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APPLICATION NUMBER:

50-742 / S-001

APPROVABLE LETTER

NDA 50-742/S-001

DIV
JUN 15 1998

Merck & Co., Inc.
Attention: Kenneth R. Brown, M.D.
Sumneytown Pike, P.O. Box 4
BLA-14B
West Point, PA 19468

Dear Dr. Brown:

Please refer to your supplemental new drug application dated December 12, 1997, received December 15, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Stromectol® (Ivermectin) Tablets, 6 mg.

We acknowledge receipt of your submission dated December 12, 1997. The user fee goal date is June 15, 1998.

The supplemental application provides for a new tablet strength (3 mg.)

We have completed the review of this supplemental application and it is approvable. Before this supplement may be approved, however, it will be necessary for you to:

1. Please provide comparative dissolution data comparing the dissolution profiles of contemporaneous batches of 3-mg and 6-mg tablets.
2. Please provide all available room temperature and accelerated stability data for lots HE36950, HE36960, and HE37080.
3. Please revise the testing schedule for annual post-approval stability batches to 0, 3, 6, 9, 12, 18, and 24 months. A reduced testing schedule may be requested in a supplemental application when data to support it is obtained from stability studies of production batches.
4. Please explain the information on page 165 that appears to indicate that batch _____ was manufactured with sufficient ivermectin for each tablet to contain _____ of the drug substance, which would appear to be nearly _____ excess.
5. Please clarify what units are used to measure tablet hardness.

Within 10 days after the date of this letter, you are required to amend this supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw this supplemental application.

This change may not be implemented until you have been notified in writing that this supplemental application is approved.

If you have any questions, please contact Mary Dempsey, Project Manager, at (301) 827-2127.

Sincerely yours,



Norman Schmidt, Ph.D.
Chemistry Team Leader, DNDC III
Division of Special Pathogen and Immunologic
Drug Products (HFD-590)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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APPROVABLE (AE)

**APPEARS THIS WAY
ON ORIGINAL**