Lupin Pharmaceuticals, Inc.

0484 6 JUN 22 A8:42

June 21, 2006

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR 10.30, as provided for in 21 CFR 314.93 and Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product Cefdinir Chewable Tablets, 187.5 mg, 250 mg and 300 mg are suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petition is submitted for changes in dosage form and strength [from "powder for oral suspension, 125 mg/5 mL and 250 mg/5 mL" to "Chewable Tablets, 187.5 mg, 250 mg and 300 mg"] from that of the reference listed drug product, Omnicef® (cefdinir) for Oral Suspension, 250 mg/5 mL manufactured by Abbott Laboratories. Cefdinir Chewable Tablets will be marketed in dosage strengths of 187.5 mg, 250 mg and 300 mg. The 250 mg tablets will be scored while 187.5 mg and 300 mg tablets would be unscored. The drug, the route of administration and the dosage regimen for use, apart from differences explained under "statement of grounds" following, are the same as the reference listed drug product.

B. Statement of Grounds

The recommended total daily dose of Omnicef® (cefdinir) for Oral Suspension for all infections is 14 mg/kg/day, up to a maximum dose of 600 mg per day. This may be administered as a single daily dose (except for skin infections) or may be given in two divided doses, as 7 mg/kg every 12 hours.

2006P-0265 C P1

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

The requested change in strength should not raise any questions regarding safety or efficacy as the proposed strengths for Cefdinir Chewable Tablets (i.e. 187.5 mg, 250 mg and 300 mg) represent intermediate strengths between the already approved lowest (62.5 mg) and highest (600 mg) dosage regimen of Omnicef® (cefdinir) for Oral Suspension and can be utilized to deliver the specific doses outlined in the Omnicef® package insert as illustrated below:

OMNICEF FOR ORAL SUSPENSION PEDIATRIC DOSAGE CHART

Weight	250 mg/5 mL
9 kg/20 lbs	Use 125 mg/5 mL product
18 kg/40 lbs	2.5 mL q12h or 5 mL q24h
27 kg/60 lbs	3.75 mL q12h or 7.5 mL q24h
36 kg/80 lbs	5 mL q12h or 10 mL q24h
≥43 kg[a]/95 lbs	6 mL q12h or 12 mL q24h

[a] Pediatric patients who weigh ≥43 kg should receive the maximum daily dose of 600 mg.

CEFDINIR CHEWABLE TABLETS PEDIATRIC DOSAGE CHART

Weight	Cefdinir Chewable Tablets	
	Once Daily	BID Dosing
9 kg/20 lbs	Use 125 mg/5 mL Suspension Product	Use 125 mg/5 mL Suspension Product
18 kg/40 lbs	1 Tablet of 250 mg	1/2 Tablet of 250 mg twice a day
27 kg/60 lbs	2 Tablets of 187.5 mg	1 Tablet of 187.5 mg twice a day
36 kg/80 lbs	2 Tablets of 250 mg	1 Tablet of 250 mg twice a day
≥43 kg[a]/95 lbs	2 Tablets of 300 mg	1 Tablet of 300 mg twice a day

[a] Pediatric patients who weigh ≥43 kg should receive the maximum daily dose of 600 mg.

Once Daily and BID dosing is not included for "9 kg/20 lbs" weight as this weight would be typical to children between age group 6 months to 12 months, who won't be able to chew the tablets.

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

Additionally, Cefdinir Chewable Tablets are expected to offer an alternative to the powder for oral suspension, which could provide for the following benefits for certain age groups and patients:

- Unit dose dispensing
- Convenience to the patient with respect to the ease of administration, even during travel
- Storage of the product will not require special conditions (e.g., refrigeration)
- Ease of carrying
- Better precision of dosage over the traditional teaspoonful
- This may lead to better patient compliance

The proposed drug product will be formulated to demonstrate bioequivalence to the reference listed drug product - Omnicef® (cefdinir) for Oral Suspension 250 mg/5 mL. Data will be submitted at a later date.

Labeling of the proposed product (provided as **Enclosure 1**) will be the same as that of the reference listed drug product (provided as **Enclosure 2**) with differences explained above.

Further, the petitioner intends to collaborate closely with the Agency on the labeling and package insert of the proposed product to assure the labeling is the same as the reference listed drug except for those changes necessitated because the drug product is manufactured by a different sponsor and due to the differences approved by this petition.

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

C. Pediatric Use Information

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food Drug and Cosmetic Act to provide the agency authority to require drug firms to study certain drugs in pediatric patients if the agency felt that such study would provide beneficial health data for that patient population. The act also provided a provision for a waiver from such requirement if:

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

Cefdinir has been extensively studied in the pediatric population in adequate and well controlled clinical studies in: Acute Bacterial Otitis Media; Pharyngitis/Tonsillitis; and Uncomplicated Skin and Skin Structure Infections. Safety and efficacy were demonstrated in these studies in about 1800 pediatric patients from <2 years of age to 13 years of age. Please refer to **Enclosure 3**.

The dosing range for the chewable tablets is the same as for the reference listed drug (14 mg/kg/day) and is consistent with the dosing recommendations of the reference listed drug, as discrete doses are recommended even though the product labeling cites a mg/kg dosing. Bioequivalence studies comparing the proposed Cefdinir Chewable Tablets with Omnicef® (cefdinir) for Oral Suspension, and demonstrating bioequivalence, will be submitted with the ANDA.

The petitioner hereby requests that a waiver from the conduct of additional pediatric studies be granted for the approval of this petition to permit a subsequent ANDA filing. The drug product subject of this petition does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients. In addition, as the package insert of Abbott Laboratory's Omnicef® (cefdinir) for Oral Suspension contains adequate dosing and administration information for the pediatric population, no additional studies are required.

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR 25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

F. Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

For Lupin Limited,

Vinita Gupta by Josie Leader

VINITA GUPTA
President – Lupin Pharmaceuticals, Inc.

Enclosures - As above

Cc: Mr. Gary Buehler, Director, Office of Generic Drugs

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com