DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 200938

ANDA APPROVAL

Samson Medical Technologies, L.L.C.
2050 Springdale Road, Suite 400
Cherry Hill, NJ 08003
Attention: Marvin Samson
Chief Executive Officer

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 25, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Cefoxitin for Injection USP, 100 g/bag, Pharmacy Bulk Package SmartPak®.

Reference is also made to the Complete Response Letter issued by this office on November 29, 2013, and to your amendments dated May 30 and November 12, 2014.

Reference is also made to the ANDA Suitability Petition (Docket No. FDA-2003-P-0227/CP 1) submitted on May, 27, 2003 under Section 505(j)(2)(c) of the Act, and approved on October 1, 2003. The petition requested involves a change in strength, both in concentration and total drug content from, the listed drug product; Mefoxin (cefoxitin) Injection[1] (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, and Drug, and Cosmetic Act.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the **ANDA is approved**, effective on the date of this letter. The drug product, Cefoxitin for Injection USP, 100 g/bag, Pharmacy Bulk Package SmartPak® can be expected to have the same therapeutic effect as that of the listed drug product upon which the agency relied as the basis of safety and effectiveness.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

[1] We note that the 10g/vial presentation of the listed drug product upon which you have based your ANDA, Mefoxin® (cefoxitin) Injection, 10 grams/vial (Merck & Co.), is no longer being marketed in the United States, and are currently listed in the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The agency announced its determination that the 10grams/vial presentations of Mefoxin Injection were not withdrawn from sale for reasons of safety or effectiveness. 72 FR 172; September 6, 2007. This determination allows the agency to approve ANDAs for the discontinued drug product.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL

files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

William P. Rickman -S

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2015.11.16 13:51:31 -05'00'

For Carol A. Holquist, R.Ph.
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research