



ANDA 065141/S-003

Samson Medical Technology, L.L.C.
Attention: Marvin Samson
2050 Springdale Road
Suite 400
Cherry Hill, NJ 08003

This is in reference to your supplemental new drug application dated January 6, 2009, submitted pursuant to 21 CFR 314.70(c)(6) (Supplement – Changes Being Effected) regarding your abbreviated new drug application for Cefazolin for Injection USP – Pharmacy Bulk Package bags SmartPak® -100 grams and 300 grams.

We acknowledge receipt of your amendments dated April 12, 2011, September 27, 2011, October 4, 2012, November 14, 2012 and July 22, 2013.

The supplemental application provides for revised insert labeling reflecting revisions to the CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION sections. In addition, the container labels and carton labeling were revised.

We have completed the review of this supplemental application and it is approved. However, further revise your label and labeling as follows:

1. CONTAINER: Inner bag
 - a. Improve the visibility of the text beneath the black line by increasing the font size.
 - b. Indicate the location of the lot number and expiration date.
2. OUTER BAG
 - a. Please refer to comments under the inner bag.
 - b. Add the statement, “Contains one Pharmacy Bulk Package bag - ___ grams”.
3. INSERT
 - a. GENERAL COMMENTS
 - i. Increase the font size of the text of the insert labeling.
 - ii. Use darker print for the bolded text, so that it is clearly distinguishable from the non-bolded text.
 - b. HIGHLIGHTS OF PRESCRIBING INFORMATION
Start printing the established name at the left side margin.
 - c. FULL PRESCRIBING INFORMATION
2 DOSAGE AND ADMINISTRATION
- In the third sentence replace “per ml” with “per mL”.
-Further improve the visibility of the diagram of the Pharmacy Bulk Package bag SmartPak® and associated text by increasing the size of each.

- Dilution

Print “50” and “mL” on the same line.

12.3 Pharmacokinetics

- In Table 3, print “2” and “g” on the same line.

- Revise the last paragraph to read, “Cefazolin is excreted unchanged in the urine. In the first 6 hours approximately 60% of the drug is excreted in the urine and this increases to 70% to 80% within 24 hours”.

- In the second paragraph beneath Table 4 revise the first sentence to read, “...reaches the concentrations at the...”.

Revised insert labels and labeling with the above changes may be submitted in an annual report provided they are described in full. We refer you to 21 CFR 314.81(b)(2)(iii) for guidance.

We 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 Act.

CONTENT OF LABELING

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.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

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 dose form (FDFs) or active pharmaceutical ingredient (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.

The material submitted is being retained in our files.

Sincerely yours,

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachments: Approved container labels, package and insert labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JACQUELINE D COUNCIL
07/30/2013

LILLIE D GOLSON
07/30/2013
for Wm. Peter Rickman