DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-961/S-012

Abbott Laboratories
Attention: Jean Kirkeleit Davis
Manager, HPD Regulatory Affairs
200 Abbott Park Road, D389, J45
Abbott Park, IL 60064-6157

Dear Ms. Davis:

Please refer to your supplemental new drug application dated August 22, 2001, received August 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chromic Chloride Injection, USP, 4 mcg/mL.

We acknowledge receipt of your submission dated February 15, 2002.

This supplemental new drug application provides for the addition of an aluminum toxicity statement to the WARNINGS section of the package insert and a maximum aluminum content statement to the vial label as required by 21 CFR 201.323.

PACKAGE INSERT (Plastic Vial)

The following have been added as the third and fourth paragraphs to the **WARNINGS** section:

> **WARNING***: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.*
>
> *Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.*

VIAL LABEL (Plastic Vial)

The following sentence was added after "See insert,"

"Contains no more than 100 micrograms/Liter of aluminum."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 15, 2002 (marked up ID# 58-6220-R4 Rev. July 2001) and immediate container label submitted August 22, 2001 (ID# 58-2139-2/R4 – 7/01).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 18-961/S-012." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and 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/

Mary Parks
4/24/02 12:32:26 PM
for Dr. Orloff