DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-561/S-013

Schering Corporation
Attention: Mary Jane Nehring
Sr. Director, Marketed Products Support
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated December 15, 1995, received December 21, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celestone Phosphate (betamethasone sodium phosphate, USP) Injection, 4.0 mg/mL.

We acknowledge receipt of your submission dated June 10, 2003 received June 11, 2003.

Your submission of June 10, 2003 constituted a complete response to our February 16, 2001 action letter.

This "Changes Being Effected" supplemental new drug application provide for the addition of the strongyloides statement in the WARNINGS section of the label. In the Approvable letter of February 16, 2001, for NDA 17-561/S-013, the Agency requested the Sponsor to submit these additional labeling changes.

We completed our review of this application, as amended. NDA 17-561/S-013 is Approved, with labeling changes as proposed by the Sponsor, except the changes related to storage conditions. FDA recommendation:

Store at 20^0- 25^0C (68^0- 77^0 F); excursions ~~are~~ permitted to 15^0- 30^0C (59^0- 86^0 F)

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-561/S-013." 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, HF-2
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) 827-2504.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesics, &
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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