



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 9, 2003

Charles J. Raubicheck
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151

Dear Mr. Raubicheck:

Your petition, on behalf of Alphapham Pty of Glebe, requesting the Food and Drug Administration to permit the filing of an abbreviated (NDA) for the drug Citalopram Hydrobromide Capsules was, received by this office on 12/09/2003. It was assigned docket number 2003P-0551/CP1 and it was filed on 12/09/2003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler, Director
Division of Dockets Management

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December 5, 2003

BY FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

SUITABILITY PETITION

Re: Citalopram Hydrobromide Capsules

Ladies/Gentlemen:

On behalf of Alphapharm Pty Ltd of Glebe, New South Wales, Australia, the undersigned hereby submits in quadruplicate this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(C), and FDA regulations 21 CFR §§ 314.93, 10.25 and 10.30.

A. Action Requested

This Suitability Petition requests a declaration by the Commissioner of Food and Drugs, head of the Food and Drug Administration ("FDA"), that an Abbreviated New Drug Application ("ANDA") may be filed for the drug citalopram in a capsule dosage form.

B. Statement of Grounds

• An ANDA may be filed for the approval of a new drug that is the same as a reference listed drug ("RLD"). 21 U.S.C. § 355 (j) (2) (A). An ANDA may also be filed for a new drug which is the same as an RLD except for a difference in dosage form, provided that FDA has granted permission to file such an ANDA upon the submission and approval of a pertinent "suitability" petition. 21 U.S.C. § 355 (j) (2) (C); 21 C.F.R. § 314.93 (b). FDA is authorized to approve a suitability petition seeking a change in dosage form from an RLD. Id.

• The specific RLD upon which this Petition is based is CELEXA (citalopram hydrobromide) tablets, a drug product which is indicated for the

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treatment of depression. (See Attachments 1 and 2 hereto). The NDA for the RLD is held by Forest Laboratories, Inc. *Id.*

- The proposed drug product will contain the same active ingredient as the RLD (citalopram hydrobromide), and will have the same strengths (10 mg, 20 mg and 40 mg) and the same route of administration (oral) as the RLD. The proposed drug product will differ from the RLD only in its dosage form -- a capsule rather than a tablet.

- The labeling of the proposed drug product will also be the same as the currently approved labeling for the RLD, except for changes which are required because of the difference in manufacturer, and the difference in dosage form proposed under this Petition (see proposed labeling in Attachment 3).

- The FDA has previously approved a number of ANDA suitability petitions allowing a change in dosage form from a tablet to a capsule. For example, FDA has approved a suitability petition for a capsule dosage form of the antidepressant drug ZOLOFT (sertraline hydrochloride), which was previously available in a tablet dosage form.

- The petitioner is seeking the change in dosage form from a tablet to a capsule in an effort to make an alternative dosage form of citalopram available to patients, particularly to those individuals who may have difficulty in swallowing a tablet or who prefer a capsule dosage form.

- In view of the above, and since citalopram has been marketed in the United States for over four years with an established safety and effectiveness profile (see Attachments 2 and 4), there is no reason to question the safety and effectiveness of the proposed citalopram drug product for its labeled use.

C. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner following review of this Petition.

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E. Certification

The undersigned certifies that, to their best knowledge and belief, this Suitability Petition includes all information and views upon which the Petition relies, and includes representative data and information known to Petitioner which are unfavorable to the Petition.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By 
Charles J. Raubicheck

CJR/bav
cc(w/attachments):
Gary J. Buehler (Director, FDA Office of Generic Drugs)

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations ("the Electronic Orange Book", current through September, 2003): CELEXA (citalopram hydrobromide) tablets, 10 mg, 20 mg and 40 mg.
2. Current approved labeling for CELEXA (citalopram hydrobromide) tablets, from FDA's website.
3. Proposed labeling for Citalopram Hydrpbromide capsules, 10 mg, 20 mg and 40 mg.
4. NDA approval letter for CELEXA (citalopram hydrobromide) tablets.