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Hospital Products Division
Abbott Laboratories
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200 Abbott Park Road
Abbott Park, Illinois 60064-6133

March 18, 2004

Division of Dockets Management
Food and Drug Administration
Fisher Lane, Room 1061
HFA - 305
Rockville, MD 20852

**RE: Citizen's Petition
NDA 19-443, 7.5% & 8.4% Sodium Bicarbonate Injection in PET
Abboject Vials**

In accordance with 21 CFR 10.20, in the format specified in 21 CFR 10.30, and required by 21 CFR 314.122, the undersigned submits this petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to determine that the above referenced drug products were not withdrawn for safety or effectiveness reasons.

On June 3, 1986, FDA approved Abbott's NDA 19-443 for Sodium Bicarbonate Injection in PET Abboject Vials. On August 5, 1996, FDA announced the withdrawal of this NDA (61 Fed. Reg. 40649) at Abbott's request. Subsequently, the Agency moved NDA 19-433 to the **Disc (Discontinued Drug Products)** section of the Orange Book.

Abbott plan to submit an ANDA for Sodium Bicarbonate Injection in pre-filled Ansyr™ Syringes. The unit of use, active ingredient, dosage form, strengths, route of administration, and condition of use for the proposed ANDA products will remain the same as for the drug products approved under NDA 19-443.

2004P-0141

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Docket Management Branch
Page Two
March 18, 2004

Action Requested

The petitioner requests the Commissioner to determine that NDA 19-443, 7.5% & 8.4% Sodium Bicarbonate Injection in PET Abboject Vials was not withdrawn for safety or effectiveness reasons.

Statement of Grounds

Abbott is the applicant and sponsor of NDA 19-443, and attests to the fact that voluntary withdrawal of this NDA was not for safety or effectiveness reasons.

Environmental Impact

We hereby request a categorical exclusion under 21 CFR 25.31(a) based on the fact that approval of this petition will not increase the use of the active moiety.

Economic Impact

This information will be submitted if requested by the Commissioner.

Certification

As required by 21 CFR 10.30(b), certification that this petition is complete and contains all information both favorable and unfavorable, is provided as Exhibit I.

We trust that the information presented in this petition is complete to allow a determination whether NDA 19-443 was withdrawn for safety or effectiveness reasons..

Sincerely,

ABBOTT LABORATORIES


Surendera K. Tyagi
Associate Director, Regulatory Affairs
Hospital Product Division
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CERTIFICATION STATEMENT

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.

Surendera K. Tyagi 3/18/04

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