DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 2 2006

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

Re: Docket No. 2006P-0201/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 May 11, 2006. Your petition requests that FDA determine whether Cefotan (cefotetan injection), equivalent 1 gram base/vial and 2 gram base/vial (new drug application 50-588), was withdrawn from sale for reasons of safety or effectiveness. If FDA determines that Cefotan was not withdrawn from sale for reasons of safety or effectiveness, you request permission to file an abbreviated new drug application.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

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