DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-853

Merck & Co., Inc.
Attention: Kenneth A. Kramer
Associate Manager
Regulatory Affairs-Domestic
BLA-20, P.O. Box 4
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated May 5, 2003, received May 6, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cuprimine (penicillamine) Capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for addition of hepatic failure, renal failure, vasculitis and yellow nail syndrome to **ADVERSE REACTIONS** section of the labeling.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 5, 2003.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Barbara Gould, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lee Simon
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