

September 29, 2006

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 161  
Rockville, MD 20862

Citizen Petition

The undersigned submits this petition under 21 CFR 10.25(a) and 21 CFR 10.30 to request the Commissioner of the Food and Drug Administration to determine whether a listed drug (Cefotan<sup>®</sup>, manufactured by AstraZeneca under NDA 63-293), that has been discontinued, was not discontinued for safety or effectiveness reasons. In addition, the undersigned submits this petition to request permission of filing an abbreviated new drug application (ANDA) if the listed drug was discontinued for reasons other than for safety and effectiveness.

**A. Action Requested**

The petitioner (B. Braun Medical Inc.) requests that the Commissioner of the Food and Drug Administration determine whether Cefotan<sup>®</sup> (cefotetan injection), equivalent 1 g ADD-vantage<sup>†</sup> vial and 2 g ADD-vantage<sup>†</sup> vial, NDA 63-293, manufactured by AstraZeneca has been voluntarily withdrawn from sale for safety and efficacy reasons.

**B. Statement of Grounds**

The Food and Drug Administration's Orange Book Cumulative Supplement 08, dated August 2006 lists Cefotan<sup>®</sup> (NDA 63-293) as a discontinued drug. According to information received online at [www.factsandcomparisons.com](http://www.factsandcomparisons.com), FDA's drug shortages website ([www.fda.gov/cder/drug/shortages/default.com](http://www.fda.gov/cder/drug/shortages/default.com)) under discontinuations and the American Society of Health-System Pharmacists website ([www.ashp.org](http://www.ashp.org)), this product was discontinued as of March 31, 2006. Copies of online web pages are enclosed.

Under FDA regulations, the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety and effectiveness before an ANDA referencing the listed drug may be approved (21 CFR 314.161(a)(1)).

B. Braun Medical Inc. has no information or evidence concerning the reason that AstraZeneca discontinued marketing Cefotan<sup>®</sup>, but nonetheless contends that the reasons were unrelated to safety and effectiveness. B. Braun Medical Inc. petitions FDA to determine that AstraZeneca's decision to discontinue marketing Cefotan<sup>®</sup> was for reasons other than safety or effectiveness.

**C. Environmental Impact**

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

2006P-0404

<sup>†</sup> ADD-Vantage is a registered trademark of Abbott Laboratories Inc.

CP 1

**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 are 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](mailto:susan.olinger@bbraun.com)