CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020974

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

PROZAC® (fluoxetine hydrochloride)
10 mg and 20 mg Tablets

PATENT INFORMATION

The undersigned declares that the following patents cover the formulation, composition, and/or method of use of fluoxetine hydrochloride, as indicated. This product is the subject of this application for which approval is being sought:

Patent No.	Expiration Date	Claim Type
4,314,081	February 2, 2001	composition
4,626,549	December 2, 2003	methods

The above patents are all owned by or exclusively licensed by Eli Lilly and Company, Indianapolis, Indiana.

EXCLUSIVITY SUMMARY for NDA # 20-974 SUPPL # _____

Trade Name Prozac Generic Name Fluoxetine HCL 10 mg and 20 mg Tablets

Applicant Name Eli Lilly HFD-120

Approval Date 3-8-99

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "YES" to one or more of the following questions about the submission.

   a) Is it an original NDA? YES /_X_/ NO /___/

   b) Is it an effectiveness supplement? YES /___/ NO /_X_/

      If yes, what type(SE1, SE2, etc.)? _____

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "NO.")

      YES /__/ NO /_X__/

   If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

   Prozac is currently approved to treat depression, OCD, and Bulimia Nervosa. The approved formulations for Prozac are 10 mg and 20 mg capsules as well as a 20 mg/5 ml solution. This application was solely a bioequivalency study comparing their approved capsule formulation to the tablet formulation.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

_____

_____

d) Did the applicant request exclusivity?

YES /___/ NO /_X_/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

_____

_____

e) Has pediatric exclusivity been granted for this Active Moiety?

YES /___/ NO /_X_/

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use?

YES /___/ NO /_X/

If yes, NDA # _____ Drug Name _____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

3. Is this drug product or indication a DESI upgrade?

YES /___/ . NO /_X_/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /X__/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # 18-936 Prozac (fluoxetine HCL) Capsules

NDA # 20-101 Prozac (fluoxetine HCL) Solution

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active

moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /_x__/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9. IF "YES," GO TO PART III.

PART III <u>THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS</u>

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /___/ NO /_x__/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /___/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval **AND GO DIRECTLY TO SIGNATURE BLOCK ON Page 9:**

_____

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

_____

© If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study #_____

Investigation #2, Study # _____

Investigation #3, Study # _____

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does

not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NDA # _____ Study # _____
NDA # _____ Study # _____
NDA # _____ Study # _____

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ON ORIGINAL

b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:

NDA # _____ Study # _____

NDA # _____ Study # _____

NDA # _____ Study # _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #___, Study #_____

Investigation #___, Study #_____

Investigation #__, Study # _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily,

substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1

IND #_____ YES /X__/ ! NO /___/ Explain: _____

! _____

! _____

Investigation #2

IND # ___ YES /_ _/ ! NO /___/ Explain: _____

! _____

! _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?
N/A

Investigation #1

YES /___/ Explain _____ ! NO /___/ Explain _____

_____ ! _____

_____ ! _____

Investigation #2

YES /___/ Explain _____

_____

_____

NO /___/ Explain _____

_____

_____

- Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /_ _/

If yes, explain: _____

_____

_____

/S/ 3-2-99

Signature of preparer Date

Title: Project Manager

/S/ 3/9/99

Signature of Division Director Date

cc:
Archival NDA 20-974
HFD-120/Division File
HFD-120/PDavid
HFD-85/Mary Ann Holovac

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Form OGD-011347
Revised 8/7/95; edited 8/8/95; revised 8/25/98

CERTIFICATION

NDA Application No.: 20-974

Drug Name: Prozac®

Pursuant to the provisions of 21 U.S.C. 335a(k)(1), Eli Lilly and Company, through Gregory T. Brophy, Ph.D., hereby certifies that it did not and will not use in any capacity the services of any person debarred under Section (a) or (b) [21 U.S.C. 335a(a) or (b)] of the Generic Drug Enforcement Act of 1992, in connection with the above referenced application.

ELI LILLY AND COMPANY

By: _____
Gregory T. Brophy, Ph.D.

Title: Director, U.S. Regulatory Affairs

Date: March 19, 1998

MEMO OF TELEPHONE CALL

Date: March 9, 1999
NDA: 20-974
Subject: Dissolution Methods and Specifications for Prozac Tablets
Firm: Eli Lilly
Drug: Prozac (fluoxetine HCl) Tablets
Contact: Reed Tarwater, Drug Regulatory Affairs
Phone #: (317) 276-4952

At the request of Dr. Katz, I contacted Dr. Tarwater to secure agreement for the dissolution methods and specifications of the Prozac 10 mg and 20 mg tablets requested by OCPB. They are as follows:

Apparatus:	USP Dissolution Apparatus I at 100 rpm
Media:	Deaerated 0.1 N HCL of 1000 ml at 37°C
Specification:	Q = at 15 minutes

This differs only in that the specifications proposed by Lilly changed from "Q = , at 30 minutes" to "Q at 15 minutes".

