



OCT 06 2004

The Weinberg Group, Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth Street, N.W.
Suite 300
Washington D.C. 20036-2400

Docket No. 2002P-0444/CP1

Dear Dr. Fleischer:

This letter is in reference to your ANDA suitability petition filed on October 11, 2002. Your ANDA suitability petition requests a change in dosage form for Cefpodoxime Proxetil from granules for oral suspension to tablets for oral suspension. Your petition is currently under review.

As you know, on December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. In addition, changes in dosage form are also evaluated by the Office of New Drugs to determine whether safety and effectiveness studies are required that would preclude the approval of your petition. If the change proposed in an ANDA suitability petition does not qualify for a full waiver of the pediatric studies, or if it is determined that clinical studies are needed to support the safety and effectiveness of the change, that petition will be denied because clinical studies are required to demonstrate the safety and effectiveness of the change (Section 505(j)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act).

The safety and effectiveness issues along with the waiver request must be evaluated as part of the petition process. The outcome of these evaluations among other considerations will determine whether the petition may be approved.

You will be notified in writing when the review of your petition is complete.

A copy of this letter will be placed on public display in the Dockets Management Branch.

Sincerely yours,

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

02P-0444

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