CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75465

CORRESPONDENCE

ANDA 75-755

JUN 29 2001

King and Spalding
US Agent for Alphapharm Pty. Ltd.
Attention: Eugene Pfeifer
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Dear Sir:

This is in reference to your abbreviated new drug application dated December 6, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Hydrochloride Tablets, 10 mg and 20 mg.

Reference is also made to your amendments dated: September 8, and December 1, 2000; and January 24, February 9, March 6, 19, 23, and 26, 2001. and April 26, 2001 mk

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application is subject to a period of patent protection which expires on August 2, 2001, (Patent No. 4,314,081) and June 2, 2004, (Patent No. 4,626,549). However, litigation is underway in the United States District Court for the Southern District of Indiana involving a challenge to the patent (Eli Lilly and Company v. Alphapharm Pty. Ltd., Civil Action No. IP00-0761 C-T/G).

Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of court decision [505(j)(5)(B)(iii)(I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,

   c. the patent has expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency whether circumstances have or have not arisen that may affect the effective date of final approval. Your amendment must provide:

1. A copy of a final order or judgement from which no appeal may be taken (which might not be the one from the district court), or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information, and

2. a. updated information related to labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

   b. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing

procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Jeen Min, Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

/S/

Gary Buehler 6/29/01
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

alphapharm

May 18, 2001

Ms Florence Fang
Director
Division of Chemistry II
Office of Generic Drugs– HFD-600,
Centre for Drug Evaluation and Research,
Food and Drug Administration
Metro Park North II,
7500 Standish Place, Document Control Room 150,
ROCKVILLE, MD 20855 USA

NEW CORRESP

Re: **ANDA 75-755**
Fluoxetine Hydrochloride Tablets, 10 mg and 20 mg
Updated Exclusivity Statement

Dear Ms Fang,

Further to our letter dated April 26, 2001, we have undertaken a review of this application and we enclose an updated Exclusivity Statement which refers to the Pediatric Exclusivity period for Prozac® Tablets.

This amendment is submitted on our behalf by our agent King & Spalding. Three copies of the Amendment have been enclosed: an Archival Copy (Blue Folder), a Chemistry Section (Red Folder) and a Field Copy (Burgundy Folder). A signed certification of the Field Copies as true copies of this amendment has also been included.

We request that all information in this file be treated as confidential within the meaning of 21 §CFR 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorised member of your Office.

A copy of the FDA Form 356h, signed by our U.S. agent, King & Spalding, is included.

CENTER FOR DRUG EVALUATION AND RESEARCH
MAY 23 2001
OGD

If you should have any questions regarding the information in this submission, please do not hesitate to contact our Agent, King and Spalding.

Yours sincerely,

Alphapharm Pty Ltd

G H Napier Munn

Georgina Napier-Munn

Regulatory Affairs Manager (R&D)

Encl.

KING & SPALDING

1730 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20006-4706
TELEPHONE: 202/737-0500
FACSIMILE: 202/626-3737

DIRECT DIAL:
202/626-2926

EMAIL:
cmarkus@kslaw.com

June 18, 2001

NC.

VIA HAND DELIVERY

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

Re: ANDA 75-755 (Fluoxetine Hydrochloride Tablets, 10 and 20 mg)

Dear Sir or Madam:

Enclosed please find a letter of authorization that Alphapharm Pty. Ltd. has asked us to file with regard to the referenced application. Please contact me should you have any questions.

Sincerely,

Christina M. Markus
U.S. Agent for Alphapharm Pty. Ltd.

cc: Mr. Jeen Min, Project Manager
(w/encl.)

Enclosure

191 PEACHTREE STREET
ATLANTA, GA 30303-1763
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FACSIMILE: 404/572-5100

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HOUSTON, TX 77002-5219
TELEPHONE: 713/751-3200
FACSIMILE: 713/751-3290

alphapharm
R & D Fax No.: +61 7 3000 6398

BM/crw

18th June, 2001

Mr. Gary Buehler,
Acting Director of Generic Drugs – HFD-600,
Office of Generic Drugs,
Centre for Drug Evaluation and Research,
Food and Drug Administration,
Metro Park North II,
7500 Standish Place, Document Control Room 150,
Rockville, Maryland, 20855
USA

Dear Mr. Buehler,

Re: Fluoxetine Hydrochloride Tablets 10 mg and 20 mg , A.N.D.A. #75-755

We hereby authorise Mr. Robert Pollock of Lachman Consultant Services to communicate with the FDA with regard to the above referenced ANDA #75-755.

If you have any questions related to the above, please do not hesitate to contact our current agent, King and Spalding, via telephone at (202) 626-2926 or via facsimile at (202) 626-3737.

Yours sincerely,
Alphapharm Pty. Ltd.

