DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

0154 5 OCT 11 A9:50

OCT - 6 2005

Lupin Pharmaceuticals, Inc.
Attention: Vinita Gupta
Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Docket No. 2004P-0263/CP1

Dear Ms. Gupta:

This is in response to your petition filed on June 14, 2004, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Cefixime Chewable Tablets, 100 mg, 150 mg and 200 mg. The reference listed drug to which you refer in your petition is Suprax® (Cefixime) for Oral Suspension, 100 mg/5 mL, approved under ANDA 65-129 held by Lupin.

Your request involves a change in dosage form (i.e., from oral suspension to chewable tablets) and a change in strength (i.e., from 100 mg/5 mL to 150 mg and 200 mg) from that of the listed drug product. The changes you request are the types of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j) (2) (C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug products.

In addition, this petition and your waiver request were evaluated with respect to the "Pediatric Research Equity Act of 2003" (PREA). 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. Your pending ANDA suitability petition is affected by this Act because it is a petition for a change in dosage form. The FDA has determined that your proposed change in dosage form is subject to PREA, but has concluded that the requirements for PREA have already been met.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a change in dosage form and/or strength that differs from the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form and/or strength.

2004P-0263

PAV 1

The FDA finds that the change in dosage form and strength for the specific proposed drug products does not pose questions of safety or effectiveness because the uses and route of administration are the same as that of the reference listed drug product, and the proposed 100 mg, 150 mg and 200 mg chewable tablets are specific doses that are included in the approved labeling of the reference listed drug product. The FDA concludes, therefore, that clinical investigations are not necessary to show safety or effectiveness in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j) (2) (A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j) (2) (A) (iv) of the Act. We suggest that you submit your protocol for these drug products to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the same drug product upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

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