Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, NW
Suite 1200
Washington, DC 20005-5929

Docket No. FDA-2019-P-5943

Dear Kurt R. Karst:

This is in response to your petition received on December 16, 2019, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug products: Doxycycline Hyclate Tablets, 20 mg, 50 mg, 75 mg and 150 mg. The listed drug product to which you refer in your petition is Vibra-Tabs® 100 mg, approved under NDA 050533 and held by Pfizer Laboratories Div. Pfizer Inc.

Your request involves a change in strength from that of the listed drug product (i.e., from 100 mg to 20 mg, 50 mg, 75 mg and 150 mg). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, that a drug product is approved in an NDA for the change described in the petition. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(vi).

For the reasons explained below, the Agency approves your request to submit an ANDA for Doxycycline Hyclate Tablets, 50 mg, and denies your request to submit an ANDA for Doxycycline Hyclate Tablets, 20 mg, 75 mg, and 150 mg.

Proposed *Doxycycline Hyclate Tablets, 50 mg*

The Agency finds that the proposed change in strength for the proposed drug product does not pose questions of safety or effectiveness. The uses, dose, dosage form, and route of administration of the proposed drug product are the same as that of the listed drug product. The proposed change is consistent with dosing recommendations in the labeling of the listed drug. In addition, if shown to meet bioequivalence requirements, the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug product. Therefore, FDA concludes that the proposed change would not jeopardize the safe or effective use of the product so as to necessitate significant labeling changes, and investigations are not necessary to show the safety and effectiveness of this proposed strength.

The approval of this petition, in part, to allow an ANDA to be submitted for the aforementioned change in strength of the proposed drug product does not mean that FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by FDA.

To permit review of your ANDA submission for this change in strength, you must submit all information required under section 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioequivalence requirements under section 505(j)(2)(A)(iv) of the Act. During the review of your application, FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you must refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. 21 CFR 314.94(a)(3)(iii). Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

Proposed *Doxycycline Hyclate Tablets, 20 mg, 75 mg, and 150 mg*

With respect to your proposed strength changes from Doxycycline Hyclate Tablets, 100 mg to Doxycycline Hyclate Tablets, 20 mg, 75 mg, and 150 mg, the Agency has determined that these proposed changes do not meet the requirement that there is not "[a] drug product …approved in an NDA for the change described in the petition." 21 CFR 314.93(e)(1)(vi). Therefore, FDA denies your petition because a drug product is approved in an NDA for the changes described in the petition (Acticlate 75 mg and 150 mg doxycycline hyclate tablets, approved under NDA 205931 and held by Almirall LLC; Periostat 20 mg doxycycline hyclate tablets, approved under NDA 050783 and held by Galderma Laboratories LP).

If you disagree with our determination concerning the approvability of your petition with regard to the proposed strengths of 20 mg, 75 mg, and 150 mg, as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter approving your petition in part and denying your petition in part will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William H. Chong -S

Digitally signed by William H. Chong -S
Date: 2024.02.06 15:27:17 -05'00'

William Chong, M.D.
Director, Office of Safety and Clinical Evaluation
for Iilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research