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MEDICAL TECHNOLOGIES, L.L.C.

May 23, 2003

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 Cefoxitin for Injection, USP, pharmacy bulk package in 100 and 300 gram dosage strengths packaged in plastic bags that are contained within foil outer wraps. This drug differs from the reference listed drug, Merck Mefoxin® (Cefoxitin for Injection, USP), 10 gram, Pharmacy Bulk Package, in their total dosage strengths 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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The reference listed drug product, Merck Mefoxin® (Cefoxitin for Injection, USP), 10 gram Pharmacy Bulk Package, 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 Cefoxitin for Injection, USP, in 100 and 300 gram dosage strengths 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. The same formulation and route of administration as the reference listed drug Pharmacy Bulk Package are proposed, i.e., Cefoxitin for Injection, USP, for intravenous injection after constitution with the specified diluent, Sterile Water for Injection. 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, Merck Mefoxin® (Cefoxitin for Injection, USP), 10 gram Pharmacy Bulk Package, is included in Exhibit B. Labeling for the proposed product is expected to be substantially the same as the sections pertaining to the pharmacy bulk package dosage form of the listed drug labeling, with the exception that reference to Merck Mefoxin® (Cefoxitin for Injection, USP), 10 gram Pharmacy Bulk Package will be replaced with "Cefoxitin for Injection, USP, 100 gram or 300 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 C.

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 constitution takes place within a closed system design, and disposable components are used. Reduced handling of the product, with one bag equivalent to 10 or 30 vials of the listed drug, further ensures that sterility of the product is maintained during constitution 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 or 300 gram pharmacy bulk packages of Cefoxitin for Injection, 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 Cefoxitin for Injection, 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 and C