DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-742/S-022

Merck & Co., Inc.
Attention: Peter Kusma
Manager, Regulatory Affairs
PO Box 1000, UG2CD-48
North Wales, PA 19454-1099

Dear Mr. Kusma:

Please refer to your supplemental new drug application dated and received on March 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for STROMECTOL™ (ivermectin) 3 mg Tablet.

This application is subject to the exemptions provisions contained in section 125 (d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated April 18, July 7, and September 12, 2008.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the package insert (underlined = added text):

1. In the **PRECAUTIONS** section, the following sections have been revised:

    a. *Information for Patients* subsection located in the last paragraph of the **PRECAUTIONS** section has been relocated to follow the **PRECAUTIONS**/*General* subsection:

    Information for Patients
    STROMECTOL should be taken on an empty stomach with water. (See CLINICAL PHARMACOLOGY, *Pharmacokinetics*.)
    Strongyloidiasis: The patient should be reminded of the need for repeated stool examinations to document clearance of infection with *Strongyloides stercoralis*.
    Onchocerciasis: The patient should be reminded that treatment with STROMECTOL does not kill the adult *Onchocerca* parasites, and therefore repeated follow-up and retreatment is usually required.

    b. A new subsection labeled *Drug Interactions* was added following the *Information for Patients* subsection as follows:

    Drug Interactions
    Post-marketing reports of increased INR (International Normalized Ratio) have been rarely reported when ivermectin was co-administered with warfarin.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on September 12, 2008.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20852

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 Hyun Son, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

9/12/2008 12:43:05 PM