



JUL 15 2004

Frommer Lawrence & Haug, LLP  
Attention: Charles J. Raubicheck  
745 Fifth Ave  
New York, New York 10151

Docket Nos. 03P-0551/CP1  
04P-0247/CP1

Dear Mr. Raubicheck:

This is in response to your letters dated June 2, 2004 and July 14, 2004. Your ANDA suitability petitions for changes in dosage form for Citalopram and Escitalopram from tablets to capsules are currently under review. As you know, on December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. Your pending ANDA suitability petitions are affected by this Act because they are petitions for a change in active ingredient/dosage form/route of administration. If the change proposed in an ANDA suitability petition does not qualify for a full waiver of the pediatric studies, that petition will be denied because, under PREA, clinical studies are required to demonstrate the safety and or effectiveness of the change (Section 505(j)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act).

The waiver requests must be evaluated along with the petition. The outcome of the waiver requests among other considerations will determine whether the petitions may be approved. You will be notified in writing when the review of your petitions is complete.

Copies of this letter and your letters of June 2 and July 14 will be placed on public display in the Dockets Management Branch.

Sincerely yours,

Gary J. Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

2004P-0247

ANS 1

## FROMMER LAWRENCE &amp; HAUG LLP

745 FIFTH AVENUE NEW YORK, NEW YORK 10151

TEL: (212) 588-0800 FAX: (212) 588-0500

June 2, 2004

WILLIAM S. FROMMER  
 WILLIAM F. LAWRENCE  
 EDGAR H. HAUG  
 MATTHEW K. RYAN  
 BARRY S. WHITE  
 THOMAS J. KOWALESKI  
 JOHN R. LANE  
 DENNIE M. SMID\*  
 DANIEL G. BROWN  
 STEVEN M. AMUNDSON  
 MARLYN MATTHEW BROGAN  
 JAMES K. STRONSKI  
 CHARLES J. RAUBICHECK  
 GRACE L. PAN\*  
 MARK W. RUSSELL\*  
 JEFFREY A. HOVDEN  
 RONALD R. SANTUCCI  
 RICHARD E. PARKS  
 LEONARD J. SANTEM  
 PORTER F. FLEMING

A. THOMAS S. SAFFORD  
 BARBARA Z. MORRISSEY  
 Of Counsel

BRUNO POLITO  
 CHRISTIAN M. SMOLIZZA  
 ROBERT E. COLLETTI  
 DEENA LEVY WEINGOUR  
 DARREN M. SIMON  
 JOHN G. TAYLOR  
 DAVID A. ZWALLY  
 SAMUEL H. MEGERDITCHIAN  
 KEVIN MURPHY  
 TERRI YOUNG NATALINE  
 PEARL TENG LING SIEW  
 TEDD W. VAN BUSKIRK  
 STEPHEN J. LIES  
 FRANCINE S. ADLER, DPM  
 HANS R. MAHR\*  
 ARTHUR L. HOAC  
 SANDRA KUZMICH, Ph.D.  
 SEAN J. GREYCEL  
 WENDY R. STEIN  
 JOYCE W. LUK  
 DELON KIM  
 LESLIE C. ALLEN\*  
 NATHAN D. WEBER  
 SAMUEL S. LEE\*  
 PAMELA FISCHER  
 MAGALI ROZENFELD  
 H. SARAH PARK  
 \*Admitted to a Bar  
 other than New York

BY FEDERAL EXPRESS

Regulatory Support Branch (HFD-615)  
 Office of Generic Drugs  
 Center for Drug Evaluation and Research  
 U.S. Food and Drug Administration  
 7500 Standish Place  
 Rockville, Maryland 20855

Attn: Martin H. Shimer

Re: Citalopram: Suitability Petition 03P-0551/CPI  
Escitalopram: Suitability Petition 04P-0247/CPI

Dear Mr. Shimer:

On December 6, 2003, on behalf of Alphapharm Pty Ltd of Glebe, New South Wales, Australia, we submitted a suitability petition for permission to file an Abbreviated New Drug Application (ANDA) for the anti-depressant drug citalopram in capsule dosage form. Upon notification from OGD, we supplemented this petition with a request for a full pediatric assessment waiver on May 10, 2004.

