DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-959/S-008, S-011

Abbott Laboratories
Attention: Jean Kirkeleit-Davis
D-389, Bldg. J45-2N
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Dear Ms. Kirkeleit-Davis:

Please refer to your supplemental new drug applications dated July 24, 1998 (S-008), and September 12, 2002 (S-011), received August 20, 2002 and September 13, 2002, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zinc Chloride Injection, USP.

We acknowledge receipt of your submissions dated July 10, 2001 and August 19, 2002 (to supplement –008). The August 19, 2002 submission constituted a complete response to the December 21, 2001 approvable letter. We also acknowledge receipt of your submission dated December 4, 2002 (to supplement –011).

These "Changes Being Effected" supplemental new drug applications provide for the following:

> Supplement-008 provides for the addition of a "Geriatric Use" subsection of the PRECAUTIONS section of the package insert.
>
> Supplement-011 provides for the addition of a warning statement about aluminum toxicity in patients with impaired kidneys and neonates receiving TPN therapy. In addition, the vial label was revised to state the aluminum content.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 12, 2002 with supplemental application –011.

In addition, submit three copies of the introductory promotional materials that you propose to use for these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

> Division of Drug Marketing, Advertising, and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, MD 20857

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Enid Galliers, Supervisory Regulatory Project Manager, at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic & Endocrine 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/

David Orloff

2/14/03 11:23:52 AM