Merck & Co., Inc.
P.O. Box 4, BLA-20
Attention: Dennis Erb, Ph.D.
Director, Regulatory Affairs
West Point, PA 19486

Dear Dr. Erb:

Please refer to your supplemental new drug applications dated January 18, 1999 and November 5, 1999, received January 19, 1999 and November 8, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Maxalt (rizatriptan) 5 and 10 mg, .

We acknowledge receipt of your submission dated May 11, 1999.

These supplemental new drug applications provide for changes to the Maxalt-MLT subsection of the Clinical Studies section of labeling in the use of Maxalt (rizatriptan) 5 and 10 mg for acute treatment of migraine.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in your submitted draft labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 18, 1999, patient package insert submitted January 18, 1999).

Additionally, the labeling submitted on January 18, 1999 and November 5, 1999 supercedes the following submissions, since it incorporates the labeling changes made to these supplemental applications. Therefore, we will not review these submissions but they will be retained in our files.

Date Submitted	NDA	Description
July 17, 1998	20-864 20-865	Final Printed Labeling for NDAs 20-864 and 20-865
January 8, 1999	20-864/S-001	Pregnancy registry, deletion of 500 count bottle, minor editorial changes
June 23, 1999	20-865	MLT trademark for blister,

		sachet and plastic carrying case

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 20-865/S-001, 20-864/S-003." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA 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.

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

Sincerely,

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