

December 22, 2006

Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

3030 '06 DEC 22 P2:16

SUITABILITY PETITION

Dear Sir or Madam:

The undersigned submits this Suitability Petition ("Petition") under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs declare a new strength (total drug content) of Sterile Vancomycin Hydrochloride USP (for intravenous use) is suitable for submission and subsequent Food and Drug Administration ("FDA") review pursuant to an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs declare Sterile Vancomycin Hydrochloride USP, 750 mg, in a vial comparable to Hospira, Inc.'s ADD-Vantage® Vial, suitable for submission in an ANDA.

The reference listed drug ("RLD") is Hospira, Inc.'s currently approved Sterile Vancomycin Hydrochloride USP 1g, ANDA # 62-933. Sterile Vancomycin Hydrochloride USP, 1g is listed in the current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). A copy of the ANDA # 62-933 Detail Record from the current electronic edition of the Orange Book is included as **Attachment 1**.

The drug, dosage form, route of administration, and recommendations for use of the proposed product are the same as those of the RLD. The proposed product would differ only in strength from the marketed Sterile Vancomycin Hydrochloride USP, 1g product approved under ANDA # 62-933.

2006P-0534

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B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for submission of an ANDA for a new drug product that differs in strength from an RLD, provided that FDA has approved a petition seeking permission to file such an application. This Petition requests to submit an ANDA for a new strength of a currently approved drug product.

In addition to the 1g RLD, FDA has approved ANDAs for Sterile Vancomycin Hydrochloride in 500 mg strength. The new proposed strength, 750 mg, will provide practitioners with a convenient, intermediate alternative to the currently approved strengths.

The proposed drug product is intended for use only as described in the **Indications and Dosage and Administration** sections of the currently approved labeling for the RLD. The labeling for the proposed drug product is essentially identical to that of the RLD and differs only with respect to the proposed strength and manufacturer-specific information (including an appropriate, alternative proprietary or non-proprietary name to describe the "ADD-Vantage®"-style vial). The currently approved RLD labeling calls for an initial dose of up to 1 gram, and supports the new product strength of 750 mg. This new strength will provide a convenient intermediate, incremental dose for practitioners without their having to compound on site. Additionally, drug waste would be minimized as the practitioner would not need to use two 500 mg vials or a 1g vial to achieve 750 mg. Draft labeling of the proposed drug is provided in **Attachment 2**. The package insert for the RLD is included in **Attachment 3**.

The proposed strength does not pose questions of safety or effectiveness because the use, dose, and route of administration of the proposed product are comparable to those of the RLD.

For the foregoing reasons, the undersigned requests that the Commissioner approve this petition and find an ANDA is suitable for submission.

C. Environmental Impact

The petitioner claims 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 by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that, to her best knowledge and belief, this Petition includes all information and views on which the Petition relies, and it includes representative data and information known to the Petitioner, which are unfavorable to the Petition.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Markus', written in a cursive style.

Christina M. Markus

Attachment 1 –
ANDA # 62-933 Detail Record from the current electronic edition of the Orange Book

Attachment 2 –
Draft Proposed Labeling, Sterile Vancomycin, Hydrochloride USP, 750 mg

Attachment 3 –
Sterile Vancomycin Hydrochloride USP, ADD-Vantage® Vials, 1g Package Insert
(RLD Labeling)