



Food and Drug
Administration
Rockville MD 20857

NDA 20-593/S-006

Abbott Laboratories
Attention: Steven E. Townsend
Associate Director, PPD Regulatory Affairs
100 Abbott Park Road
D-491/AP6B-1
Abbott Park, Illinois 60064-6108

Dear Mr. Townsend:

Please refer to your supplemental new drug application dated June 30, 2000, received July 3, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Depacon® (valproate sodium injection).

We acknowledge receipt of your submissions dated July 24, 2001 and November 20, 2001. Your submission of July 25, 2001 constituted a complete response to our May 3, 2001 action letter.

This supplemental new drug application proposes an increased rate of infusion for Depacon® (valproate sodium injection).

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). We note that you have indicated your agreement with the attached labeling in an email on January 18, 2002 to Dr. Ware of this Division.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 20-593/S-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-42
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 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 Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-5533.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure