cipher
Pharmaceuticals Limited

6560 Kennedy Rd., Mississauga, Ontario L4T 2X4
Tel: (905) 696-9380 Fax: (905) 565-1776

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 Ramipril "Caplet" product is pharmaceutically equivalent to the reference listed product, Altace® Capsules (King Pharmaceuticals), and accept an Abbreviate New Drug Application (ANDA) for the new Cipher Ramipril "Caplet" formulation.

Statement of Grounds

The Cipher Pharmaceuticals Ramipril "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. Altace® Capsules and Cipher Ramipril "Caplets" are bioequivalent with each other. The "Caplet" is shaped like a capsule but looks like a tablet. The Cipher Ramipril "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" formulation technology.

Altace Capsules are available in 1.25, 2.5, 5.0 and 10.0 strengths. Cipher Pharmaceuticals plans on manufacturing only a 2.5 and 10 mg "Caplets" of Ramipril. In this way, Cipher can provide the patient with the full range of strengths that are available with Altace® Capsules, (e.g. by dividing the 10 mg in half the patient can take 5 mg, and by taking 2 2.5 mg capsules the patient will receive a 5 mg dose, and dividing the 2.5 mg "Caplet" in half the patient will receive 1.25 mg of Ramipril).

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