DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-853/S-007, 011

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

Dear Mr. Kramer:

Please refer to your supplemental new drug applications dated September 11, 1992 and August 25, 1999, received September 14, 1992 and August 25, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cuprimine (penicillamine capsules) 125 mg, 250 mg.

We acknowledge receipt of your submissions dated October 17, 2003. Your submission of October 17, 2003 constituted a complete response to our May 12, 2003 action letter.

Supplemental new drug application S-007 provides for a new subsection to the **CLINICAL PHARMACOLOGY** section and updated the **INDICATIONS** and **WARNINGS** sections of the label and S-011 provides for editorial changes to the **INDICATIONS, WARNINGS and ADVERSE REACTIONS** sections of the label.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-853/S-007, S-011" Approval of these submissions by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Barbara Gould, Regulatory Project Manager, at (301) 827-2506.

Sincerely,

{See appended electronic signature page}

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

Enclosure