DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-800 S-014

Abbott Laboratories
Hospital Products Division
D-389, Bldg. J45/2
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Attention: Christine L. Hanke
Senior Specialist, Regulatory Affairs

Dear Ms. Hanke:

Please refer to your supplemental new drug application dated August 16, 2002, received August 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 0.9% Bacteriostatic Sodium Chloride Injection, USP, in Plastic Vials.

We acknowledge receipt of your submissions dated January 23 and February 7, 2003.

This "Changes Being Effected" supplemental new drug application provides for enhancement of the product name on the carton labeling and the relocation of the "Rx only" wording.

We have completed our review of this application, as amended, and the application is approved, effective on the date of this letter.

We strongly recommend that you implement the same labeling revisions to the immediate container labels.

The final printed labeling (FPL) must be identical to the draft carton label submitted January 23, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-800/S-014." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (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}

Bob Rappaport, M.D.
Acting 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/

Bob Rappaport

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