Brett Mooney, Ph.D.,
Senior Manager – Research & Development

c.c.: Christina Markus (King and Spalding)
Robert Pollock (Lachman Consultant Services)

Alphapharm Pty Limited
Head Office
Manufacturing / Research & Development
Customer Service
www.alphapharm.com.au

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
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PALO ALTO
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NEW CORRESP
NC

WRITER'S DIRECT DIAL NUMBER:

TOKYO
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BRUSSELS
011•322•646•0353

August 4, 2000

Food & Drug Administration
Office of Generic Drugs
(HFD-600)
7500 Standish Place
Rockville, MD 20855

VIA FEDERAL EXPRESS

Attn: Mr. Greg Davis

Re: Fluoxetine Hydrochloride Tablets, 20 mg
Abbreviated New Drug Application No. 75-755
Notification of Filing of Legal Action for Patent Infringement

Dear Mr. Davis:

We represent Eli Lilly and Company ("Lilly"), owner of United States Patent Nos. 4,314,081 and 4,626,549. We are sending you this letter on behalf of our client under 21 C.F.R. § 314.107(f)(2) to notify you of the following:

(1) Mr. Edgar H. Haug, Esq., of the law firm of Frommer Lawrence & Haug, LLP 745 Fifth Avenue, New York, NY 10151, sent a letter to Lilly on behalf of Alphapharm Pty. Limited ("Alphapharm") stating that Alphapharm was providing information pursuant to Section 505(j)(2)(B)(ii) of the Food, Drug and Cosmetic Act. The letter included the following information:

(i) The FDA has received an amendment to an abbreviated new drug application from Alphapharm containing bioavailability or bioequivalence data with respect to fluoxetine hydrochloride 20 mg tablets.

(ii) The abbreviated new drug application number is 75-755.

(iii) The established name, as defined in Section 502(e)(3) of the Food, Drug and Cosmetic Act, of the proposed drug product is Fluoxetine Hydrochloride Tablets, 20 mg.

(iv) The active ingredient, strength, and dosage form of the proposed drug product is fluoxetine hydrochloride 20 mg tablets for oral administration.

(v) The patent number and expiration date, as known to Alphapharm, each claim of which is alleged to be either invalid or not infringed, is as follows:

United States Patent No. 4,314,081, which expires February 2, 2001, and United States Patent No. 4,626,549, which expires December 2, 2003.

(2) Lilly received the letter on or about June 23, 2000.

Certification

We hereby certify that on August 3, 2000, Lilly filed an action for patent infringement against Alphapharm in the United States District Court for the Southern District of Indiana (Case Number IP 00-1238 C M/S). Lilly alleges, among other things, that under 35 U.S.C. § 271(e)(2)(A) Alphapharm's submission to the FDA of an abbreviated new drug application to obtain approval for the commercial manufacture, use, or sale of 20 mg fluoxetine hydrochloride tablets before the expiration of United States Patent Nos. 4,314,081 and 4,626,549 was an act that infringes claim 5 of U.S. Patent No. 4,314,081, and claims 6 and 7 of United States Patent No. 4,626,549.

We therefore respectfully request that the approval of Alphapharm's abbreviated new drug application for 20 mg fluoxetine hydrochloride tablets shall not be made effective until at least the expiration of the thirty-month period as provided by 21 U.S.C. § 355(j)(4)(B)(iii), subject to an appropriate ruling by the Court.

Yours sincerely,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Allen M. Sokal
Allen M. Sokal

cc: Edgar H. Haug, Esq.
Counsel for Alphapharm

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
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DAVID S. FORMAN, PH.D.
202-408-4068

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BRUSSELS
011•322•646•0353

NEW CORRESP
NC

May 19, 2000

Food & Drug Administration
Office of Generic Drugs
(HFD-600)
7500 Standish Place
Rockville, MD 20855

VIA FEDERAL EXPRESS

Attn: Mr. Greg Davis

Re: Fluoxetine Hydrochloride Tablets, 10 mg
Abbreviated New Drug Application No. 75-755
Notification of Filing of Legal Action for Patent Infringement

Dear Mr. Davis:

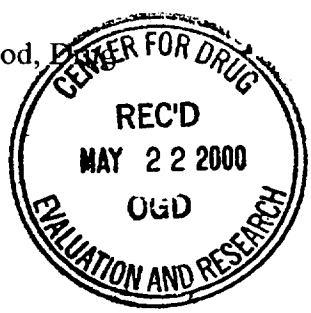
We represent Eli Lilly and Company ("Lilly"), owner of United States Patent Nos. 4,314,081 and 4,626,549. We are sending you this letter on behalf of our client under 21 C.F.R. § 314.107(f)(2) to notify you of the following:

(1) Mr. Edgar H. Haug, Esq., of the law firm of Frommer Lawrence & Haug, LLP 745 Fifth Avenue, New York, NY 10151, sent a letter to Lilly on behalf of Alphapharm Pty. Limited ("Alphapharm") stating that Alphapharm was providing information pursuant to Section 505(j)(2)(B)(ii) of the Food, Drug and Cosmetic Act. The letter included the following information:

(i) The FDA has received an abbreviated new drug application from Alphapharm containing bioavailability or bioequivalence data with respect to fluoxetine hydrochloride 10 mg tablets.

(ii) The abbreviated new drug application number is 75-755.

(iii) The established name, as defined in Section 502(e)(3) of the Food, Drug and Cosmetic Act, of the proposed drug product is Fluoxetine Hydrochloride Tablets, 10 mg.



(iv) The active ingredient, strength, and dosage form of the proposed drug product is fluoxetine hydrochloride 10 mg tablets for oral administration.

(v) The patent number and expiration date, as known to Alphapharm, each claim of which is alleged to be either invalid or not infringed, is as follows:

United States Patent No. 4,314,081, which expires February 2, 2001, and United States Patent No. 4,626,549, which expires December 2, 2003.

