DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-897/S-016

Abbott Laboratories
Hospital Products Division
D-37K, Building AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157
Attention: Jean Kirkeleit Davis
Manager, Regulatory Affairs
Home Products Division

Dear Ms. Davis:

Please refer to your supplemental new drug application dated August 22, 2001, received August 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sodium Chloride Injection, USP, in Plastic Vials.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revised labeling pursuant to the FDA final ruling on aluminum content per 21 CFR 201.323.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted August 22, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Kao, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Cynthia McCormick

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