DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-680/S-024

Abbott Laboratories
Attention: Steven F. Hoff, R.Ph., Ph.D.
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road, PA76, Building AP-30-1E
Abbott Park, Illinois 60064-6157

Dear Dr. Hoff:

Please refer to your supplemental new drug application submitted September 24, 2007, received September 24, 2007 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Depakote (divalproex sodium) Sprinkle Capsules 125 mg.

Your supplemental NDA [19-680/S-024] provided a response to the Agency's Pediatric Written Request, dated August 9, 2002, revised May 7, 2004 and December 21, 2005, and reissued January 31, 2006.

Please also refer to your amendments to October 31, 2007, January 30, 2008, and February 20, 2008.

We have completed the review of this supplemental application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling, unless we notify you otherwise.

PREA Requirements: Phase 4 Commitments for NDA 19-680/S-024
All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

NDA 19-680/S-024 does not provide for any claims that would require further pediatric studies under PREA, nor are any other Phase 4 commitments required for this submission.

Content of Labeling: Structured Product Labeling [SPL]. As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed agreed-upon labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved sNDA labeling under 19-680/S-024".

Dear Healthcare Professional Letter. If you issue a letter communicating important information about this product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to NDA 19-680, with a copy to the following address:

MEDWATCH, HFD-410
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Reporting Requirements. 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, please call Jacqueline H. Ware, Pharm.D., Senior Regulatory Project Manager, at 301-796-1040.

Sincerely,

{See appended electronic signature page}

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

Enclosure: agreed-upon labeling.

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

3/24/2008 06:23:22 PM