(2) Lilly received the letter on or about March 27, 2000.

Certification

We hereby certify that on May 8, 2000, Lilly filed an action for patent infringement against Alphapharm in the United States District Court for the Southern District of Indiana (Case Number IP 00-0761 C T/G). Lilly alleges, among other things, that under 35 U.S.C. § 271(e)(2)(A) Alphapharm's submission to the FDA of an abbreviated new drug application to obtain approval for the commercial manufacture, use, or sale of fluoxetine hydrochloride before the expiration of United States Patent Nos. 4,314,081 and 4,626,549 was an act that infringes claim 5 of U.S. Patent No. 4,314,081, and claims 6 and 7 of United States Patent No. 4,626,549.

We therefore respectfully request that the approval of Alphapharm's abbreviated new drug application shall not be made effective until at least the expiration of the thirty-month period as provided by 21 U.S.C. § 355(j)(4)(B)(iii), subject to an appropriate ruling by the Court.

Yours sincerely,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: David S Forman
David S. Forman

cc: Edgar H. Haug, Esq.
Counsel for Alphapharm

Par
Pharmaceutical,
Inc.

One Ram Ridge Road, Spring Valley, NY 10977
(914) 425-7100 • Telecopier (914) 425-7907

DR. Label
NDA ORIG AMENDMENT
AA

February 11, 2000

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

GENERAL CORRESPONDENCE

RE: ANDA 75-755
Fluoxetine Tablets 10 mg

Dear Sir/Madam

Reference is made to the above abbreviated new drug application submitted December 6, 1999, for Fluoxetine Tablets 10 mg, by Par Pharmaceutical Inc, U.S. Agent for Alphapharm Pty. Ltd.

At this time, Alphapharm submits the following amendment to provide for the 20 mg tablet strength. In addition, a copy of a Citizen's Petition, filed on February 10, 2000 by Lachman Consultant Services, Inc., is provided. The Citizen's Petition requests the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug, Prozac (Fluoxetine) Tablets 20 mg, (NDA 20-974), by Eli Lilly and Company, has been voluntarily withdrawn for safety and effectiveness reasons.

If you have any questions regarding the information contained in this submission, please contact Par Pharmaceutical, U.S. Agent for Alphapharm.

Sincerely,
PAR PHARMACEUTICAL, INC.

Robert A. Femia, Ph.D.
Vice President
Scientific & Regulatory Affairs

Enclosures

alphapharm

R&D Fax No. +61-7-300-6398

26th March 2001

Wm Peter Rickman
Acting Director, Division of Labeling and Program Support,
Office of Generic Drugs - HFD-610,
Centre for Drug Evaluation and Research,
Food and Drug Administration,
Metro Park North II,
7500 Standish Place, Room 150,
ROCKVILLE, MD 20855-2773, USA

N/A

Re: ANDA # 75-755
Labeling Amendment Fluoxetine Hydrochloride Tablets 10 mg and 20 mg: Withdrawal of Combined Package Insert

Dear Mr Rickman,

Further to a telephone request from Jeen Min on March 22, 2001, we enclose a Labeling Amendment for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg ANDA #75-755 to withdraw the combined Package Insert for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg and Fluoxetine Capsules USP 10 mg and 20 mg.

This amendment is submitted on our behalf by our Agent, King and Spalding. Three complete copies of the amendment are enclosed – an Archival copy (Blue Folder), a Chemistry section (Red folder) and a Field Copy (Burgundy Folder). A signed Certification of the Field Copies (Red and Burgundy Folders) as true copies of this amendment has also been included.

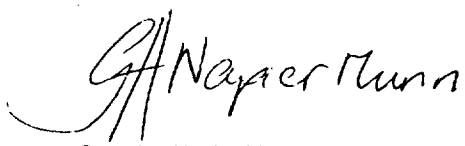
A copy of this amendment was forwarded by facsimile on March 23rd, 2001 to Jeen Min.

We request that all information in this file be treated as confidential within the meaning of CFR § 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorised member of your office.

Should you have any questions regarding the information in this amendment, please do not hesitate to contact our agent, King and Spalding.

Yours sincerely,

Alphapharm Pty Ltd



Georgina Napier-Munn.

Regulatory Affairs Manager - Research and Development

Encl.

R&D Fax No. +61-7-300-6398

19th March 2001

N 1 AC

ORIG AMENDMENT

Ms Florence Fang
Director, Division of Chemistry II,
Office of Generic Drugs - HFD-640,
Centre for Drug Evaluation and Research,
Food and Drug Administration,
Metro Park North II,
7500 Standish Place, Room 150,
ROCKVILLE, MD 20855-2773, USA

Re: ANDA # 75-755
Telephone Amendment for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg

Dear Ms Fang,

Further to a telephone request on 6th March 2001 for more information for the above ANDA, we enclose a Telephone Amendment for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg.

This amendment is submitted on our behalf by our agent, King and Spalding. Three complete copies of the amendment are enclosed – an Archival copy (Blue Folder), a Chemistry section (Red folder) and a Field Copy (Burgundy Folder). A signed Certification of the Field Copies (Red and Burgundy Folders) as true copies of this amendment has also been included.

