DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA 306

Food and Drug Administration
Rockville MD 20857

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OCT 01 2003

Samson Medical Technologies, L.L.C.
Attention: Marvin Samson
P.O. Box 2730
Cherry Hill, NJ 08034

Docket No. 03P-0227/CP1

Dear Mr. Samson:

This is in response to your petition filed on May 27, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Cefoxitin for Injection USP, 100 g and 300 g pharmacy bulk packages (PBPs) to be initally reconstituted either to 100 mg/mL or 200 mg/mL. The listed drug product to which you refer in your petition is Mefoxin® (Cefoxitin) for Injection USP, 10 g/vial PBP approved under NDA 50-517 held by Merck and Co. Inc. The concentration of Mefoxin® (Cefoxitin) for Injection USP, 10 g/vial PBP, when initially reconstituted as directed in the approved labeling, is 1 g/10 mL (i.e., 100 mg/mL).

Your request involves changes in strength, both in concentration and total drug content, from that of the listed drug product (i.e., from 10 g/vial PBP to 100 g and 300 g PBPs; and from an initial concentration of 100 mg/mL to an initial concentration of either 100 mg/mL or 200 mg/mL). The changes you request are the types of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The FDA finds that the changes in strength for the specific proposed drug products do not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug products are the same as that of the listed drug product. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug product.

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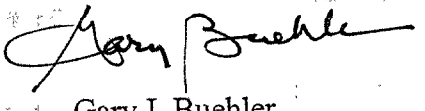
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for the drug products to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a drug product that is the same as the subject of this petition, that drug product will be a listed drug. Thereafter, the petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Docket No. 03P-0227/CP1
Cefoxitin for Injection (100 g and 300 g)
Samson Medical Technologies, L.L.C.

Concurrence:

Date: 10/1/03

Gary Buehler
Director
Office of Generic Drugs

cc: Petition File
HFA-305/Dockets Management Branch
HFD-1/CDER/Chron. File
HFD-600/G. Buehler/C.Parise/Petition File
HFD-613/Labeling Review Branch
HFD-615/Regulatory Support Staff/M.Shimer
HFD-650/Division of Bioequivalence
GCF-1/K. Dettelbach/L. Whipkey
RD by M.Shimer 7/16/03
Edited by C.Parise 9/30/03
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FT by
Petition Letter!