DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 14-602/S-047

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Meni Melek, PhD
Director and Liaison, Global Regulatory Affairs

Dear Dr. Melek:

Please refer to your supplemental new drug application dated July 10, 2007, received July 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celestone® Soluspan® (betamethasone sodium phosphate and betamethasone acetate) Injectable Suspension.

We also acknowledge receipt of your submission dated March 14, 2008.

This supplemental new drug application provides for a revised WARNINGS section of the package insert. A new warning regarding the use of high doses of corticosteroids to treat patients with traumatic brain injury and an increase in early and late mortality was added.

We have completed our review of this application, as amended, and it is 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 and the patient package insert.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "**FPL for approved supplement NDA 14-602/S-047**." 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Sharon Turner-Rinehardt, Regulatory Health Project Manager, at (301) 796-2254.

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

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

/s/

Bob Rappaport

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