DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-742/S-024
NDA 50-742/S-025

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

Dear Mr. Kusma:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Stromectol™ (ivermectin), Tablets 3 mg as follows:

Supplement number	Submission date	Receipt date
NDA 50-742/S-024	November 14, 2008	November 14, 2008
NDA 50-742/S-025	February 23, 2009	February 25, 2009

We acknowledge receipt of your submissions dated December 17, 2008 and April 22, 2009 for NDA 50-742/S-024 and April 1, 2009 for NDA 50-742/S-025. Your submissions dated April 1, 2009 contained the final printed labeling for both supplements S-024 and S-025.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the formatting of the **ADVERSE REACTIONS/Post-Marketing experience** subsection of the package insert and addition of *Onchocerciasis*/conjunctival hemorrhage (S-024) and addition of hepatitis (S-025) to the same subsection of the package insert as follows (underlined text = addition, ~~strikethrough~~ text = deletion):

The **ADVERSE REACTIONS/Post-Marketing experience** subsection is revised as follows:

Post-Marketing Experience
The following adverse reactions have been reported since the drug was registered overseas:
Onchocerciasis
Conjunctival hemorrhage

~~*Post-Marketing Experience for*~~*All Indications*
~~The following adverse reactions have been reported since the drug was registered overseas~~:H~~h~~ypotension (mainly orthostatic hypotension), worsening of bronchial asthma, toxic epidermal necrolysis, Stevens-Johnson syndrome, seizures, hepatitis, elevation of liver enzymes, and elevation of bilirubin.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text for the package insert submitted on April 1, 2009.

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 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 Judit Milstein, Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Deputy Director for Safety
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/

Ozlem Belen

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