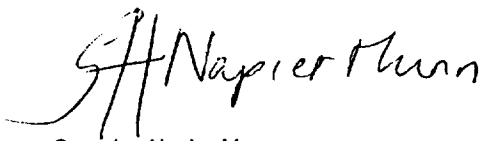
A copy of this amendment was forwarded by facsimile on March 16th, 2001 to Jeen Min. For ease of reference, the enclosed copies of the amendment have been paginated. Because of the volume of paper involved, the facsimile contained selected pages and was not paginated.

We request that all information in this file be treated as confidential within the meaning of CFR § 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorised member of your office.

Should you have any questions regarding the information in this amendment, please do not hesitate to contact our agent, King and Spalding.

Yours sincerely,

Alphapharm Pty Ltd



Georgina Napier-Munn.

Regulatory Affairs Manager - Research and Development

Encl.

alphapharm

PATENT AMENDMENT

March 15, 2001

Mr. Gary Buehler
Acting Director of Generic Drugs
Office of Generic Drugs– HFD-600,
Centre for Drug Evaluation and Research,
Food and Drug Administration
Metro Park North II,
7500 Standish Place, Document Control Room 150,
ROCKVILLE, MD 20855 USA

NC

NEW CORRESP

Re: **ANDA 75-755**
Fluoxetine Hydrochloride Tablets, 10 mg and 20 mg

Dear Mr. Buehler,

Pursuant to a review of this application and in accordance with 21 C.F.R. § 314.95, Alphapharm Pty. Ltd. is amending the subject application to fulfil the requirements of 21 C.F.R. § 314.95(b), 21 C.F.R. § 314.95(e) and 21 C.F.R. § 314.107(f)(2). We have enclosed letters detailing the notification to the FDA that our Notices of Paragraph IV Certification comply with 21 C.F.R. § 314.95(b) and notification that Legal Action was taken by the Patentee within the 45 day period as required by 21 C.F.R. § 314.107(f)(2). Alphapharm has also provided Evidence of Notification as required by 21 C.F.R. § 314.95(e) by Return Receipt or admission in the Legal Action by the Patentee and/or NDA Holder.

A copy of the FDA Form 356h, signed by our U.S. agent, King & Spalding, is included.

Yours sincerely,
Alphapharm Pty Ltd

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
MAR 19 2001
OGD

Brett Mooney Ph. D.,
Senior Manager - Research and Development

alphapharm

R&D Fax No. +61-7-300-6398

9th February 2001

Mr. Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs,
Centre for Drug Evaluation and Research,
Food and Drug Administration,
Metro Park North II,
7500 Standish Place, Room 150,
ROCKVILLE, MD 20855-2773
USA

Re: Labeling Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA # 75-755

Dear Mr Rickman,

Further to your correspondence of 19th January, 2001, requesting labeling changes to the above ANDA, we enclose a Labeling Amendment for Fluoxetine Tablets 10 mg and 20 mg.

Please find enclosed three complete copies of this amendment – an Archival copy (Blue Folder), a Chemistry section (Red folder) and a Field Copy (Burgundy Folder). A signed Certification of the Field Copies (Red and Burgundy Folders) as true copies of the Labeling Amendment is also included.

12 copies of the final package inserts and 4 copies of the side by side comparison with annotated changes have been included in the Archival Copy (Blue Folder).

Copies of the FDA labeling amendment request and the Form FDA 356h, signed by our U.S. Agent, King and Spalding, are also included.

Should you have any further questions regarding the information in this Labeling Amendment, please do not hesitate to contact our agent, King and Spalding.

Yours sincerely,
Alphapharm Pty Ltd

Georgina Napier-Munn.
Regulatory Affairs Manager - Research and Development

Encl.

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
FEB 14 2001
OGD

alphapharm

24th January 2001

ORIG AMENDMENT

N/AC

Dr Dale P. Conner
Director, Division of Bioequivalence
OFFICE OF GENERIC DRUGS,
Document Control Room,
Metro Park North II,
7500 Standish Place, Room 150,
***Rockville**, MD 20855-2773*
USA

Dear Dr Conner,

Re: Bioequivalency Telephone Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA #75-755.

Further to a telephone request of January 18th, 2001, for long term stability data (of at least 106 days duration) on Fluoxetine and Norfluoxetine for the comparative bioavailability study (study number 00-354), we enclose a Bioequivalency Telephone Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA # 75-755.

Please find enclosed two complete copies of this amendment – an Archival copy (Blue Folder) and a Pharmacokinetic Copy (Orange Folder). A signed Certification of the Field copy (Orange Folder) as a true copy of the Bioequivalency Telephone Amendment is also included.

A copy of this amendment was forwarded by facsimile on January 24th, 2001 to Dr Krista Scardina.

The Form FDA 356h, signed by our U.S. agent, King and Spalding, is also included.

Should you have any further questions regarding this Bioequivalency Telephone Amendment, please do not hesitate to contact our agent, King and Spalding.

Yours sincerely,
Alphapharm Pty Ltd

GH Napier Munn

Georgina Napier-Munn
Manager of Regulatory Affairs (Research & Development)

Encl.