On May 24, 2004, also on behalf of Alphapharm, we filed a suitability petition seeking permission to file an ANDA for the anti-depressant drug escitalopram in capsule dosage form. This petition contains a request for a full pediatric assessment waiver.

This letter requests that both these suitability petitions be considered and ruled upon at the next meeting of OGD's Suitability Petition Committee that decides the merits of suitability petitions, on the following grounds:

- The Pediatric Research Equity Act, now requiring pediatric assessments for suitability petitions, was enacted during the same week in December, 2003 when the instant citalopram suitability petition was undergoing the filing and docketing process at FDA;

Regulatory Support Branch (HFD-615)  
June 2, 2004  
Page 2

- FDA did not rule on this suitability petition within the 90-day period required by 21 U.S.C. §355(j)(2)(C);
- OGD advised us that a pediatric assessment or waiver request was required on April 16, 2004, and we promptly responded with a waiver request;
- under the circumstances, the citalopram suitability petition should be reviewed expeditiously, and should not have to undergo another 90-day cycle; and
- the escitalopram suitability petition can and should be ruled upon at the same time as the citalopram petition, because:
  - (i) escitalopram is a related active drug ingredient, namely, the active isomer of racemic citalopram;
  - (ii) both drugs are currently marketed in tablet form, and each of the instant petitions simply seeks change to a capsule form, a change routinely allowed by OGD; and
  - (iii) both of the instant petitions seek a full pediatric assessment waiver on the same ground: SSRI anti-depressants lacking safety in a pediatric population.

Please (a) advise us of the date of the next meeting of OGD's Suitability Petition Committee, (b) confirm to us that these petitions will be reviewed at that meeting, and (c) inform us promptly of the Committee's decision.

Sincerely yours,



Charles J. Raubicheck

CJR:bav

cc: Gary J. Buchler  
Alphapharm Pty Ltd

# FROMMER LAWRENCE & HAUG LLP

745 FIFTH AVENUE NEW YORK, NEW YORK 10151

TEL: (212) 588-0800 FAX: (212) 588-0500

July 14, 2004

## BY FAX AND FEDERAL EXPRESS

Mr. Gary J. Buehler  
Director, Office of Generic Drugs (HFD-600)  
U.S. Food and Drug Administration  
7500 Standish Place  
Rockville, Maryland 20855

Re: Citalopram: Suitability Petition 03P-0551/CPI  
Escitalopram: Suitability Petition 04P-0247/CPI

Dear Mr. Buehler:

We have recently been advised by Emily Thakur of OGD's Regulatory Support Branch that the above-identified suitability petitions, which we have filed on behalf of Alphapharm Pty Ltd, have been consolidated for review.

However, Ms. Thakur also informed us that FDA has implemented a three-tiered system to review suitability petitions (a consult by the pertinent NDE review division, a second review by CDER's pediatric committee, and a third review by your office's suitability petition committee). Whether such an elaborate review process is needed to evaluate suitability petitions, for such minor changes as the dosage form changes proposed by the instant petitions, is debatable. Certainly, this process makes it difficult for FDA to rule on suitability petitions within the 90-day period required by statute.

We urge FDA to grant Alphapharm's citalopram and escitalopram suitability petitions as promptly as possible, for the reasons set forth in the petitions themselves, and in our letter of June 2, 2004 to Martin Shimer of OGD (copy enclosed), to which we have received no reply.

Sincerely yours,



Charles J. Raubicheck

CJR:bav

Encl.

cc(w/encl.): Martin Shimer  
Emily Thakur  
Alphapharm Pty Ltd

WILLIAM S. FROMMER  
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MATTHEW K. RYAN  
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\*Admitted to a Bar other than New York