DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-962/S-011

Abbott Laboratories
Attention: Nicohl R. Wilding
Regulatory Specialist
D-389, Bldg. J45-2N
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Dear Ms. Wilding:

Please refer to your supplemental new drug application dated June 6, 2002, received June 7, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Manganese Chloride Injection, USP, 0.1 mg/mL.

We acknowledge receipt of your submissions dated June 21, July 26, and October 31, 2002.

This "Changes Being Effected" supplemental new drug application provides for (1) the addition of a statement regarding aluminum toxicity in patients with impaired kidneys and neonates receiving TPN therapy to the WARNINGS section of the package insert and (2) the addition of the statement "Contains no more than 100 mcg/mL of aluminum" to the vial label. It also makes a required editorial change to the carton label – replacing the "CAUTION: Federal (US) law prohibits . . ." statement with "Rx only."

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) of the package insert, vial label, and carton submitted June 21, 2002.

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 to comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We note that you have not responded to our December 27, 2001, approvable letter for Supplement-007. Please amend that supplement promptly.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Division Director
Division of Metabolic and
Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES

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

/s/

David Orloff

12/6/02 12:18:00 PM