DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-957/S-032

Fresenius Kabi Clayton, L.P.
P.O.Box 597
Clayton, N.C. 27520-0597

Attention: Janet B. Sherrod, R.A.C.
Senior Regulatory Associate

Dear Ms. Sherrod:

Please refer to your supplemental new drug application dated May 31, 1990, received June 1, 1990, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Novamine 15% Amino Acids Pharmacy Bulk Package.

We also refer to your amendments dated May 3, 1993 and February 20, 2001.

The supplement provided for the labeling for the Pharmacy Bulk Package.

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

The final printed labeling (FPL) must be identical to the submitted draft labeling dated February 20, 2001.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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 17-957/S-032." 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 Sara Stradley, Regulatory Health Project Manager, at (301) 827-7410.

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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