Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act (FDC Act), and in accordance with 21 C.F.R.314.93, 10.20, and 10.30, to request that the Commissioner of Food and Drugs Administration (FDA) determine an additional strength (different total drug content) of Vancomycin Hydrochloride for Injection, USP, ADD-Vantage® Vial, is suitable for submission and subsequent FDA review as an Abbreviated New Drug Application (ANDA).

A. ACTION REQUESTED

This petitioner requests that FDA determine that Vancomycin Hydrochloride for Injection, USP, ADD-Vantage® Vial, 1.25 grams (base)/vial is suitable for ANDA submission as an additional strength.

B. STATEMENT OF GROUNDS

Section 505(j)(2)(C) of the FDC Act permits the submission of an ANDA for a new drug product that differs in strength from the referenced drug, provided that FDA has approved a petition seeking permission to file such an application. This petition requests permission to seek approval, through the ANDA process, for an additional strength of a currently approved drug product.

The referenced drug upon which this petition is based is Hospira, Inc.'s (Hospira) currently approved Vancomycin Hydrochloride for Injection, USP, ADD-Vantage® Vial, 1 gram (base)/vial, ANDA 062933. In addition to the 1 gram strength referenced drug, a 750 mg strength is approved under ANDA 062933. A copy of the ANDA 062933 entry from the current electronic edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) is included as **Attachment 1**.

This petition seeks permission from FDA to submit a supplemental ANDA 062933 for a product that differs from the referenced drug by increasing the strength (total drug content) from 1 gram (base)/vial to 1.25 grams (base)/vial.

The active ingredient, formulation, dosage form, route of administration, dosage and administration, and indications and usage of the proposed product would be the same as those of the referenced drug. The proposed product would differ only in strength (total drug content) from the referenced drug.

The proposed drug product would be intended for use only as described in the Indications and Usage and Dosage and Administration sections of the currently approved labeling for the referenced drug. The labeling for the proposed drug product would be essentially identical to that of the referenced drug and would differ only with respect to the proposed strength.

Draft labeling of the proposed product is included as **Attachment 2** (the draft labeling assumes the petitioner will obtain approval for all approved strengths of Vancomycin Hydrochloride for Injection, USP, ADD-Vantage® Vial). The labeling for the referenced drug is included in **Attachment 3**.

The proposed increase in strength is consistent with FDA's approved labeling for the referenced drug. The current labeling for the referenced drug states, "The usual daily intravenous dose is 2 g divided either as 500 mg every 6 hours or 1 g every 12 hours... Other patient factors, such as age or obesity, may call for modification of the usual intravenous daily dose*".* The 1.25 gram presentation would be appropriate for patients when a 1 gram dose is not sufficient for their body weight.

The proposed strength would not pose questions of safety or effectiveness because the use, dosing, and route of administration of the proposed product would be the same as those of the referenced drug.

For the foregoing reasons, the undersigned requests that FDA approve this petition and permit the proposed additional strength (different total drug content) to be addressed through the ANDA process.

A Suitability Petition was previously submitted to the FDA on October 2, 2023 requesting permission to submit an Abbreviated New Drug Application (ANDA) for Vancomycin Hydrochloride for Injection 1.25 gram base/vial and was assigned Docket No. FDA-2023-P-4334. On November 17, 2023 FDA denied the petition indicating that although a change in strength is the type of change that is permissible under section 5050(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, one of the requirements for approval of a petition 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). Reference was made to Vancomycin Hydrochloride for Injection, 1.25 gram base/vial, approved under NDA 209481, held by Mylan Laboratories Limited (Mylan).

A comparison between Hospira's proposed product, the proposed Hospira reference product, and the product approved in NDA 209481 held by Mylan is provided in **Table 1** below. To obtain an optimal pH during manufacturing, the proposed product and Hospira reference product contain Hydrochloric Acid and Sodium Hydroxide for pH adjustment. These excipients are not described in the Mylan product formulation. As the proposed product contains additional excipients compared to the Mylan product, the formulations differ qualitatively in a manner that is not permitted under 21 CFR 314.94(a)(9)(iii). It is the petitioner's view that an ANDA referencing Mylan NDA 209481 would not be appropriate, as it would not be accepted for review.

Table 1. Comparison Between Proposed Product, Proposed Hospira Reference Product, and Mylan Laboratories 1.25g/vial

	Vancomycin Hydrochloride for Injection 1.25 gram ADD-Vantage Vial	**Vancomycin Hydrochloride for Injection 1 gram ADD-Vantage Vial**	**Vancomycin Hydrochloride for Injection 1.25 gram Vial**
	Hospira ANDA 062933 **Proposed Product**	Hospira ANDA 062933 **Proposed Reference Product**	Mylan NDA 209481
Indication	Treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (β-lactam-resistant) staphylococci	Treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (β-lactam-resistant) staphylococci	Treatment of: Septicemia Infective Endocarditis Skin and Sink Structure Infections Bone Infections Lower Respiratory Tract Infections
Active Ingredient(s)	Vancomycin Hydrochloride, USP	Vancomycin Hydrochloride, USP	Vancomycin Hydrochloride, USP
Inactive Ingredient(s)	Water for Injection, USP (vehicle) Hydrochloric Acid, NF* (pH adjustment) Sodium Hydroxide, NF* (pH adjustment)	Water for Injection, USP (vehicle) Hydrochloric Acid, NF* (pH adjustment) Sodium Hydroxide, NF* (pH adjustment)	Water for Injection, USP (vehicle)
Route of Administration	Injection (Intravenous)	Injection (Intravenous)	Injection (Intravenous)
Dosage Form	Injectable	Injectable	Injectable
Strength	1.25 gram/vial	1 gram/vial	1.25 gram/vial

*Hydrochloric Acid and Sodium Hydroxide are not included in the formulation as preservative, buffer or anti-oxidant, the permitted exceptions defined in 21 CFR 314.94(a)(9)(iii).

C. ENVIRONMENTAL IMPACT

The petitioner requests a categorical exclusion under 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT

In accordance with 21 CFR 10.30(b), the petitioner will, upon request, submit economic impact information.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Sincerely,

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