Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue NW
Washington, D.C. 20004
Tel. 202.739.3000
Fax: 202.739.3001
eFax: 877.432.9652
www.morganlewis.com

Morgan Lewis
COUNSELORS AT LAW

FAX MESSAGE

Send To:

Name:	Dockets Management Branch	FAX Number:	301-827-6870
Firm:	Food & Drug Administration Rm 1-23	Telephone Number:	

From:

Name	Donald J. Bird	Floor: 3	Operator Sending:
Telephone Number:	202.739.5320	Time Sent:	Date Sent: June 16, 2003

Number of Pages (INCLUDING COVER PAGE): 7

Note:

THE INFORMATION CONTAINED IN THIS FAX MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE RECIPIENT(S) NAMED ABOVE. THIS MESSAGE MAY BE AN ATTORNEY-CLIENT COMMUNICATION AND AS SUCH IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR AN AGENT RESPONSIBLE FOR DELIVERING IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR AND THAT ANY REVIEW, DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE, AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.

Comments: Request for Revision of Regulatory Review Period
FASLODEX
Docket No. 03-D0030

DO NOT SEND TO CLIENTS – TEAR ALONG DOTTED LINE – THIS PORTION FOR BILLING PURPOSES ONLY

Date Sent:	6/16/03	Attorney Name:	Donald J. Bird
Client Name:	AstraZeneca	Number Pages Transmitted: (including cover page)	8
(1) Fax No.:	301-827-6870		
Client/Matter Number:	056291-5080	☐ Firm Charge (check box if applicable)	
ID #:	13950	Time Sent: 16:24	Receipt Confirmed:

[WA-06]

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: 202.739.3000
Fax: 202.739.3001
www.morganlewis.com

Morgan Lewis
COUNSELORS AT LAW

Donald J. Bird
Partner
202-739-5320
dbird@morganlewis.com

June 16, 2003

VIA FACSIMILE
CONFIRMATION WITH EXHIBITS TO FOLLOW

Dockets Management Branch
(HFA-305), Food & Drug Administration, rm 1-23,
12420 Parklaw Drive
Rockville, MD 20857

Re: Request for Revision of Regulatory Review Period
FASLODEX
Docket No. 03-E0030
Client/Matter No. 056291-5080

Dear Sir:

Applicant on the subject Request for Extension of Patent Term, through undersigned counsel, hereby requests reconsideration and revision of the Regulatory Review Determination published in the Federal Register on April 17, 2003 (F.R. 68, No. 74 at 18992). In accordance with 21 C.F.R. § 60.24(a) the following information is provided:

(1) The Type of Action Requested

It is respectfully requested that the "date and exemption under § 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.P. 355(i)) became effective be corrected from the January 8, 1997 date given in the Notice to the January 5, 1997 dated claimed by applicants, for the reasons detailed below, and that the Regulatory Review Period be recalculated accordingly.

(2) The Identity of the Product

The product for which this regulatory review period was determined is FASOLODEX.

(3) The Identity of the Applicant

The applicant on the Request for Extension of Patent Term is **AstraZeneca UK Ltd.** This Request for Revision is being filed on behalf of applicant.

(4) The FDA Docket Number

The FDA Docket Number is **Docket No. 03E-0030**.

(5) The Basis for the Request for Revision, Including any Documentary Evidence

At page 17 of Applicants' Request for Extension of Patent Term Pursuant to 35 U.S.C. § 156, Applicants stated that the IND application for FASLODEX® (fulvestrant) Injection was submitted on December 6, 1996 and the IND became effective on January 5, 1997. In support of these dates, Applicants attached thereto as Exhibit 5 a letter from the FDA dated December 13, 1996, acknowledging receipt of the IND application on December 6, 1996. A further copy of this letter is attached to this Request as **Exhibit A**. The IND application was hand-delivered to the FDA on December 6, 1966, and a copy of the cover letter under which the IND application was filed was acknowledged and stamped by the Center for Drug Evaluation and Research as having been received on December 6, 1996. A copy of Applicants' cover letter submitting the IND application bearing this received stamp is attached hereto as **Exhibit B**.

It is respectfully submitted that the FDA acknowledgements submitted herewith as **Exhibits A** and **B** clearly establish that the receipt date of Applicants' IND application was December 6, 1996. Since no "clinical hold" was placed on this IND, the effective date of the IND application was 30 days thereafter, that is, January 5, 1997. Applicants therefore request that the regulatory review period determination for FASOLDEX® be revised to correct the **receipt** date to December 6, 1996, and an IND effective date of January 5, 1997.

Applicants further request that the length of the regulatory review period be recalculated to take into the account the corrected IND receipt date.