Alphapharm Pty Limited
Manufacturing / Research & Development
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www.alphapharm.com.au

KING & SPALDING

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TELEPHONE: 202/737-0500
FACSIMILE: 202/626-3737

DIRECT DIAL:
202-626-2926

January 3, 2001

NEW CORRESP
NC/Bio

BIOAVAILABILITY

Dr. Dale P. Conner
Director, Division of Bioequivalence
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

Re: Alphapharm Pty Ltd —
Fluoxetine Tablets, 10 mg and 20 mg (ANDA #75-755)

Dear Dr. Conner:

King & Spalding serves as United States agent for Alphapharm Pty Limited in connection with the above-referenced application. Alphapharm has asked us to clarify that hard copy printouts of plasma Fluoxetine and Norfluoxetine concentration and pharmacokinetic data were included, along with computer diskettes containing the same data, in the Bioequivalency Telephone Amendment delivered to the agency on December 21, 2000. Alphapharm's cover letter dated December 18, 2000 (which was included in the Amendment) made reference to the computer diskettes, but did not refer to the hard copy printouts.

Please contact me with any questions concerning this letter.

Sincerely,

Christina M. Markus

cc: Brett Mooney, Ph.D., Alphapharm Pty Ltd
Eugene M. Pfeifer, King & Spalding

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FACSIMILE: 713/751-3290

ALPHAPHARM
PHARMACEUTICALS

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Manufacturing
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CAROLE PARK
QLD 4300
Tel 07 3271 3244
Fax 07 3271 5037

18th December 2000

Dr Dale P. Conner
Director, Division of Bioequivalence
OFFICE OF GENERIC DRUGS,
Document Control Room,
Metro Park North II,
7500 Standish Place, Room 150,
***Rockville**, MD 20855-2773*
USA

NEW CORRESP
NA/Bio

Dear Dr Conner,

Re: Bioequivalency Telephone Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA #75-755.

Further to the telephone request for computer diskettes containing the pharmacokinetic statistical analysis for the comparative bioavailability study (study number 00-354), we enclose a Bioequivalency Telephone Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA # 75-755.

The computer diskette included in the enclosed Bioequivalency Telephone Amendment, contains plasma Fluoxetine and Norfluoxetine concentrations and pharmacokinetic data for the following comparative bioavailability study.

- *An Open Label, Single-Dose, 2-Way Randomized Crossover Study to Determine the Relative Bioavailability of Two Formulations of Fluoxetine Hydrochloride, 20 mg, in Normal, Healthy, Male Subjects, Under Fasting Conditions (Study Number 00-354)*

Please find enclosed two complete copies of this amendment – an Archival copy (Blue Folder) and a Pharmacokinetic Copy (Orange Folder). Each of these two copies contains a computer diskette. A signed Certification of the Field copy (Orange Folder) as a true copy of the Bioequivalency Telephone Amendment is also included.

The Form FDA 356h, signed by our U.S. agent, King and Spalding, is also included.

CENTER FOR DRUG
DEC 21 2000
OGD
EVALUATION AND RESEARCH

Should you have any further questions regarding this Bioequivalency Telephone Amendment, please do not hesitate to contact our agent, King and Spalding.

Yours sincerely,
Alphapharm Pty Ltd

Brett Mooney Ph.D.
Senior Manager (Reasearch & Development)

Encl.

alphapharm

R&D Fax No. +61 7 3000-6398

26th April, 2001

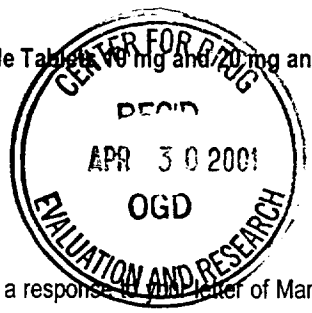
labeling review
drafted 5/8/01
A. Vezza

ORIG AMENDMENT

N/A

Ms Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs– HFD-600
Centre for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 USA

Re: ANDA # 75-755
Minor Amendment for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg and
Notice of Patent Amendment



Dear Ms Fang,

We refer to your deficiency letter of April 19, 2001, seeking a response to your letter of March 16, 2001. In reply, we enclose a Minor Amendment for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg ANDA # 75-755. This amendment removes the bulimia nervosa indication and all associated text from the package insert for Fluoxetine Hydrochloride Tablets 10 mg and 20 mg. The text changes made to remove this indication from our package insert are based on discussion between Christina Markus (a representative of our Agent, King and Spalding) and Mr. Adolph Vezza, of OGD's Labeling Review Branch.

In association with this amendment, we have also added a Statement of Inapplicable Use under Section 505 (j) (2) (A) (viii) to our current Patent Certification.

This amendment is submitted on our behalf by our Agent, King and Spalding. Three copies of the amendment have been enclosed: an Archival copy (Blue Folder), a Chemistry Section (Red Folder) and a Field Copy (Burgundy Folder). A signed certification of these Field copies as true copies of this amendment has also been included. Secured in plastic sleeves in the Archival copy (Blue Folder) are twelve copies of the final package insert, along with four copies of the side by side comparison of the proposed package insert versus our last submitted text.

5/7/01

We request that all information in this file be treated as confidential within the meaning of 21 §CFR 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorised member of your Office.

If you should have any questions regarding the information in this submission, please do not hesitate to contact our Agent, King and Spalding.

Yours sincerely,

Alphapharm Pty Ltd

G H Napier Munn

Georgina Napier-Munn

Regulatory Affairs Manager (R&D)

Encl.

