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December 3, 2001

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

Re: Docket No. 01P-0428/CP 1
Supplemental Citizen Petition Regarding Proposed Generic Cefuroxime Axetil Products

Dear Sir or Madam:

SUPPLEMENTAL CITZEN PETITION

We write to further supplement the Citizen's Petition filed on September 19, 2001 by Professional Detailing, Inc. and its wholly-owned affiliate LifeCycle Ventures (collectively, "PDI"), the exclusive distributor of CEFTIN® Tablets (cefuroxime axetil tablets) and CEFTIN® for Oral Suspension (cefuroxime axetil powder for oral suspension) in the United States. In its Petition, Docket No. 01P-0428/CP 1, PDI has requested that the Food and Drug Administration ("FDA"):

1. Decline to approve any Abbreviated New Drug Application ("ANDA") that seeks approval for a generic product containing a mixture of amorphous and crystalline cefuroxime axetil.

2. Decline to approve the pending ANDA submitted by Ranbaxy Laboratories, Inc. ("Ranbaxy"), in which Ranbaxy proposes to market a drug containing a mixture of amorphous and crystalline

01P-0428 SUP 2

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cefuroxime axetil as a generic substitute for CEFTIN®, which contains wholly amorphous cefuroxime axetil.

3. Decline to make effective any approval of the pending ANDA submitted by Ranbaxy or the pending ANDA submitted by Apotex, Inc. ("Apotex") for a generic drug containing a mixture of amorphous and crystalline cefuroxime axetil until either (a) thirty months from the date on which Glaxo commenced a patent infringement action against that applicant, or (b) the date on which a court enters a final order or judgment declaring Glaxo's U.S. Patent No. 4,562,181 to be invalid and/or not infringed by that applicant's ANDA.

4. Issue a regulation to set uniform standards for new drug applications in which the applicants seek approval for drugs that contain a different form of an active ingredient that is contained in a reference listed drug.

On October 16, 2001, PDI filed a Supplemental Citizen's Petition in which PDI discussed and attached major international pharmacopoeia monographs that provide further support for its Citizen's Petition. PDI appended to its October 16, 2001 Supplemental Citizen's Petition copies of the European, British and Chinese Pharmacopoeia monographs for cefuroxime axetil. In each case, the monograph provides that the drug substance must be in amorphous form and must have a specified isomeric mixture. None of these pharmacopoeial authorities permits the inclusion of crystalline material to this drug substance.

The Japanese Pharmacopoeia monograph for cefuroxime axetil similarly provides that the drug substance must be in amorphous form and have a specified isomeric mixture. (A copy of the Japanese Pharmacopoeia monograph is appended hereto as Exhibit 24.) PDI has filed this second supplement to its Citizen's Petition to bring the Japanese Pharmacopoeia reference to the Agency's attention.

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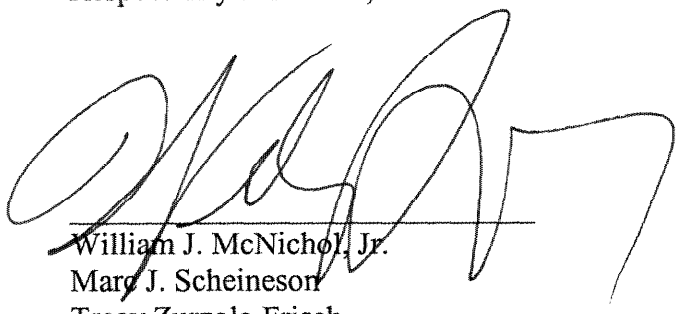
For all the reasons set forth in its Citizen's Petition and the supplements thereto, PDI renews its request that FDA take the action described above.

Respectfully submitted,



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Enclosure

cc: Ms. Jane A. Axelrad (w/enc.) (via overnight mail)
Mr. Gary J. Buehler (w/enc.) (via overnight mail)

SUPPLEMENT II
TO
THE JAPANESE PHARMACOPOEIA
THIRTEENTH EDITION

Official from January 1, 2000

YAKUJI NIPPO, LTD.

