



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-514/S-058

Abbott Laboratories
D-389, Bldg. J45-2
200 Abbott Park Road
Abbott Park, Illinois 60064

Attention: Jeremy Rybicki
Specialist, Regulatory Affairs

Dear Mr. Rybicki:

Please refer to your supplemental new drug application dated January 27, 2004, received January 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 0.9% Sodium Chloride Irrigation Solution in Semi-Rigid Container.

This supplemental new drug application provides for a revised **PRECAUTIONS** section. A **Geriatric Use** subsection is added in accordance with the requirements of 21 CFR 201.57(f)(10).

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

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, HFD-410
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 Pratibha Rana, Regulatory Project Manager, at (301) 827-7431.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, 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
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/s/

Bob Rappaport
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