Dr. Tarwater left a message on my voice mail stating that Lilly agreed to the above.

/S/

Paul A. David, R.Ph.
Regulatory Project Manager

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ON ORIGINAL

NDA:ORIG 20-974
IND:DIV FILE
HFD-120/RKatz/TLaughren
HFD-120/PDavid
HFD-860/CSahajwalla/RYuan
DOC

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ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac 10mg and 20mg Tablets
DATE:	May 8 & 12, 1998
CONVERSATION WITH:	Dr. Brophy, Director, Regulatory Affairs; Mr. Dave Johnson, Regulatory Scientist
FIRM NAME:	Eli Lilly; Dr. Tarwater, Regulatory Affairs.
SUBJECT:	Question about proposed expiration period
PHONE#:	(317)277-3799

2:36PM-2:39,(5/8/98): I called Dr. Brophy and left a phonemail message requesting clarification of the proposed expiration period for the 10mg and 20mg tablets.
4:03-4:04PM,(5/8/98): Mr. Johnson returned my call to Dr. Brophy and Mr. Johnson stated that the proposed expiration period is 24 months.
1:15PM,(5/12/98): Dr. Tarwater called and left the following phone message: He called to confirm that the expiration dating period is 24 months.

/S/ 5/12/98

APPEARS THIS WAY
ON ORIGINAL

Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File:

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac 10mg and 20mg Tablets
DATE:	May 28 & 29, 1998
CONVERSATION WITH:	Mr. Dave Johnson, Regulatory Scientist Ms. Barb Unger, Associate Regulatory Consultant in the CMC Regulatory Section
FIRM NAME:	Eli Lilly
SUBJECT:	Request to discuss container/closure request
PHONE#:	Mr. Johnson: (317)277-1806 Ms. Unger: (317)277-2892

9:45AM-9:48AM, (5/28/98): At the suggestion of Mr. Paul David, Project Manger, I called Mr. Johnson to discuss my request for examples of the container/closure system and he told me that Ms. Barb Unger would like to discuss with me my request for examples of the container/closure systems in NDA 20-974. Ms. Unger will be calling me.

Approx. 1:35PM, (5/28/98): Ms. Unger called and I told her that it would be helpful in reviewing NDA 20-974 if Eli Lilly provided examples of the container/closure system. She stated she would be check with the packaging department and call me back. I also asked if the CMC section was available electronically. Ms. Unger stated that the CMC section wasn't available electronically.

5:03PM-5:04PM, (5/28/98): I left the following phonemail message with Ms. Unger: I have questions about the tables on pages 17 and 18 in Vol. 1.2 and the table on page 121 in Vol. 1.3.

11:10AM, (5/29/98): Ms. Unger called and left a phonemail message stating that she was returning my call.

11:21-11:25AM, (5/29/98): I called Ms. Unger and asked the following questions: **1**. Refer to the tables on page 17 and 18 in Volume 1.2: Are the blank spaces under the "Reasonable Variations" meant to show that there are no variations for those specific ingredients? **Answer: That is correct. 2**. Refer to tables on pages 120 and 121 in Volume 1.3: Under "Package Description, Bottles," is a typo and it should be **Answer: That is correct.**

Ms. Unger told me that Eli Lilly would be providing the container/closure systems described in NDA 20-974. I told her how to mail the container/closure systems to me.

/S/ 5/29/98
Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File:

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac® 10mg and 20mg Tablets
DATE:	June 4 and 8, 1998
CONVERSATION WITH:	Ms. Barb Unger, Associate Regulatory Consultant in the CMC Regulatory Section
FIRM NAME:	Eli Lilly
SUBJECT:	Follow-up to request for the container-closure system
PHONE#:	Ms. Unger: (317)277-2892

6:25PM,(6/4/98): Ms. Unger called and left the following phonemail message: Examples of the container-closure system would be shipped to me on 6/5/98. A copy of the amendment would also be included.

6/8/98: Received the examples of the container/closure system and the listed is attached along with a copy of the NDA amendment to be filed to NDA 20-974.

10:21AM-10:23AM,(6/8/98): I called Ms. Unger to thank her for the examples of the container/closure system I received this morning. On page 2 of the amendment there is a reference to DMF ____ and I asked if this should be DMF ____. **Ms. Unger's answer: Correct, it should be DMF ____**

/S/ 6/8/98

Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File: ____

APPEARS THIS WAY
ON ORIGINAL

Received on 6/8/98

Lilly

Lilly Research Laboratories
A Division of Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-2000

June 5, 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological
Drug Products, HFD-120
5600 Fishers Lane
Rockville, MD 20857-1706

RE: NDA 20-974 Prozac, Fluoxetine HCl

This NDA amendment provides the following information:

1. Details about closures sent to the chemistry reviewer under separate cover, and
2. Correction to original NDA submission regarding the supplier of screw cap container closures.

