DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Susan Olinger
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

MAR 28 2007 MAR 29 A9:43

Re: Docket No. 2006P-0404/CP1

Dear Ms. Olinger:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 2, 2006. Your petition requests that FDA determine whether Cefotan (cefotetan injection), equivalent 1 gram ADD-vantage vial and 2 gram ADD-vantage vial (new drug application 63-293), was withdrawn from sale for reasons of safety or effectiveness. If FDA determines that Cefotan was not withdrawn from sale for reasons of safety or effectiveness, you request permission to file an abbreviated new drug application.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0404

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