DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 14-215/S-009, S-015

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Yvette Henderson
Regulatory Affairs Manager
Global Regulatory Affairs

Dear Ms. Henderson:

Please refer to your supplemental new drug applications dated December 22, 1987 (S-009) and January 2, 1996 (S-015), received December 28, 1987 (S-009) and January 4, 1996 (S-015), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celestone (betamethasone) Syrup.

We acknowledge receipt of your submission dated April 22, 2004, which constituted a complete response to our February 16, 2001, action letter.

These "Changes Being Effected" supplemental new drug applications provide for addition of inactive ingredients to the **DESCRIPTION** section (S-009), and a statement regarding use of corticosteroids in patients with known or suspected *strongyloides* (threadwarm) infestation (S-015) to the **WARNINGS** section of the package insert.

We have completed our review of these applications, as amended, and they 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 agreed upon in your email dated June 28, 2006.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 14-215/S-009, S-015**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Parinda Jani, Chief, Project Management Staff, at (301) 796-2280.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure