NDA 19-445/S-004, S-006

Abbott Laboratories
Hospital Products Division
Attention: Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
D-389 Bldg. AP30
200 Abbott Park Road
ABBOTT PARK, ILLINOIS 60064-3537

Dear Dr. Willer:

Please refer to your supplemental new drug applications (S-004 and S-006) dated November 21, 1997, received November 25, 1997, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Dextrose 50% Injection in PET Abboject Vials.

For administrative purposes the change described in supplement S-005, which provided for manufacture of a new strength, 25% Dextrose in a new 10 mL Ansyr plastic syringe has been incorporated in S-004 and S-006. Supplement 005 has been canceled.

We acknowledge receipt of your submissions dated April 3 and 8, May 11, July 23, October 16, and November 18 and 19, 1998.

The user fee goal date for these applications is November 25, 1998.

These supplemental new drug applications provide for the use of a new strength of Dextrose 25% Injection in a new container, a 10 mL Ansyr plastic syringe as follows:

S-004: This supplement provides for a new sub-population - neonates and infants for approved use as a minimal source of carbohydrates and calories in this population.

S-006: This supplement provides for a new indication in the treatment of acute symptomatic episodes of hypoglycemia in the neonate and older infant to restore depressed blood glucose levels and control symptoms.

We have completed the review of these supplemental applications, 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 supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels) and submitted draft labeling (package insert submitted November 19, 1998, immediate container and carton labels submitted November 19, 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 supplements NDA 19-445/S-004, 006." 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

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, contact Steve McCort, Project Manager, at (301) 827-6415.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE
(November 19, 1998, approved draft labeling text)