DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-664/S-062

Merck & Co., Inc.
Attention: Kenneth A. Kramer
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 August 26, 2003, received August 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Decadron (dexamethasone) Tablets.

This supplemental new drug application provides for revisions to the **PRECAUTIONS** section of the labeling.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the submitted labeling with the minor editorial revision listed below:

Under **PRECAUTIONS, Drug Interactions**, *Hepatic Enzyme Inducers* subsection, "Co-administration" is misspelled.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted August 26 2003). These revisions are terms of the approval of this application.

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, this submission should be designated "FPL for approved supplement NDA 11-664/S-062." Approval of this submission 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 Stacey Welch, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V

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

/s/

Sharon Hertz

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