If you have any questions please call either Barbara Unger at (317)-277-2892 or me at (317) 276-0368.

Sincerely,

ELI LILLY AND COMPANY

for: Tobias Massa Ph.D.
Director Regulatory Affairs,
Chemistry, Manufacturing and Control

Received on 6/8/98

NDA 20-974
Amendment, CMC
Eli Lilly and Company

NOTE TO REVIEWER

This NDA amendment contains the following information:

SECTION	INFORMATION
1.	At the request of the reviewing chemist, Dr. Donald Klein, examples of container closures described in the NDA are being provided. These example container closures are being shipped directly to Dr. Klein under separate cover
2.	In the original NDA, screw caps were inadvertantly identified as being supplied by Both container closures are actually supplied by Inc. and are covered under DMF respectively. A corrected page is provided in this amendment.

DMF ? should be (checked with Ms. Unger on 6/8/98)

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac® 10mg and 20mg Tablets
DATE:	July 23, 24, 29, & 30, 1998 August 3, 1998
CONVERSATION WITH:	Ms. Barb Unger, Associate Regulatory Consultant in the CMC Regulatory Section
FIRM NAME:	Eli Lilly
SUBJECT:	Question regarding the use of blister packaging
PHONE#:	Ms. Unger: (317)277-2892

2:22PM-2:31PM(7/23/98): I called Ms. Unger to request clarification regarding the possible packaging of the Prozac® Tablets in blister packaging. I referred to page 121 in Volume 1.1 where it states that the Prozac® tablets may be packaged into the blisters. I told Ms. Unger that I needed to know if the Prozac tablets are or are not being packaged in blister packaging. I pointed-out to Ms. Unger that if the Prozac tablets are not packaged in blister packaging, then there is no reason for me to review the DMFs that are referenced in the NDA. Ms. Unger stated she would let me know if the Prozac® tablets will be packaged in blisters.
Ms. Unger told me that Eli Lilly would be submitting additional stability data probably by mid-August, 1998. She asked how I wanted this information submitted and I told her that I would prefer that the additional stability data be submitted in the same format as in the original NDA. She asked if I wanted the statistical analysis of the updated stability data and I told her that it was Eli Lilly's decision if the statistical analysis is submitted.

After 4:26PM(7/23/98): Ms. Unger left a phone message stating that Eli Lilly has decided that the Prozac tablets will be packaged in blister packaging.

1:15PM-1:17PM(7/24/98): I called Ms. Unger and left the following phone message: Please submit an amendment to NDA 20-974 stating that Eli Lilly has decided to market the Prozac tablets in the blister packaging. I also requested that a copy be faxed to me directly.

7/29/98: Fax received from Ms. Unger. Section of the fax entitled, "Modifications to Information in Original NDA 20-974 Submission" and "Clarification of Intent to Market Blister Packaged 10mg and 20mg Tablets of Fluoxetine Hydrochloride". Fax attached.

9:50AM-9:51AM(7/30/98): I left the following phone message with Ms. Unger: I have follow-up questions to the 7/29/98 fax.

2:08-2:10PM(7/30/98): Ms. Unger called and I asked the following questions: 1. Page 209 in Vol. 1.5: there is no ID# stating that it is deviation report # IL0614. Provide the location of the deviation report IL0694 referred to in the 7/29/98 fax.

Ms. Unger had to retrieve the information and call back.

6:00PM(7/30/98): Ms. Unger called and stated the following: The fax is incorrect, IL0694 and IL0614 should be IM0694 and IM0614. IM0614 affects all the lots(D20554, D20555, D20556, D20577, D20578, and D20579) and IM0694 affects only lot D20556. Ms. Unger will submit an amendment to the NDA correcting this error.

8/3/98: 4 page fax received. Fax attached.

APPEARS THIS WAY
ON ORIGINAL

/S/ 8/15/98
Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File:

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac® 10mg and 20mg Tablets
DATE:	August 15, 19, & 21, 1998
CONVERSATION WITH:	Ms. Barb Unger, Associate Regulatory Consultant in the CMC Regulatory Section; Ms. Cheryl Clemens, CMC Regulatory Affairs
FIRM NAME:	Eli Lilly
SUBJECT:	Questions pertaining to the Eli Lilly 7/29/98 fax
PHONE#:	Ms. Unger: (317)277-2892

8/15/98: I faxed the attached fax. The fax contained questions pertaining to Section II.A in the Eli Lilly 7/29/98 fax.

