DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-521/S-062, S-063

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round lake, IL 60073-0490

Attention: Marcia Marconi
Vice President, regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug applications dated January 26 and February 26, 2001, received January 29 and February 27, 2001, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dextrose 10%, 20%, 30%, 40%, 50%, 60%, and 70% injection in plastic container.

Supplement S-062 is submitted to comply with the requirements of 21 CFR 201.323 regarding "Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition." This supplement has been superseded by supplement S-063; therefore, it is being retained in our files.

Supplement S-063 is submitted in response to revisions of 21 CFR 201.57 and in accordance with the information provided in the Guidance for Industry on Content and Format for Geriatric labeling.

We have completed our review of supplement S-063, 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 26, 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 17-521/S-063." 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 Ms. Lisa Marie Malandro, 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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