DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-864
NDA 20-865

JUN 29 1998

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 new drug applications dated June 30, 1997, received June 30, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Maxalt (rizatriptan benzoate) tablet and RPD 5 mg and 10 mg.

We acknowledge receipt of your submissions to NDA 20-864 dated:

June 30, 1997	October 31, 1997	February 11, 1998	May 14, 1998
July 9, 1997	November 4, 1997	March 5, 1998	May 29, 1998
July 15, 1997	November 13, 1997	March 9, 1998	June 1, 1998
July 16, 1997	November 26, 1997	March 13, 1998	June 4, 1998
July 21, 1997	December 15, 1997	March 27, 1998	June 8, 1998
August 20, 1997	December 23, 1997	April 2, 1998	June 15, 1998
September 11, 1997	December 26, 1997	April 6, 1998 (2)	June 19, 1998
October 1, 1997	December 29, 1997	April 24, 1998.	June 24, 1998 (2)
October 16, 1997	February 2, 1998	April 27, 1998	June 25, 1998
October 30, 1997 (2)			

We also acknowledge receipt of your submissions to NDA 20-865 dated:

June 30, 1997	October 30, 1997 (2)	March 27, 1998	June 1, 1998
July 9, 1997	November 13, 1997	April 2, 1998 (2)	June 4, 1998
July 15, 1997	December 26, 1997	April 6, 1998 (2)	June 8, 1998
July 16, 1997	December 29, 1997	April 24, 1998	June 9, 1998
August 20, 1997	February 11, 1998	May 13, 1998	June 15, 1998
September 11, 1997	March 5, 1998	May 14, 1998	June 24, 1998 (2)
October 1, 1997	March 6, 1998	May 21, 1998	June 25, 1998
October 16, 1997	March 13, 1998	May 29, 1998	

The User Fee goal date for these applications is June 30, 1998.

These new drug applications provide for the acute treatment of migraine headache.

We have completed the review of these applications, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug

products are safe and effective for use as recommended in the enclosed marked-up draft labeling. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the products with FPL that is not identical to this draft labeling may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDAs 20-864, 20-865. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drugs become available, revision of that labeling may be required.

We remind you of your Phase 4 commitment specified in your June 25, 1998 submission to do

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1998, we request that you submit the protocol for our concurrence prior to initiation of the study.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of the commitment. The status summary should include the expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to this Phase 4 commitment must be clearly designated "Phase 4 Commitment."

In addition, please submit three copies of the introductory promotional material that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional material and

the package inserts directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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

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, please contact Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely yours,

/S/

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE