DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-742/S-011

Attention: Brenda A. Maguire, M.S., R.N.
Associate Director, Regulatory Affairs
Merck Research Laboratories
Sumneytown Pike
P.O. Box 4, BLX-29
West Point, PA 19486

Dear Ms. Maguire:

Please refer to your supplemental new drug application dated October 22, 2002, received October 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Stromectal™ (ivermectin) Tablets, 3 mg, 6 mg.

This "Changes Being Effected (CBE)" supplemental new drug application provides for the following changes to the Stromectal™ package insert. Added text is noted by double underline:

PRECAUTIONS

· In the second paragraph of the **General** subsection, the following sentence was added and is now the second sentence in this paragraph:

> In these patients, the following adverse experiences have also been reported: back pain, conjunctival hemorrhage, dyspnea, urinary and/or fecal incontinence, difficulty in standing, mental status changes, confusion, lethargy, stupor, or coma.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted on October 22, 2002. Accordingly, this supplemental application is approved effective on the date of this letter.

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, call Robin Anderson, 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 this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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