DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 40-620

RECEIVED

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REGULATORY AFFAIRS

OCT 2 7 2006

SICOR Pharmaceuticals, Inc.
Attention: Rosalie Lowe
Director, Regulatory Affairs
19 Hughes
Irvine, CA 92618

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 26, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Methylprednisolone Acetate Injectable Suspension USP, 40 mg/mL (5 mL and 10 mL multiple-dose vials), and 80 mg/mL (5 mL multiple-dose vials).

Reference is also made to your amendments dated January 17, January 20, April 21, August 4, August 19, November 28, and December 22, 2005; and January 5, and April 12, 2006.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Methylprednisolone Acetate Injectable Suspension USP, 40 mg/mL and 80 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Depo-Medrol Injectable Suspension, 40 mg/mL and 80 mg/mL, respectively, of Pharmacia & Upjohn Co. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

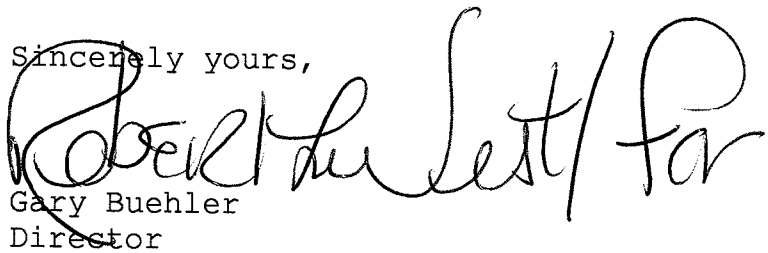
Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 40-620



# *OFFICE OF GENERIC DRUGS*

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-827-9274

## FAX TRANSMISSION COVER SHEET

DATE: 10/27/06

TO: APPLICANT: Scor Pharmaceuticals TEL: 949-455-4767

ATTN: Rosalie Lowe FAX: 949-583-7351

FROM: Lisa Kwok PROJECT MANAGER: 301-827-5739

TOTAL NUMBER OF PAGES : 2
(EXCLUDING COVER SHEET)

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Congratulations!

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OCT 27 2006

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