Hospira Inc.
275 North Field Drive, Building H1
Lake Forest, IL 60045
Attn: Jae Encarnado

Sent via email to: jae.encarnado@pfizer.com

Docket No. FDA-2024-P-2085

Dear Jae Encarnado:

This is in response to your petition received on April 26, 2024, 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 product: Vancomycin Hydrochloride for Injection, 1.25 g base/vial. The listed drug product to which you refer in your petition is Vancomycin Hydrochloride for Injection, 750 mg base/vial and 1 g base/vial approved under ANDA 062933 and held by Hospira, Inc.

Your petition requests a change in strength (total drug content) from that of the listed drug product (i.e., from 750 mg base/vial and 1 g base/vial to 1.25 g base/vial). A change in strength 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.

However, one of the requirements for approval of a petition under section 505(j)(2)(C) of the Act is 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). You note that FDA previously denied a suitability petition requesting permission to submit an ANDA for Vancomycin Hydrochloride for Injection 1.25 g base/vial on the basis that a drug product is approved for the change described in the petition (Vancomycin Hydrochloride for Injection, 1.25 g base/vial, under NDA 209481, held by Mylan Laboratories Limited).[1] You assert that your proposed product contains excipients not described in the product approved in NDA 209481's formula and that "the formulations differ qualitatively in a manner that is not permitted under 21 CFR 314.94(a)(9)(iii)."[2] As a result, you assert that "an ANDA referencing Mylan NDA 209481 would not be appropriate, as it would not be accepted for review."[3] This argument does not support approval of your petition. As explained above, FDA will not approve a suitability petition if a drug product is approved in an NDA for the change described in the petition. Instead, "[i]f a

[1] Suitability Petition, at 4.
[2] Id. at 5.
[3] Id.

pharmaceutically equivalent drug product has been approved in an NDA, the ANDA applicant should refer to the approved pharmaceutical equivalent designated by the Agency as the RLD as its basis for ANDA submission."[4] In this case, FDA has approved Vancomycin Hydrochloride for Injection, 1.25 g base/vial, under NDA 209481 – a drug product that is pharmaceutically equivalent to the drug product proposed in your suitability petition.[5] Thus, your petition is denied under 21 CFR 314.93(e)(1)(vi).

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the decision not to approve your petition 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 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 Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Iilun Murphy, M.D.
Director
Office of Generic Drugs

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[4] Abbreviated New Drug Applications and 505(b)(2) Applications, Proposed Rule, 80 Fed. Reg. 6802, 6856-67 (Feb. 6, 2015); see also Letter to Mark S. Aikman, Pharm. D., Osmotica Pharmaceutical Corp., from Janet Woodcock, M.D., Center for Drug Evaluation and Research, Docket No. FDA-2009-P-0329 (Nov. 25, 2008), at 4 ("[A] suitability petition will not be granted for a product for which a pharmaceutical equivalent been approved, as the suitability petition process is intended for a proposed 'drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug' (§ 314.93(b))").

[5] We further note that a suitability petition may be submitted only for a drug product that is not identical to the listed drug in route of administration, dosage form, or strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug. 21 CFR 314.93(a)-(b). A change in excipients in a parenteral product is not a change for which the Agency will accept a petition under section 505(j)(2)(C) of the Act.

Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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William Chong

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