DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-673/S-067

Abbott Laboratories
Hospital Products Division
D-389, Building AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Attention: Nicohl R. Wilding
Regulatory Specialist, Hospital Products Division

Dear Ms. Wilding:

Please refer to your supplemental new drug application dated September 27, 2002, received September 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cysteine Hydrochloride Injection, USP.

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

The "Changes Being Effected" supplemental new drug application provides for a revised package insert per the requirements of 21 CFR 201.323 and revised stability protocols, which include a test for aluminum determination with the acceptance criterion of "NMT 15,000 mcg/L of aluminum."

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter.

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

If you have any questions, call Victoria Kao, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
And Addiction 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/

Bob Rappaport

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