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CAROLE PARK
QLD 4300
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Fax 07 3271 5037

1st December 2000

Dr Dale P. Conner
Director, Division of Bioequivalence
OFFICE OF GENERIC DRUGS,
Document Control Room,
Metro Park North II,
7500 Standish Place, Room 150,
***Rockville**, MD 20855-2773*
USA

NDA ORIG AMENDMENT
N/AB

Dear Dr Conner,

Re: Bioequivalency Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA #75-755.

Further to your correspondence of 3rd May 2000, detailing the comments and deficiencies pertaining to the above ANDA, we enclose a Bioequivalency Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA # 75-755.

The comments and deficiencies in the Bioequivalence section have been addressed in the enclosed Bioequivalency Amendment.

Please find enclosed two complete copies of this amendment – an Archival copy (Blue Folder) and a Pharmacokinetic Copy (Orange Folder). A signed Certification of the Field copy (Orange Folder) as a true copy of the Bioequivalency Amendment is also included.

A copy of the deficiency letter and the FDA Form 356h, signed by our U.S. agent, King and Spalding, are included.

We recently changed our agent from Par Pharmaceutical Inc. to King and Spalding. A letter appointing King and Spalding as our agent is attached. Should you have any further questions regarding this Bioequivalency Amendment, please do not hesitate to contact our agent.

Yours sincerely,
Alphapharm Pty Ltd

Georgina Napier-Munn
Head of Regulatory Affairs (R & D)

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RECD
DEC 04 2000
OGD
EVALUATION AND RESEARCH

Encl.

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1st December 2000

Dr Dale P. Conner
Director, Division of Bioequivalence
OFFICE OF GENERIC DRUGS,
Document Control Room,
Metro Park North II,
7500 Standish Place, Room 150,
***Rockville**, MD 20855-2773*
USA

Re: Bioequivalency Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA #75-755.

Dear Dr Conner,

This is to advise you that Alphapharm Pty Ltd has now appointed King and Spalding, 1730 Pennsylvania Avenue, Washington D.C. 20006-4706, as its U.S. Agent and that Eugene Pfeifer and Christina Markus are authorised to personally represent Alphapharm Pty Ltd in connection with this application and associated regulatory matters until further notice.

Alphapharm Pty Ltd will no longer use Par Pharmaceutical Inc., One Ram Ridge Road, Spring Valley NY 10977, as their agent for the above ANDA.

Yours sincerely,
Alphapharm Pty Ltd

G Napier Munn

Georgina Napier-Munn.
Head of Regulatory Affairs (R & D)

ALPHAPHARM
PHARMACEUTICALS

8th September 2000

Labeling review drafted 9/21/00 A. Vega

NDA ORIG AMENDMENT
N/AC

Florence Fang
Director, Division of Chemistry II
OFFICE OF GENERIC DRUGS,
Document Control Room,
Metro Park North II,
7500 Standish Place, Room 150,
***Rockville**, MD 20855-2773*
USA

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Dear Ms Fang,

Re: Major Amendment for Fluoxetine Tablets 10 mg and 20 mg ANDA #75-755.

Further to your correspondence of 16 June 2000, detailing the comments and deficiencies pertaining to the above ANDA, we enclose a Major Amendment for Fluoxetine Tablets 10 mg and 20 mg.

The comments and deficiencies in the Chemistry Section and Labelling Section have been addressed in the enclosed Major Amendment.

Please find enclosed three complete copies of this amendment – an Archival copy (Blue Folder), a Chemistry Copy (Red Folder) and a Field Copy (Maroon Folder). Signed Certifications of the Field copies (Red and Maroon Folders) as true copies of the Major Amendment are also included.

In the Archival copy, there is a secure copy of each of the following: final printed labels, final package insert, the side by side comparison of Alphapharm's revised package insert and the original package insert with annotated differences. Also attached to this folder (in plastic sleeves) are 12 copies of the final printed labels and final package inserts and 4 copies of the side by side comparison with annotated differences.

A copy of the deficiency letter and the FDA Form 356h, signed by our U.S. agent, Par Pharmaceutical Inc., are included.

Should you have any further questions regarding this Major Amendment, please do not hesitate to contact our agent, Par Pharmaceutical, Inc..

Yours sincerely,
Alphapharm Pty. Limited

Brett Mooney, Ph.D.,
Senior Manager Research and Development

Encl.

ALPHAPHARM

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Certification of the Field Copy of the Major Amendment to ANDA #75-755

Alphapharm Pty. Ltd. herewith certifies that the Field copy (Red folder) of the Major Amendment to the Abbreviated New Drug Application for Fluoxetine Tablets 10 mg and 20 mg, ANDA #75-755 is a true copy of the Major Amendment.

Elaine Lobley
Regulatory Affairs Associate (R.&D.)

Dated 8/9/00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Reddy-Cheminor, Inc.
Attention: Paul V. Campanelli
66 South Maple Avenue
Ridgewood, New Jersey, 07450

Reference Number: OGD 99-221

Dear Mr. Campanelli:

This letter is in response to your correspondence dated June 4, 1999. You request that the Office of Generic Drugs (OGD) provide advice regarding your approach to demonstrate bioequivalence for Fluoxetine Hydrochloride Tablets, 10 mg and 20 mg. You state that the reference listed drug for this product is not being marketed for the 20 mg strength. You propose to demonstrate bioequivalence with Fluoxetine Hydrochloride Tablets, 10 mg and request a waiver of in vivo bioequivalence for the 20 mg strength. OGD provides the following comments:

1. The proposal to request a waiver of *in vivo* bioequivalence studies for Fluoxetine Hydrochloride Tablets, 20 mg is not acceptable to OGD.

