CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20849

APPROVAL LETTER

NDA 20-849

AUG 26 1998

Baxter Healthcare
I.V. Systems Division
Attention: Marcia Marconi
Vice President, Regulatory Affairs
Route 120 & Wilson Road
Round Lake Illinois 60073-0490

Dear Ms. Marconi:

Please refer to your new drug application (NDA) dated August 25, 1997, received August 27, 1997, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 20% ProSol™ - sulfite free (Amino Acid) Injection in PL 146® Plastic Container.

We acknowledge receipt of your submissions dated November 5 and 11, and December 19, 1997, and June 30, July 14, and August 3, 6, 10, and 11, 1998. The user fee goal date for this application is August 27, 1998.

This new drug application provides for the use of 20% ProSol™ - sulfite free (Amino Acid) Injection in PL 146® in Plastic Container:

1. As an adjunct in the offsetting of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (a) the alimentary tract cannot or should not be used, (b) gastrointestinal absorption of protein is impaired, or (c) metabolic requirements for protein are substantially increased, as with extensive burns.

2. To reduce fluid intake in patients who require both fluid restriction and total parenteral nutrition (TPN).

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

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated August 11, 1998, immediate container and carton labels dated August 11, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 20-849." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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, contact Steve McCort, Project Manager, at (301) 827-6415.

Sincerely,

/S/ 8/25/94

Sólomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL