



NDA 18-960/S-013

Abbott Laboratories
Attention: Jean Kirkeleit Davis
Manager, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road. D-0389, J45/2N
Abbott Park, Illinois 60064-6157

Dear Ms. Davis:

Please refer to your supplemental new drug application dated September 12, 2002, received September 13, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cupric Chloride Injection.

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

This supplemental application, submitted as "Supplement - Changes Being Effected" proposes to add the following paragraph to the WARNINGS Section, to comply with 21 CFR 201.323:

"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."

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the package insert and immediate container labeling submitted on September 12, 2002.

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 Su Yang, Regulatory Project Manager, at (301) 827-6385.

Sincerely,

{See appended electronic signature page}

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

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/s/

David Orloff
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