

***cipher***  
**Pharmaceuticals Limited**

9617 '01 MAY 24 P1 52

6560 Kennedy Rd, Mississauga, Ontario L5T 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 Amlodipine "Caplet" product is pharmaceutically equivalent to the reference listed product, Norvasc® Tablets (Pfizer), and accept an Abbreviate New Drug Application (ANDA) for the new Cipher Amlodipine "Caplet" formulation.

**Statement of Grounds**

The Cipher Pharmaceuticals Amlodipine "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 is shaped like a caplet. Norvasc® Tablets and Cipher Amlodipine "Caplets" are bioequivalent with each other. The "Caplet" is shaped like a capsule but feels like a tablet. The Cipher Amlodipine "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.

Norvasc® Tablets are available in 2.5, 5.0 and 10 mg strengths. Cipher Pharmaceuticals plans on manufacturing only a 5 and 10 mg "Caplets" of Amlodipine. In this way, Cipher can provide the patient with the full range of strengths that are available with Norvasc® Tablets, (e.g. by dividing the 5 mg in half the patient can take 2.5 mg.

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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**Pharmaceuticals Limited**

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May 14, 2001

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

**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.

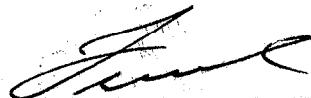
The products are:

Amlodipine  
Ramipril  
Paroxetine  
Simvastatin  
Fluoxetine

I look forward to hearing the response to these petitions.

Thank you.

Yours sincerely,



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