DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 005856/S-021

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Abbott Laboratories
Attention: Jeremy M. McCumber
Manager, Regulatory Affairs
200 Abbott Park Rd.
PA76, AP-30-1E
Abbott Park, IL 60064-6157

Dear Mr. McCumber:

Please refer to your supplemental New Drug Application (sNDA), dated January 14, 2009, received January 15, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tridione® (trimethadione) Tablets.

We acknowledge receipt of your amendments dated February 5, and April 16, 2009, August 25, 2010, and April 21 and 25, 2011.

This "Prior Approval" supplemental new drug application provides for a comprehensive Medication Guide.

We have completed our review of this 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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as any annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

IMMEDIATE CONTAINER LABEL

Submit the final printed container label that is identical to immediate container label submitted on April 21, 2011 as soon as it is available, but no more than 30 days after it is printed.

Please submit this label electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence - Final Printed Container Label for approved NDA 005856/S-021.**" Approval of this submission by FDA is not required before the labeling is used.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

In our letter dated December 16, 2008, we notified you that a risk evaluation and mitigation strategy (REMS) was required for Tridione® (trimethadione) to ensure that the benefits of the drug outweigh the risk of suicidality. We indicated that your REMS must include a Medication Guide and timetable for submission of assessments of the REMS.

We acknowledge receipt of your proposed REMS as described in your January 14, February 5, and April 16, 2009, and August 25, 2010 submissions. The proposed REMS, as amended, contains a Medication Guide and a timetable for submission of assessments of the REMS.

We have determined that it is not necessary for the Medication Guide to be part of a REMS to ensure that the benefits of Tridione (trimethadione) outweigh its risks. We believe that the Medication Guide is necessary for patients' safe and effective use of Tridione (trimethadione), and it will be part of the approved labeling and subject to the requirements under 21 CFR 208.

PROMOTIONAL MATERIALS

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

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, call Captain Jacqueline Ware, Pharm.D., Senior Regulatory Project Manager, at (301) 796-0878.

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

Enclosures:
Content of Labeling
Carton and Container 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 G KATZ
06/06/2012