DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-081/S-044
NDA 20-593/S-015
NDA 18-082/S-027
NDA 18-723/S-033
NDA 19-680/S-022
NDA 21-168/S-014

Abbott Laboratories
Attention: Steven F. Hoff, Ph.D.
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
D-491/AP30-1NE
Abbott Park, IL 60064-6157

Dear Dr. Hoff:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	**Drug Product**	**Submitted on:**	**Received on:**	**This "Changes Being Effected" Supplement provides for:**
NDA 18-081/S-044	Depakene (valproic acid) Capsules	August 2, 2006	August 3, 2006	Changes to the label regarding usage during pregnancy and the risk of teratogenicity (**WARNINGS-Usage in Pregnancy**).
NDA 18-082/S-027	Depakene (valproic acid) Syrup			
NDA 18-723/S-033	Depakote (divalproex sodium) Delayed Release Tablets	April 18, 2005	April 19, 2005	Changes to the label regarding usage during pregnancy and the risk of teratogenicity (**WARNINGS-Usage in Pregnancy**).
NDA 19-680/S-022	Depakote (divalproex sodium) Sprinkle Capsules	August 2, 2006	August 3, 2006	Changes to the label regarding usage during pregnancy and the risk of teratogenicity (**WARNINGS-Usage in Pregnancy**).
NDA 20-593/S-015	Depacon (valproate sodium) Injection	August 2, 2006	August 3, 2006	Changes to the label regarding usage during pregnancy and the risk of teratogenicity (**WARNINGS-Usage in Pregnancy**).
NDA 21-168/S-014	Depakote ER (divalproex sodium) Extended Release Tablets	August 2, 2006	August 3, 2006	Changes to the label regarding usage during pregnancy and the risk of teratogenicity (**WARNINGS-Usage in Pregnancy**).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient information leaflet).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement** NDA 18-081/S-044, NDA 20-593/S-015, NDA 18-082/S-027, NDA 18-723/S-033, NDA 19-680/S-022, NDA 21-168/S-014." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Courtney Calder, PharmD, Regulatory Project Manager, at (301) 796-1050.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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