



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 65-141

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 20, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cefazolin for Injection USP, packaged in 100 gram and 300 gram Pharmacy Bulk Packages. We note that this product is subject to the exception provisions of section 125 d) (2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated February 6, October 11, October 18, October 27, and November 16, 2006. Reference is also made to the ANDA Suitability Petition submitted under Section 505(j) (2) (c) of the Act and approved by the agency on March 4, 2002. This approved petition permitted you to file this ANDA for a drug product that differs in strength from the reference listed drug product (RLD). Specifically, the reference listed drug, Kefzol[®] for Injection, of Eli Lilly is approved as a Pharmacy Bulk Package containing 20 grams of cefazolin per vial. Your ANDA provides for containers providing 100 grams and 300 grams of cefazolin per Pharmacy Bulk Package.

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, Cefazolin for Injection USP, 100 gram and 300 gram (Pharmacy Bulk Packages) can be expected to provide the same therapeutic effect as an equivalent dose obtained from the reference listed drug product

upon which the agency relied as the basis of safety and effectiveness.

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

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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Amundson 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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

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