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June 16, 2005

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20857

### CITIZEN'S PETITION

The undersigned submits this petition pursuant to 21 CFR 314.93 to request that the Commissioner of Food and Drug permit the filing of an Abbreviated New Drug Application for a drug that has the same active ingredient and dosage form listed in FDA's publication entitled, *Approved Drug Products with Therapeutic Equivalence Evaluations*, current Internet edition, but differs in its dosage strength (total quantity of active ingredient in the package).

#### A. Action Requested

By this petition, we hereby request the Agency to permit the filing of an Abbreviated New Drug Application for a Sterile Vancomycin Hydrochloride, USP, pharmacy bulk package in a 100 gram dosage strength packaged in plastic bags that are contained within foil outer wraps. This drug differs from the reference listed drug, Baxter's Vancocin<sup>®</sup> HCl (Vancomycin Injection, USP) in GALAXY plastic container in its total dosage strength but not the dosage amount recommended for administration to the patient.

#### B. Statement of Grounds

In accordance with section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, a petition may be filed, with the Agency, seeking permission to file an Abbreviated New Drug Application for a new drug, which differs from a "listed" drug in dosage strength. The Act stipulates that such a petition must be approved by the Agency unless there is a finding that investigations are needed to demonstrate the safety and effectiveness of the proposed drug product.

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2005P-0242

CP1

## Citizen's Petition

June 16, 2005

Page 2

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The reference listed drug product, Baxter's Vancocin<sup>®</sup> HCl (Vancomycin Injection, USP) in GALAXY Plastic Container, is identified in the Prescription Product List of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) as supplied in the CDER Internet home page. A printout of this listing by active ingredient detail is provided in Exhibit A.

We propose to develop a pharmacy bulk package of Sterile Vancomycin Hydrochloride, USP, in a 100 gram dosage strength packaged in plastic bags that are contained within secondary foil outer wraps. The inner (product) bag is provided with an injection port to allow aseptic constitution of the solution and transfer into dispensing units. A similar formulation and the same route of administration as the reference listed drug are proposed, i.e., Sterile Vancomycin Hydrochloride, USP, for intravenous injection after reconstitution with the specified diluent, Sterile Water for Injection. It should be noted that the proposed product will have the same formulation and route of administration as the reference listed product, Baxter's Vancoled<sup>®</sup> (Sterile Vancomycin Hydrochloride, USP) and American Pharmaceutical Partners' Sterile Vancomycin Hydrochloride, USP. The proposed product will be administered at the same dosage recommendations as the listed drug and is expected to have the same therapeutic effect when administered for use as indicated in the product labeling.

Labeling for the reference listed drug, Baxter's Vancocin<sup>®</sup> HCl (Vancomycin Injection, USP), in GALAXY Plastic Container, is included in Exhibit B; labeling for American Pharmaceutical Partners' Sterile Vancomycin Hydrochloride, USP is included in Exhibit C. Labeling for the proposed product is expected to be substantially the same as the sections pertaining to Clinical Pharmacology, Indications and Usage, Contraindication, Warnings, Precautions, Adverse Reactions, Overdosage and Dosage of the listed drug labeling. In addition, it will be substantially the same as American Pharmaceutical Partners' labeling, with the exception that reference to the 5 or 10 gram Pharmacy Bulk Package will be replaced with "100 gram Pharmacy Bulk Package," and references to other dosage forms will be eliminated. A copy of the proposed draft package insert is provided in Exhibit D.

The proposed strength is designed to be used by hospital pharmacies or centralized compounding pharmacies that provide hospitals, organized into networks, with a standard platform of the prepared formulation reconstituted to the required concentration and filled into syringes for intravenous delivery of medication. The benefit of this dosage strength is the optimization of drug therapy and delivery of hospital pharmacy services. This new dosage strength enhances aseptic control, since product reconstitution takes place within a closed system design, and disposable components are used. Reduced handling of the product, with one bag equivalent to 10 to 20 vials of the American Pharmaceutical Partners drug, further ensures that sterility of the product is maintained during reconstitution and filling into syringes. This proposed bag system configuration is particularly well adapted for use in the hospital or compounding pharmacy.

Thus, the use of the 100 gram pharmacy bulk package of Sterile Vancomycin Hydrochloride, USP, in the double plastic and foil bag container, will not only increase efficiency at the hospital or compounding pharmacy level, but it will also permit minimal handling of the product that will result in improved quality assurance.

Introduction of the double bag container will not have an impact on the established safety and efficacy of Sterile Vancomycin Hydrochloride, USP, and since the product is an injectable preparation to be administered at the same strength as the listed drug, a bioequivalence study is not viewed as a requirement.

**C. Environmental Impact**

An environmental impact analysis report is not required for this petition per 21 CFR 25.24.

**D. Economic Impact**

This information will be provided upon request from the Agency.

**E. Certification**

The undersigned certifies that, to the best knowledge 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 are unfavorable to the petition.

If you have any questions or need additional information, please feel free to contact me.

Sincerely,

SAMSON MEDICAL TECHNOLOGIES, L.L.C.



Marvin Samson  
Chief Executive Officer

Enclosures: Exhibits A, B, C and D