DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-864/S-011, S-016, S-017, S-018, S-019
NDA 20-865/S-012, S-016, S-018, S-020, S-021

SUPPLEMENT APPROVAL

Merck Research Laboratories
Attention: Scott L. Grossman, Ph.D.
P.O. Box 1000, UG2CD-48
North Wales, PA 19454

Dear Dr. Grossman:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received March 25, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Maxalt (rizatriptan) tablets and Maxalt-MLT(rizatriptan) orally disintegrating tablets.

We acknowledge receipt of your 2011 amendments dated May 2, May 6, May 10, June 2, July 22, September 21, and September 23.

These "Prior Approval" supplemental new drug applications propose to extend the acute treatment of migraine indication to pediatric patients from 6 through 17 years of age.

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

LABELING SUPPLEMENTS

Additionally, we have reviewed the following "Changes Being Effected" (CBE) labeling supplements, and have incorporated the changes, as applicable, in the enclosed, agreed-upon labeling text.

NDA 20-864/S-011	Proposes adding phenylalanine/aspartame statement to the Patient Package Insert (PPI), to be consistent with the Professional Insert (PI)
NDA 20-864/S-016	Proposes adding anaphylaxis/anaphylactoid reactions to the Adverse Reactions: Post-Marketing Experience section
NDA 20-864/S-017	Proposes adding "peripheral vascular ischemia" to the Adverse Reactions: Postmarketing Experience section; Proposes patient friendly language for the PPI

NDA 20-864/S-019	Proposes adding ECG abnormalities and ischemic colitis to the Adverse Reactions: Postmarketing Experience section
NDA 20-865/S-012	Proposes adding phenylalanine/aspartame statement to the PPI, to be consistent with the PI
NDA 20-865/S-016	Proposed adding anaphylaxis/anaphylactoid reactions to the Adverse Reactions: Post-Marketing Experience section
NDA 20-865/S-018	Proposes adding "peripheral vascular ischemia" to the Adverse Reactions: Postmarketing Experience section; Proposes patient friendly language for the PPI
NDA 20-865/S-021	Proposes adding ECG abnormalities and ischemic colitis to the Adverse Reactions: Postmarketing Experience section

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, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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 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, including supplement number(s) and annual report date(s).

MARKET PACKAGE

Please submit one market package of the drug product when it is available to:

Lana Chen, RPh
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 4353
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

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 that include representations about your drug product must be promptly revised to be 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 address above or by fax to 301-847-8444.

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 Lana Chen, Regulatory Project Manager, at (301) 796-1056.

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: Content of Labeling

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

/s/

LANA Y CHEN
12/16/2011

RUSSELL G KATZ
12/16/2011