



SEP 14 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:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated March 18, 2004. You request that the Agency determine whether the drug product 7.5% and 8.4% sodium bicarbonate injection in PET Abboject Vials (NDA 19-443) was withdrawn or withheld from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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 we have reached a decision on your request.

Sincerely,

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

2004P-0141

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