2. A single-dose fasting comparative bioavailability study should be conducted on the proposed formulation of Fluoxetine Hydrochloride Tablets, 20 mg using Prozac® (Fluoxetine Hydrochloride) Capsules, 20 mg as the comparator drug for bioavailability purposes only.

3. A single-dose fasting bioequivalence study should be conducted on the proposed formulation of Fluoxetine Hydrochloride Tablets, 10 mg using the currently listed reference drug, Prozac® (Fluoxetine Hydrochloride) Tablets, 10 mg.

4. A food study is recommended for Fluoxetine Hydrochloride Tablets, 10 mg to demonstrate that the proposed drug product will behave similarly to Prozac® under non-fasting conditions. Please be advised that the Draft Guidance for Industry: Food-Effect Bioavailability and Bioequivalence Studies issued December 30, 1997, is for comment purposes only and has not been finalized. Our previous criteria for a limited food-study effect have not changed.

5 When submitting an ANDA that refers to a drug that has been discontinued from marketing, or a drug that has been approved but not marketed, the ANDA must be accompanied by a citizen petition as outlined under 21 C.F.R. § 314.122. The citizen petition is necessary to obtain the Agency's determination that the listed drug was not withdrawn or discontinued due to safety or effectiveness reasons.

6. Reddy-Cheminor should be advised that it is assuming a risk by submitting an ANDA that references the approved but not marketed dosage form of Fluoxetine Hydrochloride Tablets, 20 mg. If Eli Lilly begins to market the discontinued 20 mg tablet, the FDA may request that Reddy-Cheminor conduct a bioequivalence study using the marketed Prozac® (Fluoxetine Hydrochloride) Tablets, 20 mg. If Reddy-Cheminor does not conduct the requested bioequivalence study the therapeutic equivalence evaluation code for the Reddy-Cheminor product, Fluoxetine Hydrochloride Tablets, 20 mg, may be listed as BX in the publication Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

If you have any questions, please call Ms. Cecelia Parise, R.Ph., Special Assistant to the Director, at (301) 827-5845. In future correspondence regarding this issue, please include a copy of this letter.

Sincerely yours,

/S/

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-755

Par Pharmaceutical Inc.,
U.S. Agent for: Alphapharm Pty. Ltd.
Attention: Dr. Robert Femia
One Ram Ridge Road,
Spring Valley, NY. 10977

FEB 4

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Fluoxetine Hydrochloride Tablets, 10 mg (base)

DATE OF APPLICATION: December 6, 1999

DATE (RECEIVED) ACCEPTABLE FOR FILING: December 17, 1999

You have filed a Paragraph IV patent certification, in accordance with 21 CFR 314.94(a)(12)(i)(A)(4) and Section 505(j)(2)(A)(vii)(IV) of the Act. Please be aware that you need to comply with the notice requirements, as outlined below. In order to facilitate review of this application, we suggest that you follow the outlined procedures below:

CONTENTS OF THE NOTICE

You must cite section 505(j)(2)(B)(ii) of the Act in the notice and should include, but not be limited to, the information as described in 21 CFR 314.95(c).

SENDING THE NOTICE

In accordance with 21 CFR 314.95(a):

- Send notice by U.S. registered or certified mail with return receipt requested to each of the following:

  1) Each owner of the patent or the representative designated by the owner to receive the notice;

2) The holder of the approved application under section 505(b) of the Act for the listed drug claimed by the patent and for which the applicant is seeking approval.

3) An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

DOCUMENTATION OF NOTIFICATION/RECEIPT OF NOTICE

You must submit an amendment to this application with the following:

- In accordance with 21 CFR 314.95(b), provide a statement certifying that the notice has been provided to each person identified under 314.95(a) and that notice met the content requirements under 314.95(c).

- In accordance with 21 CFR 314.95(e), provide documentation of receipt of notice by providing a copy of the return receipt or a letter acknowledging receipt by each person provided the notice.

- A designation on the exterior of the envelope and above the body of the cover letter should clearly state "PATENT AMENDMENT". This amendment should be submitted to your application as soon as documentation of receipt by the patent owner and patent holder is received.

DOCUMENTATION OF LITIGATION/SETTLEMENT OUTCOME

You are requested to submit an amendment to this application that is plainly marked on the cover sheet "PATENT AMENDMENT" with the following:

- If litigation occurs within the 45-day period as provided for in section 505(j)(4)(B)(iii) of the Act, we ask that you provide a copy of the pertinent notification.

- Although 21 CFR 314.95(f) states that the FDA will presume the notice to be complete and sufficient, we ask that if you are not sued within the 45-day period, that you provide a letter immediately after the 45 day period elapses, stating that no legal action was taken by each person provided notice.

- You must submit a copy of a final order or judgement from which no appeal may be taken (which might not be the one from the District Court), or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information. We ask that this information be submitted promptly to the application.

If you have further questions you may contact Nasser Mahmud, Chief, Regulatory Support Branch, at (301)827-5862.

