



**Arent Fox Kintner Plotkin & Kahn, PLLC**  
1050 Connecticut Avenue, NW  
Washington, DC 20036-5339  
Phone 202/857-6000  
Fax 202/857-6395  
www.arentfox.com

**Peter S. Reichertz**  
202/857-6378  
reicherp@arentfox.com

February 8, 2001

**BY HAND**

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20857

4007 '01 FEB -8 P2:48

**RE: SECOND RESPONSE OF C. B. FLEET COMPANY, INCORPORATED,  
TO CITIZEN PETITION FILED ON BEHALF OF BRAINTREE  
LABORATORIES, INC.**

**DOCKET NO. 00P-1472(CP1)**

Dear Sir/Madam:

We represent C. B. Fleet Company, Incorporated, of Lynchburg, Virginia. ("Fleet"). On August 23, 2000, a Citizen Petition was filed on behalf of Braintree Laboratories, Inc. ("Braintree"), which was assigned the above-referenced docket number. On behalf of Fleet, we submitted an Initial Response to that Citizen Petition on November 17, 2000, indicating that Fleet disagrees not only with the assertions of fact upon which the action is requested, but the actions requested in that Citizen Petition as well. The other purpose of that Initial Submission was to indicate that Fleet would file a more complete response to that petition by January 19, 2000, and to outline what would be contained in that more complete submission. Until receipt of Fleet's more complete submission, we requested on

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*RC2*

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behalf of Fleet that the Agency defer any consideration or action on the Braintree Citizen Petition, unless it decided in the interim to deny that petition. Fleet believes it should based on the arguments stated therein.

While Fleet believes that its Initial Submission of November 17, 2000, alone was sufficient to summarily deny the Braintree Citizen Petition, it indicated it would, in order to assist the Agency, supply a more detailed response by January 19, 2000. Fleet is still in the process of preparing that complete submission, and will now submit it on April 30, 2001. Unless the Agency decides to deny the Citizen Petition in the interim, as Fleet believes it should, Fleet requests that the Agency defers any consideration of the Braintree Citizen Petition until Fleet's more complete submission is filed.

Respectfully submitted,



Peter S. Reichertz  
Michael D. Bernstein

Counsel to C.B. Fleet Company, Incorporated