12:25PM(8/19/98): I called Ms. Unger and left the following phone message: Was the 8/15/98 fax received?

12:45PM(8/19/98): Ms. Unger called; 8/15/98 fax received.

8/21/98: Fax received from Ms. Unger. Fax attached.

APPEARS THIS WAY
ON ORIGINAL

/S/ 8/25/98

Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File:

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac® 10mg and 20mg Tablets
DATE:	August 17 and 26, 1998
CONVERSATION WITH:	Dr. Tarwater, Regulatory Affairs
FIRM NAME:	Eli Lilly
SUBJECT:	CMC Information request
PHONE#:	(317)276-4952

8/17/98: At the request of Don Klein, Mr. Paul David,R.Ph., Project Manager, contacted Eli Lilly and requested the following:

a. A copy of the fluoxetine hydrochloride drug substance specifications at the time of the NDA 18-936 approval.

b. A copy of the fluoxetine hydrochloride drug substance most recent revised specifications prior to the USP 11/15/97 monograph.

8/26/98: Fax received from Eli Lilly. Fax attached.

APPEARS THIS WAY
ON ORIGINAL

/S/

Donald N. Klein, Ph.D.
Review Chemist
HFD-120

10/7/98

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File:

APPEARS THIS WAY
ON ORIGINAL

Lilly

Lilly Research Laboratories
A Division of Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-2000

August 26, 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological
Drug Products, HFD-120
Attn.: Document Control Room
5600 Fishers Lane
Rockville, MD 20857-1706

Re: NDA 20-974; 10 & 20-mg Prozac® Tablets

Enclosed is a copy of the information requested by Mr. Paul David of the FDA in a phone call to Dr. Tarwater of Lilly on Monday 17 August 1998.

Please contact either Dr. Reed Tarwater at (317) 276-4952, or me at (317) 277-3799 if you have any questions. Thank you for your continued cooperation and assistance.

Sincerely

ELI LILLY AND COMPANY

Gregory T. Brophy, Ph.D.
Director
U.S. Regulatory Affairs,

cc: Mr. Paul David (FDA)

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac® 10mg and 20mg Tablets
DATE:	September 4, 1998
CONVERSATION WITH:	Ms. Barb Unger, Associate Regulatory Consultant in the CMC Regulatory Section
FIRM NAME:	Eli Lilly
SUBJECT:	CMC Questions
PHONE#:	Ms. Unger: (317)277-2892

2:28PM(9/4/98): I called Ms. Unger and told her that I would be faxing to her CMC questions that primarily pertained to the method validation Volume 1.6. Fax attached. Ms. Unger told me that the additional stability data would be submitted to the NDA by the end of September.

APPEARS THIS WAY
ON ORIGINAL

/S/ 10/6/98
Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File: [redacted] 74TC97.doc

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELEPHONE CONVERSATION

NDA#:	20-974
PRODUCT NAME:	Prozac® 10mg and 20mg Tablets
DATE:	November 13, 16, & 20, 1998
CONVERSATION WITH:	Ms. Barb Unger, Regulatory Affairs
FIRM NAME:	Eli Lilly
SUBJECT:	Information describing the bottles?; updated LOA for DMF
PHONE#:	(317)277-2892

11:34AM,(11/13/98): I left the following phone message: When will the information describing the bottles be submitted to NDA 20-974?

6:50AM,(11/16/98): Ms. Unger left a phone message stating that the information describing the bottles should be provided to me by 11/20/98. The information will initially be provided by fax.

3:14PM,(11/16/98): I left a phone message with Ms. Unger: Please provide an updated LOA for DMF because as of November, 1997 the company change the name to

11:10AM,(11/20/98): Ms. Unger called to make sure that I received the fax.

/S/ 11/23/98

APPEARS THIS WAY
ON ORIGINAL

Donald N. Klein, Ph.D.
Review Chemist
HFD-120

cc:
NDA 20-974
HFD-120/Division File
HFD-120/DKlein
HFD-120/PDavid
File:

APPEARS THIS WAY
ON ORIGINAL

NDA 20-974

APR 1 1998

Lilly Research Laboratories
Attention: Gregory T. Brophy, Ph.D.
Director Regulatory Affairs
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Brophy:

We have received your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Prozac (fluoxetine hydrochloride) 10 mg and 20 mg Tablets
Therapeutic Classification:	Standard
Date of Application:	March 19, 1998
Date of Receipt:	March 20, 1998
Our Reference Number:	20-974

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 22, 1998 in accordance with 21 CFR 314.101(a).

If you have any questions, please contact Paul David, R.Ph., Project Manager, at (301) 594-5530.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

/S/

Paul Leber, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I