

B|BRAUN

0268 8 AUG 18 A10 :09

August 15, 2008

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Petition # 2006P-0461
Withdrawal of Suitability Petition

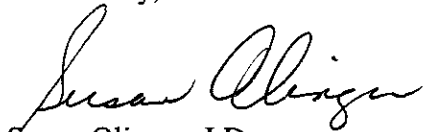
Dear Sir/Madam:

In accordance with 21 CFR 10.30, B. Braun Medical Inc. (B. Braun) hereby requests withdrawal of the above mentioned Suitability Petition. This petition was originally submitted on November 10, 2006 with the purpose of determining whether B. Braun's proposed product, Cefepime for Injection, administered for intravenous use only, is suitable for submission as an Abbreviated New Drug Application (ANDA) using the reference listed drug (RLD), Maxipime, application holder Bristol Myers-Squibb (NDA 050679).

Since the filing of this petition, B. Braun met with the Agency to determine the application pathway for the proposed product, Cefepime for Injection and Dextrose Injection in the Duplex[®] Container. The Agency determined that all future Duplex[®] products must be filed as NDA 505(b)(2) applications; therefore, the ANDA pathway is no longer feasible. There is no longer a need for B. Braun to petition for this answer. Henceforth, B. Braun requests withdrawal of Suitability Petition 2006P-0461 without prejudice to future filings.

If you should have any questions regarding this withdrawal, please do not hesitate to contact Patti Smith via telephone at (610) 596-2638, facsimile (610) 266-4962 or via email at patti.smith@bbraun.com.

Yours truly,



Susan Olinger, J.D.

Corporate Vice President, Regulatory Affairs

FDA-2006-P-0015

WDL

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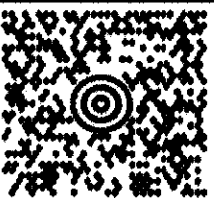
JENNIFER DAVID
610-266-0500
B BRAUN MEDICAL INC
901 MARCON BLVD.
ALLENTOWN PA 18109

LTR

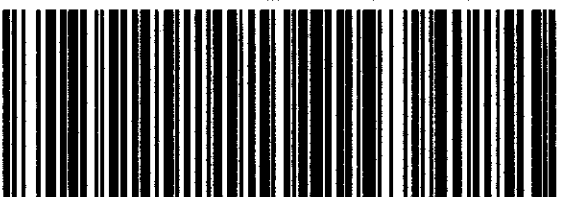
1 OF 1

SHIP TO:

DIVISION OF DOCKET'S MGMNT
610-596-2665
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, RM 1061 (HFA-305)
DEPARTMENT OF HEALTH AND HUMAN SVCS
ROCKVILLE MD 20857-0001

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