CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-250

TENTATIVE APPROVAL LETTER(S)

ANDA 75-250

WE Pharmaceuticals, Inc.
Attention: Craig H. Wheeler
P.O. Box 1142
1142 "D" Street
Ramona, CA 92605

JAN 17 2002

Sent by Facsimile and U.S. Mail

Dear Mr. Wheeler:

This is in reference to your abbreviated new drug application (ANDA) dated November 10, 1997, for Prednisolone Sodium Phosphate Oral Solution, 15 mg (base)/5 mL, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act). This letter is to inform you that, in light of the patent certification requirements of the Act, which were not complied with in the approval of ANDA 75-250, the January 4, 2002, final approval of your ANDA is hereby rescinded.

The ANDA submitted by WE Pharmaceuticals, Inc. (WE) does not meet the statutory requirements for approval, and did not do so at the time it was mistakenly approved by FDA. The mistake arose from the status of the WE ANDA as a subsequent ANDA to that approved for Ascent Pharmaceuticals Orapred (ANDA 75-117). Both your ANDA and the Ascent ANDA are for drug products for which a suitability petition was approved for a change to a listed drug (87P-0237/CP1). The listed drug referenced in the approved suitability petition is Celltech Pharmaceuticals, USA's (Celltech) Pediapred (NDA 19-157). The listed drug product referenced in ANDA 75-250, by recent amendment, was Ascent's Orapred, which has no listed patent protection. Pediapred is subject to patent protection that expires on December 22, 2002: U.S. Patent No. 4,448,774 (the '774 patent).

Although the Agency considers Ascent's Orapred to be the reference listed drug for bioequivalence purposes, this does not obviate the need for WE to provide a patent certification and notification to the holder of the original listed drug upon which the approved suitability petition was based. In fact, your application contains a paragraph IV patent certification that the manufacture, use, or sale of the Prednisolone Phosphate Oral Solution 15 mg (base)/mL will not infringe on the '774 patent. Moreover, WE notified Celltech of its paragraph IV certification to the '774 patent by letter of November 29, 2001. This notice was received by Celltech on December 5, 2001.

The Agency notes that FDA approval of ANDA 75-250 may not be made effective before the 45-day period from the date of notification. Section 505(j)(5)(B)(iii). During this 45-day period, a patent owner or NDA holder may bring a suit for patent infringement. The 45-day period is due to expire on January 21, 2002. If the NDA holder or patent owner brings a patent infringement suit against WE, approval may not be made effective until entry of a final judgment of the court that all of the asserted claims of the '774 patent are either invalid, unenforceable or not infringed by the WE drug product; the expiration of the '774 patent including any extensions; or 30 months after the patent notification, whichever comes first. 21 CFR 314.107.

The Agency notes that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time, i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug products, and is subject to change on the basis of new information that may come to our attention. Final approval cannot be granted earlier than the date of a court decision finding the patents invalid, not infringed or unenforceable, or the expiration date of the patent.

Because the Agency is granting a **tentative approval** for this application, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency whether circumstances have or have not arisen that may affect the effective date of final approval. To reactivate your application, please submit an amendment at least 60 days (but not more than 90 days) prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. Please note that this amendment should be submitted even if none of these changes were made. The amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above. Any changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery or introduction into interstate commerce of this drug before the effective final approval date is prohibited under Section 301(d) of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book").

Please contact Cecelia Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs at (301) 827-5845, for further information regarding this issue.

Sincerely yours,

Gary Buehler

Gary J. Buehler 1/17/02
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-250

cc: ANDA 75-250
Division File
Field Copy
Elizabeth Dickinson, GCF-1
HFD-600/C. Parise
HFD-610/P. Rickman 1/17/02
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HFD-630/P.Beers Block
HFD-210/B. Pool
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Drafted by: C. Parise, 1/16/02
Revised by: L. Dickinson 1/17/01