DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-117/S-002

Abbott Laboratories
Hospital Products Division
D-389, Building AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Attention: Nicohl R. Wilding
Regulatory Specialist

Dear Ms. Wilding:

Please refer to your supplemental new drug application dated September 26, 2002, received September 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 10% Calcium Chloride Injection, USP, Plastic Syringe.

We acknowledge receipt of your submission dated December 4, 2002.

The "Changes Being Effected" supplemental new drug application provides for a revised package insert and immediate container label per the requirements of 21 CFR 201.323 and stability specifications, which include a test for aluminum determination with the acceptance criterion of "NMT 1,000 mcg/L of aluminum."

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, 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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