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November 10, 2006

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Suitability Petition

The undersigned submits this petition under 21 CFR 10.20 and 21 CFR 10.30 as provided for in 21 CFR 314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10, to request the Commissioner of the Food and Drug Administration to declare that the drug product, Cefepime for Injection, administered for intravenous use only, is suitable for submission as an Abbreviated New Drug Application (ANDA) under 21 CFR 314.92. This request is also proposing to use Bristol-Myers Squibb Company's Maxipime® in glass vials as the reference listed drug (RLD).

A. Action Requested

The petitioner (B. Braun Medical Inc.) requests that the Commissioner of the Food and Drug Administration declare that the drug product, Cefepime for Injection, administered for intravenous use only, is suitable for submission as an abbreviated new drug application (ANDA) under 21 CFR 314.92. The RLD product upon which this petition is based is Maxipime® (Cefepime Hydrochloride, USP for Injection), equivalent 1 g base/vial and 2 g base/vial under New Drug Application (NDA) 50-679, manufactured by Bristol-Myers Squibb Company. Maxipime® labeling (both in hard copy and electronic) is enclosed as **Attachment 1**. Currently, Bristol-Myers Squibb Company contains both intravenous and intramuscular administration in their labeling. This petition is submitted because the petitioner proposes to remove all references to intramuscular administration in the labeling. The intravenous conditions for use will remain identical to the RLD as will the active ingredients, dosage form and strengths (with the exception of the 500 mg). B. Braun Medical Inc. is not intending to manufacture a 500 mg strength of Cefepime for Injection.

In addition, this petition is to request the glass vials be used as the reference listed drug for the proposed ANDA. Currently, the Bristol-Myers Squibb Company has the glass vial, the ADD-vantage vial and the Piggyback bottle approved under NDA 50-679. Please see the enclosed pages of the electronic Orange Book referencing NDA 50-679 in **Attachment 2**. B. Braun Medical Inc. is petitioning the Maxipime® in glass vials to be used as the reference listed drug to B. Braun's Medical Inc.'s Cefepime for Injection in the Duplex®Container.

B. Statement of Grounds

The Federal Food , Drug and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in route of administration from that of a RLD provided the FDA has approved a petition that proposes the filing of such an application. This petition requests a deletion of one of the routes of administration for the proposed drug from that of the RLD. Specifically, the petitioner is requesting that the proposed ANDA only have intravenous administration instead of both intravenous and intramuscular administration as the RLD.

The Food and Drug Administration's Orange Book lists Maxipime® as an active reference listed drug. Copies of the electronic Orange Book pages are enclosed in **Attachment 2**. The proposed

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drug product, Cefepime for Injection, uses the same active ingredient, cefepime hydrochloride (arginine formulation) and one of the compatible I.V. infusion fluids, 5% Dextrose Injection for reconstitution.

The proposed labeling for the Cefepime for Injection will be equivalent with the reference listed drug labeling with regards to formulation, indications, contraindications, warnings, precautions, dosage form and intravenous route of administration and differs only with the inclusion of information related to B. Braun's Duplex® container closure/system and will not include the intramuscular administration. The proposed labeling for Cefepime for Injection (both in hard copy and electronic) can be found in **Attachment 3**. Any reference to the intramuscular indications has been removed.

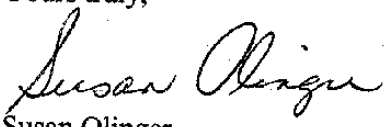
The petitioner has based the proposed labeling on the Maxipime® glass vials. B. Braun proposes to use the Maxipime® glass vial labeling as the RLD labeling based on precedent that FDA set during review of B. Braun's approved ANDA 65-214, Cefoxitin for Injection in the Duplex® Container. The RLD used to support Cefoxitin for Injection, Mefoxin® manufactured by Merck & Co. Inc., contained both glass vials and Add-Vantage vials. FDA requested that B. Braun use the glass vials as the RLD.

C. Environmental Impact
An environmental assessment report on the action requested in this petition is not required under 21 CFR 25.31.

D. Economic Impact
In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. B. Braun Medical Inc. hereby commits to promptly provide this information, if so requested.

E. Certification
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Yours truly,



Susan Olinger
Corporate Vice President, Regulatory Affairs

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
Telephone: 610-596-2517
Fax: 610-266-4962
Email: susan.olinger@bbraun.com

Enclosures