



NDA 16-096/S-033

NDA 16-097/S-026

Merck & Co., Inc.
Attn: Virginia G. Snyder
Manager, Regulatory Affairs
BLA-20
P.O. Box 4
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug applications, dated August 14, 2002, received August 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MINTEZOL™ (thiabendazole) Chewable Tablets, NDA 16-096/S-033, and MINTEZOL™ (thiabendazole) Oral Suspension, NDA 16-097/S-026.

We acknowledge the receipt of your submissions dated September 25, 2002.

These supplemental new drug applications provide for the addition of a new *Geriatric Use* subsection at the end of the **PRECAUTIONS** section of the package insert in accordance with the August 27, 1997 final rule and 21 CFR 201.57(f)(10).

The changes were as follows. Added text is double underlined.

Geriatric Use

Clinical studies of MINTEZOL did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is metabolized almost completely by the liver, and the metabolites are known to be substantially excreted by the kidney, therefore the risk of toxicity may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted September 25, 2002).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper 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 heavyweight paper or similar material. For administrative purposes, these submissions should be designated “FPL for approved supplement NDA 16-096/S-033 and NDA 16-097/S-026.” Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to each 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Christine Lincoln, RN, MS, MBA, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
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
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/s/

Renata Albrecht
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