



NDA 19-510/S-028
NDA 20-249/S-011

Merck and Co., Inc.
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
c/o Merck Research Laboratories (BLA-20)
Sumneytown Pike, P.O. Box 4
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug applications dated August 28, 2000, received August 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 19-510/S-028: Pepcid™ Injection (famotidine)
NDA 20-249/S-011: Pepcid™ Injection Premixed (famotidine)

We acknowledge receipt of your submissions dated July, 02; and August 10, 2001. Your submission of August 10, 2001 constituted a complete response to our June 28, 2001 action letter.

These supplemental new drug applications for Pepcid™ provide for changes to the following sections of the currently approved labeling: CLINICAL PHARMACOLOGY IN PEDIATRIC PATIENTS, PRECAUTIONS, DOSAGE AND ADMINISTRATION, and ADVERSE REACTIONS. These applications include study reports in support of a six-month extension to patent protection based upon pediatric exclusivity as well as information regarding the bioavailability of the famotidine oral formulations used in the studies and information concerning the safety of famotidine use in infants.

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 the submitted final printed labeling (package insert submitted August 10, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We note that you have fulfilled the pediatric study requirement at this time.

In addition, please submit three copies of the introductory promotional materials 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 this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (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 this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Paul E. Levine, Jr., R.Ph., Regulatory Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal
and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Attachment:

**This is a representation of an electronic record that was signed electronically and
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/s/

Victor Raczkowski
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