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Tim Ames
Project Manager
(301) 827-5862

Sincerely yours,

/S/

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-755
DUP/Jacket
Division File
Field Copy
HFD-610/R.West
HFD-610/P.Rickman
HFD-92
HFD-615/M.Bennett

Endorsement: HFD-615/NMahmud, Chief, RSB /S/ date 2/4/00
HFD-615,PPatel, CSO /S/ date 2/3/00
HFD-600, UVenkataram, Sup. Chem. _____ date
Word File V:\Firmsam\Alphapha\ltrs&rev\75755.ack
FT/mjl/2/3/00
ANDA Acknowledgment Letter!

ALPHAPHARM

PHARMACEUTICALS

6th December 1999

Labeling review completed 2/18/00 ALZ

N 75-762

ALPHAPHARM
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Dr. D. L. Sporn,
Director of Generic Drugs,
Office of Generic Drugs,
Centre for Drug Evaluation and Research,
Food and Drug Administration
Metro Park North II,
7500 Standish Place, Room 600,
***ROCKVILLE**, MD 20855*
USA

Re: Original Abbreviated New Drug Application for Fluoxetine Tablets 10 mg

Dear Dr. Sporn,

Pursuant to Section 505 (j) of the Food, Drug and Cosmetics Act, Alphapharm Pty. Ltd. herewith submits an Abbreviated New Drug Application for Fluoxetine Tablets 10 mg. This Application is submitted on our behalf by our agent, Par Pharmaceutical Inc.. A letter appointing Par Pharmaceutical Inc. as our Agent in the United States immediately follows this cover letter.

In support of this Application, the information outlined below is provided:

1) *Patent Certification.*

2) *Form F.D.A. 356h , signed by our Agent, Par Pharmaceutical Inc.*

3) *Form F.D.A. 3454 - Certification: Financial Interests and Arrangements of Clinical Investigators.*

4) *Index.*

5) *Chemistry, Manufacturing and Controls Information.*

6) *Draft Labels/Labelling and Package Insert. (The additional 4 copies of the Draft Labels/Labelling, Package Insert and Side by Side Comparison with annotations explaining the differences are presented in plastic sleeves in the Archival folder section 5 labelled accordingly).*

7) *Methods Validation Package : one copy in the Archival (Blue Folder), one copy in the Review (Red Folder) and one copy in the Field Submission Chemistry (Maroon Folder).*
The Analytical Methods and Methods Validation for Fluoxetine Tablets 10 mg contained in section 16 of the ANDA are also presented in 3 copies (one copy in each Maroon Folder - Field Submission Chemistry Section) for use at FDA Laboratories.

8) *Bioavailability Study for Fluoxetine Tablets 10 mg.*

   a) *An Open Label, 2-Way Randomized Crossover Comparative Fasting Bioavailability Study of Fluoxetine Hydrochloride 10 mg Tablets In Healthy Male Volunteers (Study Number 436-99-202) .*

   b) *An Open Label, 3-Way Randomized Crossover Comparative Food Effect Bioavailability Study of Fluoxetine Hydrochloride 10 mg Tablets in Healthy Male Volunteers (Study Number 436-99-199).*

Included in the Pharmacokinetic Section are 2 diskettes containing plasma Fluoxetine and Norfluoxetine concentrations and pharmacokinetic data for the fed and fasting studies. This information can be found in the files entitled "Fluoxetine202_PK.txt" and Norfluoxetine202_PK.txt" for the study under fasting conditions and "Fluoxetine199_PK.txt" and Norfluoxetine199_PK.txt" for the study under fed conditions.

Enclosed please find three copies of this application. An Archival copy (Blue Folder), a Review copy divided into two parts: a Chemistry, Manufacturing and Controls data part (Red Folder) and a Bioavailability/bioequivalence data part (Orange Folder) and a Field Submission copy (Maroon Folder) of the Chemistry, Manufacturing and Controls Information, for use prior to Preapproval Inspections.
Three copies of Section 16 of the ANDA are also included in Field Submission Chemistry Section Folders (Maroon Folder) labelled appropriately.

We request that all information in this file be treated as confidential within the meaning of 21 CFR section 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorised member of your Office.

If you should have any questions regarding the information in this submission, please do not hesitate to contact our Agent, Par Pharmaceutical Inc.

Yours Sincerely,
Alphapharm Pty. Ltd.

Brett Mooney Ph. D.,
RESEARCH and DEVELOPMENT MANAGER

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6th December 1999

Dr. D. L. Sporn,
Director of Generic Drugs,
Office of Generic Drugs,
Centre for Drug Evaluation and Research,
Food and Drug Administration
Metro Park North II,
7500 Standish Place, Room 600,
***ROCKVILLE**, MD 20855*
USA

Re: Original Abbreviated New Drug Application for Fluoxetine Tablets 10 mg

Dear Dr. Sporn,

This is to advise that Alphapharm Pty. Ltd. has nominated and appointed Par Pharmaceutical Inc., One Ram Ridge Road, Spring Valley, New York, NY 10977, as its U.S. Agent and that Dr Robert Femia and other counsel at Par Pharmaceutical Inc. are authorised to personally represent Alphapharm Pty. Ltd. in connection with this application and regulatory matters until further notice.

Yours sincerely
Alphapharm Pty. Ltd.

Mooney

Brett Mooney, Ph.D.,
Research and Development Manager