Exhibit 14

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE for:

APPLICATION NUMBER: 050742

TRADE NAME: Mectizan

GENERIC NAME: Ivermectin

SPONSOR: Merck Research Laboratories

APPROVAL DATE: 11/22/96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-742

Kenneth R. Brown, M.D.
Exetutive Director
Worldwide Regulatory Liaison
Biologics/Vaccines
Merck & Co., Inc
West Point, PA 19486-0004

NOV 22 1996

Dear Dr. Brown:

Reference is made to your March 29, 1996 new drug application (NDA) and your resubmission dated October 15, 1996, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act for Tablet STROMECTOL® (ivermectin) 6-mg.

We acknowledge receipt of your amendments dated April 16, June 28, July 9, 16, 22, and 31, August 23, and 28, and October 4, 1996.

This new drug application provides for the treatment of strongyloidiasis and onchocerciasis.

We have completed the review of this application, including the submitted draft labeling, 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 enclosed draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen 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 heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 50-742. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Anti-Infective Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug when it is available.

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, please contact:

Ms. Pauline Fogarty
Regulatory Health Project Manager
(301) 827-2125

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE