

NDA 18-960/S-010

AUG 3 2000

Abbott Laboratories
Attention: Thomas P. Sampogna
Manager, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road, D-389, AP3O
Abbott Park, IL 60064-3537

Dear Mr. Sampogna:

Please refer to your 'Changes Being Effected' supplemental new drug application dated July 24, 1998, received August 10, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cupric Chloride Injection.

This supplemental new drug application provides for a labeling revision in response to the final rule, effective August 27, 1998, entitled "*Specific Requirements on Content and Format of Labeling for Human Drugs: Addition of Geriatric Use Subsection in the Labeling*". More specifically, the proposed labeling revision is as follows:

To the **PRECAUTIONS** section of the package insert, the following paragraph has been added:

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

We have completed the review of this supplemental application 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 enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

NDA 18-960/S-010

Page 2

The final printed labeling (FPL) must be identical to the submitted draft labeling dated July 24, 1998.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 18-960/S-010." 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 Practitioner" 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,

John K. Jenkins, M.D.
Acting Director
Division of Metabolic and
Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research