CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-250

APPROVAL LETTERS

ANDA 75-250

JUL 12 2002

WE Pharmaceuticals, Inc.
Attention: Craig H. Wheeler
P.O. Box 1142
1142 D Street
Ramona, CA 92065

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 10, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Prednisolone Sodium Phosphate Oral Solution, 15 mg (base)/5 mL.

Reference is also made to the Tentative Approval letter issued by this Office on January 17, 2002, and to your amendment dated February 25, 2002.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Prednisolone Sodium Phosphate Oral Solution, 15 mg (base)/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Orapred Oral Solution, 15 mg (base)/5 mL, of Ascent Pediatrics Inc.).

The approvals of your ANDA and the ANDA for the listed drug product are based upon a suitability petition (87-P-237/CP1) approved by the agency to permit a change to the original listed drug, Celltech Pharmaceuticals, USA's Pediapred (NDA 19-157). Although the Agency considers Ascent's Orapred to be the reference listed drug for bioequivalence purposes, this did not obviate the need for WE Pharmaceuticals, Inc. (WE) to provide a patent certification and notification to the holder of the original listed drug upon which the approved suitability petition was based, Celltech. Celltech is subject to patent protection for Pediapred that expires on December 22, 2002 (U.S. Patent No. 4,448,774, the '774 patent).

Your application contains a "Paragraph IV Certification" under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Prednisolone Phosphate Oral Solution 15 mg (base)/5 mL will not infringe upon the '774 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against WE for infringement of the '774 patent. This action must be brought against WE prior to the expiration of forty-five (45) days from the date the notice provided by WE under paragraph (2)(B)(I) was received. You have notified FDA that WE has complied with the requirements of Section 505(j)(2)(B) of the Act and that a lawsuit was filed by Celltech in the United States District Court for the Southern District of California involving your challenge to the '774 patent (Celltech Manufacturing, Inc. and Celltech Pharmaceuticals Inc., v. WE Pharmaceuticals, Inc., Civil Action No. 02CV0107 IEG (CGA)). In your February 25, 2002 amendment, you notified the agency that Celltech Pharmaceuticals, USA and WE Pharmaceuticals, Inc. entered into a Settlement and License Agreement granting WE a non-exclusive license to make, use, offer to sell, or sell any product containing the formulation set in WE's ANDA 75-250 relating to the Prednisolone Sodium Phosphate Oral Solution for the 15 mg (base)/5 mL strength. You also notified the agency that the parties settled the patent infringement lawsuit, and that the litigation was dismissed by the court on February 20, 2002.

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

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) 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

7/12/02

APPEARS THIS WAY
ON ORIGINAL

cc: ANDA 75-250
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205

Robert West 7/12/2002

Endorsements:
HFD-623/U.Atwal/ 7/9/02
HFD-623/D.Gill/ DSGill 7-10-02
HFD-617/S.Kim/ S Kim 7/10/02
HFD-613/D.Catterson/ Debra M. Catterson 7/10/02
HFD-613/J.Grace/ 7/11/2002

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F/T by:

7/11/02

APPROVAL

ANDA 75-250

JAN 4 2002

WE Pharmaceuticals, Inc.
Attention: Craig H. Wheeler
P.O. Box 1142
1142 "D" Street
Ramona, CA 92065

Dear Sir:

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Reference is also made to your amendments dated July 31, September 10, October 19, October 26, and November 16, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Prednisolone Sodium Phosphate Oral Solution, 15 mg (base)/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Orapred® Oral Solution, 15 mg (base)/5 mL, of Ascent Pediatrics Inc.).

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and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler 1/4/02
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-250
Division File
Field Copy
HFD-610/R. West
HFD-210/B. Poole
HFD-330
HFD-205

Endorsements:
HFD-623/U.Atwal/ U Atwal 01/02/02
HFD-623/D.Gill/ D. Gill 01/02/02
HFD-617/R.Wu/ RWu 1/2/02
HFD-613/D.Catterson/ Debra M. Catterson 1/2/02
HFD-613/J.Grace/ 1/3/2002

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F/T by: DJ 12/26/01

DS Gill
for Dr. Pater
1-3-02

APPROVAL

Robert L. West
1/4/2002