



Food and Drug
Administration
Rockville MD 20857

NDA 20-864/S-008
NDA 20-865/S-009

Merck Research Laboratories
A Division of Merck & Co., Inc.
Attention: Charlene G. Sanders, M.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O. Box 4, GL A-20
West Point, PA 19486

Dear Dr. Sanders:

Please refer to your supplemental new drug applications dated May 4, 2001, received May 7, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MAXALT™ (rizatriptan benzoate) Tablets and MAXALT-MLT™ (rizatriptan benzoate) Orally Disintegrating Tablets.

These "Changes Being Effected" supplemental new drug applications provide for revisions to ADVERSE REACTION, *Post-Marketing Experience* section. Specifically, the terms "angioedema" and "wheezing" are included under a new subheading titled, "General: Hypersensitivity" and the term "Toxic Epidermal Necrolysis (TEN)" has been relocated to this section. Additionally, the Patient Package Insert (PPI) has been updated to reflect the changes to the package insert. Lastly, the company address has been revised to indicate the worldwide headquarters location of Merck & Co., Inc.

We have completed the review of these supplemental applications. They are approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 4, 2001.

If a letter communicating important information about these drug products (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 these NDAs 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.

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If you have questions, call Lana Y. Chen, R.Ph., Regulatory Management Officer, at (301) 594-5529.

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

**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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