Sincerely,

Donald J. Byrd

DJB:mk
Attachments

96/278

DEPARTMENT OF HEALTH & HUMAN SERVICES

4 Public Health Service

INDEX 5

Food and Drug Administration
Rockville MD 20857

IND 52,121

Date

DEC 13 1996

Zeneca Pharmaceuticals
A Business Unit of Zeneca Inc.
1800 Concord Pike, PO Box 15437
Wilmington, DE 19850-5437

Attention: Frances M. Kelleher, Ph.D.

Dear Sir or Madam.

We acknowledge receipt of your Investigational New Drug Application (IND) submitted pursuant to Section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 52,121

Sponsor: Zeneca Pharmaceuticals

Name of Drug: Faslodex(ZD9238)

Date of Submission: December 6, 1996

Date of Receipt: December 6, 1996

Studies in humans may not be initiated until 30 days after the date of receipt shown above. If, within the 30-day waiting period, we identify deficiencies in the IND that require correction before human studies begin or that require restriction of human studies until correction, we will notify you immediately that the study may not be initiated ("clinical hold") or that certain restrictions must be placed on it. In the event of such notification, you must continue to withhold, or to restrict, such studies until you have submitted material to correct the deficiencies, and we have notified you that the material you submitted is satisfactory.

It has not been our policy to object to a sponsor, upon receipt of this acknowledgement letter, either obtaining supplies of the investigational drug or shipping it to investigators listed in the IND. However, if drug is shipped to investigators, they should be reminded that studies may not begin under the IND until 30 days after the IND receipt date or later if the IND is placed on clinical hold

Exhibit A

You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the regulations implementing that Act (Title 21 of the Code of Federal Regulations). Those responsibilities include reporting any adverse experience associated with use of the drug that is both serious and unexpected to the FDA as soon as possible and in no event later than 10 working days after initial receipt of the information and reporting any unexpected fatal or life-threatening experience to the FDA by telephone no later than 3 working days after receipt of the information (21 CFR 312.32), and submission of annual progress reports (21 CFR 312.33).

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-150)
Attention: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Should you have any questions concerning this IND, please contact: Leslie Vaccari, Project Manager, at (301) 594-5778.

Sincerely yours,

Chief, Project Management Staff
Division of Oncologic Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

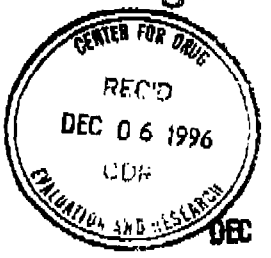
cc: Original IND - pink
HFD-150 - yellow
HFD-150/CSO - green

IND ACKNOWLEDGEMENT

Acknowledgement Letter

ZENECA
Pharmaceuticals
A Business Unit of Zeneca Inc.

1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437



DEC 6 1996

HAND DELIVERED

Signature X
Date 12-06-96

Food and Drug Administration
c/o Central Document Room
12229 Wilkins Avenue
Rockville, MD 20852

Dear Madam/Sir:

Re: FASLODEX® (Zeneca ZD9238) [formerly ICI 182,780]
Investigational New Drug Application

In accordance with 21 CFR §312, Zeneca Pharmaceuticals hereby submit an Investigational New Drug Application (IND) for our product FASLODEX® (ZD9238) [formerly ICI 182,780]. FASLODEX is a pure anti-estrogen being developed for use in treatment of breast cancer.

This IND application is prepared in the format described in Form FDA 1571 and consists of 30 volumes submitted in triplicate.

The initial clinical trial conducted under the IND will be Trial 0021, A Double-Blind, Randomized, Phase II/III Multicenter Trial Comparing the Efficacy and Tolerability of 125 and 250 mg FASLODEX (long acting ICI 182,780) With Anastrozole (ARIMIDEX) 1 mg in Postmenopausal Women With Advanced Breast Cancer.

Please note that the anastrazole tablets will be manufactured and released in accordance with Zeneca's approved ARIMIDEX® (anastrozole) NDA 20-541 (see Item 7 regarding Comparator Drug information). Because of the double-blinded design of the trial, the anastrazole tablets used in this trial will not tagliated.

The information contained in this application is considered confidential. Under the provisions of 21 USC §331(j) and /or 18 USC §1905, we hereby claim confidentiality of this material.

Exhibit B

If you have any questions on this application, please do not hesitate to contact me. In my absence, please contact Dr. Frances M. Kelleher, Manager, Drug Registration at (302) 886-8457.

Sincerely,

E. Jane Valas, Ph.D.
Regulatory Consultant, Drug Registration
Drug Regulatory Affairs Department
(302) 886-2122
(302) 886-2822 (fax)

EJV/jr/4843/49

TRANSMISSION REPORT

(MON) JUN 16 2003 16:24

DOCUMENT #	3560278—655
TIME STORED	06. 16 16:21
TIME SENT	06. 16 16:22
DURATION	1' 42"
DESTINATION	3018276870
DST. TEL#	13950#562915080#13018276870#
MODE	ECM
PAGE(S)	7PAGE(S)
RESULT	OK
DEPARTMENT	