This *English Version* of the Japanese Pharmacopoeia is published for the convenience of users unfamiliar with the Japanese language. When and if any discrepancy arises between the Japanese original and its English translation, the former is authentic.

Supplement II to The Japanese Pharmacopoeia Thirteenth Edition

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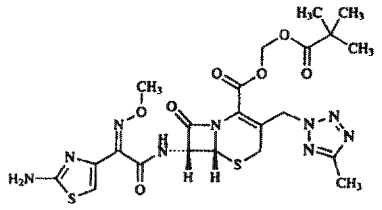
ish white crystalline powder.

It is slightly soluble in water, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

Add the following:

Cefteram Pivoxil



$C_{22}H_{27}N_9O_7S_2$: 593.64

Pivaloyloxymethyl (6*R*,7*R*)-7-[(*Z*)-2-(2-aminothiazol-4-yl)-2-(methoxyimino)acetamido]-3-[(5-methyl-2*H*-tetrazol-2-yl)methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [*82547-58-8*, Cefteram]

Cefteram Pivoxil conforms to the requirements of Cefteram Pivoxil in the Requirements for Antibiotic Products of Japan.

Description Cefteram Pivoxil occurs as a white to yellowish white powder. It has a bitter taste.

It is freely soluble in methanol and in ethanol (95), slightly soluble in diethyl ether, and practically insoluble in water.

Ceftizoxime Sodium

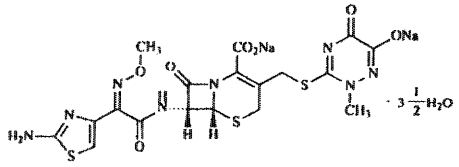
Change the Description to read:

Description Ceftizoxime Sodium occurs as white to light yellow crystals or crystalline powder.

It is very soluble in water, slightly soluble in methanol, and practically insoluble in ethanol (95) and in diethyl ether.

Add the following:

Ceftriaxone Sodium



$C_{18}H_{16}N_8Na_2O_7S_3.3\frac{1}{2}H_2O$: 661.61

Disodium (6*R*,7*R*)-7-[(*Z*)-2-(2-aminothiazol-4-yl)-2-(methoxyimino)acetamido]-3-[(2,5-dihydro-2-methyl-6-oxido-5-oxo-1,2,4-triazin-3-yl)sulfanylmethyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate hemiheptahydrate [*104376-79-6*]

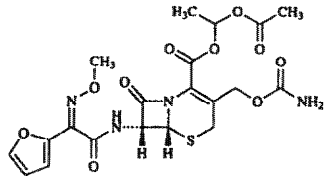
Ceftriaxone Sodium conforms to the requirements of Ceftriaxone Sodium in the Requirements for Antibiotic Products of Japan.

Description Ceftriaxone Sodium occurs as a white to light yellowish white crystalline powder.

It is freely soluble in water, sparingly soluble in methanol, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

Add the following:

Cefuroxime Axetil



$C_{20}H_{22}N_4O_{10}S$: 510.48

(*RS*)-1-Acetoxyethyl (6*R*,7*R*)-3-carbamoyloxymethyl-7-[2-(2-furyl)-2-[(*Z*)-methoxyimino]acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [*64544-07-6*]

Cefuroxime Axetil conforms to the requirements of Cefuroxime Axetil in the Requirements for Antibiotic Products of Japan.

Description Cefuroxime Axetil occurs as a white to yellowish white amorphous powder. It has a faint characteristic odor and a bitter taste.

It is freely soluble in 1,4-dioxane, soluble in methanol, sparingly soluble in ethanol (95), slightly soluble in diethyl ether, and very slightly soluble in water.

Cefuroxime Sodium

Change the Description to read:

Description Cefuroxime Sodium occurs as white to light yellowish white crystals or crystalline powder.

It is freely soluble in water, sparingly soluble in methanol, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

Cetraxate Hydrochloride

Change the Identification (2) to read:

Identification

(2) Dissolve 0.5 g of Cetraxate Hydrochloride in 5 mL

SUPPLEMENT II

THE JAPANESE PHARMACOPOEIA

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