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

Docket No. 03P-0184/CP1

Dear Mr. Samson:

This is in response to your petition filed on May 1, 2003, requesting permission to file an
Abbreviated New Drug Application (ANDA) for the following drug product: Nafcillin [Sodium]
for Injection USP, 200 g Pharmacy Bulk Package. The listed drug product to which you refer in
your petition is Nafcillin [Sodium] for Injection USP, 10 g Pharmacy Bulk Package (PBP)
approved under ANDA 62-527 held by Apothecon Inc., Division of Bristol Myers Squibb.

Your request involves a change in strength (total-drug-content) from that of the listed drug
product (i.e., from 10 g PBP to 200 g PBP). The change you request is the type of change that is
authorized under the Federal Food, Drug, and Cosmetic Act (Act). It is noted that your proposed
product does not represent a change in the salt of the active ingredient, Nafcillin Sodium, utilized
to formulate the product. Nafcillin for Injection is an article in the USP that is, by definition, the
sodium salt of Nafcillin.

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 product.

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 change in strength for the specific proposed drug product does not pose
questions of safety or effectiveness because the uses, dose, and route of administration of the
proposed drug product is 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 product can be expected to have the same
therapeutic effect as the listed reference drug product.

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Docket No. 03P-0184/CP1
Samson Medical Technologies, L.L.C.
Nafcillin for Injection USP, 200 g Pharmacy Bulk Package

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. 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 product 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 this drug product 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 drug product that is the subject of this petition, then 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