cipher
Pharmaceuticals Limited

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MAY 24 P1:52

May 14, 2001

The Office of Generic Drugs
Food & Drug Administration
Department of Health & Human Services
7500 Standish Place
Rockville, MD 20855

ANDA SUITABILITY PETITION

Cipher Pharmaceuticals would like the FDA's Office of Generic Drugs to declare that a new Cipher Pharmaceutical Paroxetine "Caplet" product is pharmaceutically equivalent to the reference listed product, Paxel® Tablet (SmithklineBeecham), and accept an Abbreviate New Drug Application (ANDA) for the new Cipher Paroxetine "Caplet" formulation.

Statement of Grounds

The Cipher Pharmaceuticals Paroxetine "Caplet" is manufactured as a tablet and then cold-pressed with a layer of gelatin. The gelatin is placed over each half of the tablet, and the final dosage form it shaped like a caplet. Paxil® Tablets and Cipher Paroxetine "Caplets" are bioequivalent with each other. The "Caplet" is shaped like a capsule but feels like a tablet. The Cipher Paroxetine "Caplet" is readily and easily divided into two equal halves, using fingers only. When the tablet splits there is a very clean fracture line, with no residue. The two halves each contain half of the total content of the "caplet".

The product concept is licensed from Capsugel as their "Press-Fit" technology.

Paxil® Tablets are available in 10, 20, 30 and 40 mg strengths. Cipher Pharmaceuticals plans on manufacturing only a 20 and 40 mg "Caplets" of Paroxetine. In this way, Cipher can provide the patient with the full range of strengths that are available with Paxil® Tablets, (e.g. by dividing the 20 mg in half the patient can take 10 mg, and by taking one and one-half (11/2) of the 20 mg strength the patient will receive a 30 mg dose).

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CP1

In addition to the advantage that the physician can adjust or regulate the patients dose readily, and the patient can use all of the prescribed medication even when the physician changes the dose. Also, the pharmacy has to stock fewer strengths, which will, in the end, save patient's money.

Environmental Impact

Cipher Pharmaceuticals claims a categorical exclusion under Secs 25.40 CFR Title 21.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, 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 unfavourable to the petition.

Ian W. French, Ph.D.
Chairman and Chief
Scientific Officer

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ANDA SUITABILITY PETITIONS

I have included five (5) ANDA Suitability Petitions with this cover letter. They are for different products, but they all contain the same request and the concept of the products are the same.

The products are:

Amlodipine
Ramipril
Paroxetine
Simvastatin
Fluoxetine

I look forward to hearing the response to these petitions.

Thank you.

Yours sincerely,

Ian W. French, Ph.D.
Chairman and Chief
Scientific Officer