CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-742 / S-001

ADMINISTRATIVE AND CORRESPONDENCE DOCUMENTS

NDA 50-742/Final Printed Labeling

Labeling and Clinical Review of Final Printed Labeling:

Sponsor: Merck Research Laboratories

Product: Stromectol ™ (Ivermectin) 3 mg tablets (New Formulation)

Background:
NDA 50-742 (Stromectol ™ Tablets) 6 mg was originally approved for the treatment of strongyloidiasis of the intestinal tract and onchocerciasis on November 22, 1996. No labeling changes have been approved since the original approval date. On December 15, 1997, FDA received SLR 001 for NDA 50-742. The supplemental labeling revision provided for a new 3 mg tablet formulation. The supplement was amended once during the course of the review with the submission received on June 24, 1998. The supplement was approved on October 8, 1998.

Review of Submissions:
The final printed labeling for NDA 50-742/S-001 dated, June 2, 1999, received June 8, 1999 was compared to the proposed draft labeling submitted December 12, 1997, received December 15, 1997, and approved on October 8, 1998.

Conclusions/Recommendations:
The final printed labeling dated June 2, 1999, received June 8, 1999 is identical to the proposed draft labeling submitted December 12, 1997, received December 15, 1997 and approved on October 8, 1998.. An Acknowledge and Retain letter should be drafted and forwarded to the sponsor.

Lisa M. Hubbard, R.Ph.
Senior Regulatory Management Officer,
HFD-590

Andrea Meyerhoff, M.D.
Medical Officer
HFD-590

cc:
NDAs 50-742
HFD-590/Division file
HFD-590/ActingDivDir/R. Albrecht
HFD-590/MedTL/R. Roca
HFD-590/MO/A. Meyerhoff
HFD-590/PM/V. Jensen

Concurrence:

HFD-590/ActingDivDir/R. Albrecht
HFD-590/MedTL/R. Roca

DFS keywords:
admin review
class, other
indic, other

/s/

Lisa Hubbard
9/15/00 12:24:35 PM
CSO

THIS IS A REVIEW REVISED AT RENATA'S SUGGESTION. pLEASE REVIEW AND SI
GN

Andrea Meyerhoff
1/24/01 09:43:24 AM
MEDICAL OFFICER

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Merck & Co., Inc.
West Point, PA 19486

ORIGINAL

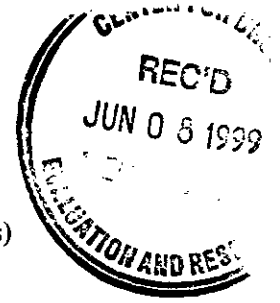
SCF-001/FA

June 2, 1999

MERCK
Research Laboratories

Mark Goldberger, MD, Director
Division of Special Pathogens and
Immunologic Drug Products, HFD-590, Rm. S-444
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

NDA SUPPL AMEND



NDA 50-742/S-001: STROMECTOL™ (Ivermectin Tablets)
FINAL PRINTED LABELING

Dear Dr. Goldberger:

Reference is made to the Supplemental New Drug Application 50-742/S-001 for STROMECTOL™ submitted on December 12, 1997. Reference is also made to your approval letter dated October 8, 1998 regarding this supplemental application.

Attached for submission are the following:

1. A summary of revisions
2. An annotated circular, illustrating the revisions
3. Printed package circular #9032301 (20 copies)
4. Printed aluminum foil pouches (20 copies)
5. Printed carton (20 copies)

The circular has been revised to include the 3 mg tablet. The revised label will be used in all products sold or distributed on or before September 1, 1999.

Questions concerning this supplemental application should be directed to Frank Ricci (610/397-2975) or, in my absence, to Edwin Hemwall, Ph.D. (610/397-2306).

Sincerely,

Frank Ricci
Merck Research Laboratories
Division of Merck & Co., Inc.
Sumneytown Pike
West Point, PA 19486

q:graz/amy/SNDA3

Attachments
Certified No. P 971 230 003

NDA# 50-742

STROMECTOL®
(Ivermectin)

SUMMARY OF REVISIONS

The circular for STROMECTOL® has been revised as follows, to include the 3 mg tablet:

DESCRIPTION

Second paragraph: The availability of the 3 mg tablet is added.

DOSAGE AND ADMINISTRATION

Since the 3 mg tablet is an exact submultiple of the 6 mg tablet, the dosage is twice that of the 6 mg tablet. The dosage recommendations for the 3 mg tablet have been included under Tables 1 and 2.

HOW SUPPLIED

The availability of the 3 mg tablets in packages of 20 has been added.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-742/S-001

SEP 29 2000

Merck Research Laboratories
Attention: Frank Ricci
Sumney Pike, P.O. Box 4
BLA-33
West Point, PA 19486

Dear Mr. Ricci:

We acknowledge the receipt of your June 2, 1999 submission containing final printed labeling in response to our October 8, 1998 letter approving your supplemental new drug application (NDA) for Stromectol® (ivermectin) tablets, 3 mg and 6 mg.

We have reviewed the labeling that you submitted in accordance with our October 8, 1998 letter, and we find it acceptable.

If you have any questions, call Lisa M. Hubbard, R.Ph., Senior Regulatory Project Manager, at (301) 827-2127.

Sincerely,

S 9/29/00

Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

05074Z_5001