycycline hyclate) Oral Capsule	S-034
50480	Vibramycin (doxycycline calcium) for Oral Suspension	S-058
50533	Vibramycin (doxycycline hyclate) Film Coated Oral Tablets	S-047

These supplemental applications were submitted as “Changes Being Effected” supplements in response to the Agency supplement request letter dated November 6, 2019, requiring the Applicant under Section 409I of the Public Service Act, also known as the Best Pharmaceutical for Children Act which mandates the critical need for pediatric labeling to update the label with pediatric information.

APPROVAL & LABELING

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

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.[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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[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.

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-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

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
12/20/2019 11:48:20 AM