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*APPLICATION NUMBER:*

**50-742 / S-001**

**APPROVAL LETTER**

NDA 50-742/S-001

OCT 8 1998

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

866L 8 130

Dear Mr. Ricci:

Reference is made to your supplemental New Drug Application dated December 12, 1997, submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for Stromectol® (Ivermectin) Tablets, 6 mg. Reference is also made to your amendment dated October 7, 1998.

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

We have completed the review of this supplemental application, as amended, and it is approved, effective on the date of this letter.

We remind you that you must comply with requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours, */S/*

Norman Schmuff, 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

**Distribution:**

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**APPEARS THIS WAY  
ON ORIGINAL**