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HAND DELIVERED

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned submits this citizen petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs determine a new strength (different total drug content) of Vancomycin Hydrochloride For Injection, USP, Fliptop Vial For Intravenous Use, is suitable for submission and subsequent Food and Drug Administration ("FDA") review as an abbreviated new drug application ("ANDA").

A. Action Requested

The petitioner requests that FDA determine that Vancomycin Hydrochloride USP, 1.5 grams (base)/vial is suitable for ANDA submission as a new 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 reference listed drug ("RLD"), 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 a new strength of a currently approved drug product.

The RLD upon which this petition is based is Hospira Inc.'s ("Hospira") currently approved Vancomycin Hydrochloride For Injection, USP, Fliptop Vial For Intravenous Use, 1 gram (base)/ vial, ANDA # 62-912. A copy of the ANDA #62-912 entry from the current electronic edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") is included as **Attachment 1.**

In addition to the 1 gram (base)/vial RLD, FDA has approved a supplement to Hospira's ANDA #62-912 for Vancomycin Hydrochloride in a 750 mg strength pursuant to a previously submitted Suitability Petition (Docket No. 2006P-0533/CP1). FDA approved the Suitability Petition on August 22, 2007, thereby permitting the filing of an application for a drug product that differs in strength (total drug content) from the RLD – from 1 gram (base)/vial in the RLD to 750 mg (base)/vial.

This petition seeks similar permission to submit an ANDA for a product that differs from the RLD by increasing the strength (total drug content) from 1 gram (base)/vial to 1.5 grams (base)/vial. The proposed drug would have the same concentration as the RLD after reconstitution.

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

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 RLD. The labeling for the proposed drug product would be essentially identical to that of the RLD and would differ only with respect to the proposed strength and manufacturer-specific information.

Draft labeling of the proposed product is included as **Attachment 2.** (The draft labeling assumes the petitioner has or will obtain approval for all approved strengths of Vancomycin Hydrochloride For Injection). The labeling for the RLD is included in **Attachment 3.**

The proposed increase in strength is consistent with FDA's approved labeling for the RLD. The RLD labeling calls for an initial dose range of up to 1 gram, but supports the proposed new product strength of a 1.5 gram (base)/vial. The current labeling for the RLD instructs using a minimum dose of 15 mg/kg in patients with mild to moderate renal impairment and an initial dose of 15 mg/kg in functionally anephric patients. The 1.5 gram presentation would be appropriate for patients where a 1 gram dose is not sufficient for their body weight.

The 1.5 gram presentation can be used to reconstitute a dose of 15 mg/kg for those patients who weigh between 67 and 100 kg without manipulating multiple vials. As a result, a clinician would be able to use one vial to reconstitute a dose between 1 and 1.5 grams.

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

For the forgoing reasons, the undersigned requests that FDA approve this petition and permit the proposed new strength (different total drug content at the same concentration after reconstitution) to be addressed through the ANDA process.

C. Environmental Impact

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

D. Economic Impact Statement

In accordance with 21 C.F.R. § 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 it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Respectfully submitted,

Tish E. Pahl

Tish E. Pahl, Esq.

TEP:jmw
Attachments

Attachment 1 – ANDA #62-912 entry from *Approved Drug Products with Therapeutic Equivalence Evaluations*
Attachment 2 – Draft labeling
Attachment 3 – Current labeling for Vancomycin Hydrochloride For Injection, USP, Fliptop Vial For Intravenous Use, 1 gram (base)/ vial, ANDA # 62-912