DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-096/S-030
NDA 16-097/S-024

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

Dear Dr. Erb:

Please refer to your supplemental new drug applications dated April 3, 1998 and received on April 7, 1998 which were submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mintezole® (thiabendazole) chewable tablets and suspension.

These "Changes Being Effected" supplemental new drug applications provide for changes to the WARNINGS and ADVERSE REACTIONS sections based on WAES reports (Worldwide Adverse Experience Systems database at Merck). "Sicca syndrome" and "abdominal pain" have been added.

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 April 3, 1998 and received April 7, 1998. Accordingly, these supplemental applications are approved effective on the date of this letter.

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

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 Valerie Jensen, R.Ph., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
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/

Mark Goldberger
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