



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

November 30, 2004

Surendera K. Tyagi  
Abbott Laboratories  
D-389, Bldg. J45-2N  
200 Abbott Park Road  
Abbott Park, Illinois 60064-6133

Re: Docket No. 2004P-0141/CP1

Dear Ms. Tyagi:

This letter responds to your citizen petition dated March 18, 2004, requesting that the Food and Drug Administration (FDA) determine whether the drug product 7.5% and 8.4% sodium bicarbonate injection in PET Abboject Vials (NDA 19-443) was withdrawn or withheld from sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that the drug product 7.5% and 8.4% sodium bicarbonate injection in PET Abboject Vials was not withdrawn from sale for reasons of safety or effectiveness. The FDA will maintain 7.5% and 8.4% sodium bicarbonate injection in the "Discontinued Drug Product List" of *Approved Drugs with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, do not hesitate to contact me at (301) 443-5542.

Sincerely,

Nikki Mueller  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure

2004P-0141

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