ATTACHMENT TO IMPORT ALERT #66-41

Unapproved new drugs that may be subject to DWPE

Note: The full attachment identifying the products that may be subject to this guidance was not reissued with the text revision of this alert.

DATE: SEPTEMBER 28, 2000

FROM: [redacted] DIVISION OF IMPORT OPERATIONS & POLICY (HFC-170)

SUBJ: REVISION OF THE ATTACHMENT TO IMPORT ALERT #66-41, "UNAPPROVED NEW DRUGS PROMOTED IN THE U.S."

TO: IMPORT PROGRAM MANAGERS

The following product has met the criteria for detention without physical examination:

PRODUCT/ PRODUCT CODE	SOURCE	COUNTRY
Mifepristone 65J[] [] [] []/ 65D[] [] [] []	All	All

FDA has determined that unapproved versions of mifepristone manufactured outside the U.S. are being promoted in this country for use to end pregnancy. Due to the risks to the safety of the user in inadequately controlled settings, mifepristone should be considered inappropriate for release under the Personal Import Guidance. Districts encountering entries of mifepristone should determine whether the importer of record for the article being entered is Danco Laboratories, LLC, New York, New York (distributor of the U.S. approved product) or whether the article is being entered under an IND that is in effect. In such circumstances (when the article is being imported by the distributor of the U.S. approved product or under an IND that is in effect), the article is outside the scope of this guidance.

(Districts should contact CDER for verification of IND status.)

Please add this product to the attachment for Import Alert #66-41.

RECOMMENDED BY: DIOP (HFC-170)

FOI: No purging required

PREPARED BY: DIOP, Operations & Policy Branch

DATE LOADED INTO FIARS: September 28, 2000

/s/

UNIVERSITY OF
ROCHESTER
MEDICAL CENTER

EASTMAN DENTAL CENTER
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
STRONG MEMORIAL HOSPITAL
UNIVERSITY MEDICAL FACULTY GROUP

DEPARTMENT OF FAMILY MEDICINE
UNIVERSITY OF ROCHESTER/HIGHLAND HOSPITAL

9-1-00

To. _____

From: Eric Seleff, MD

IND - _____

INTERNET — CALL FOR MIFEPRISTONE

Respected DOCTORS

We are pleased to inform you that we will start selling 200MG / 25MG
MIFEPRISTONE tablet dose along with misnprostol From 1 september 2000 onward.

Keeping in mind possiablity's of longterm association with you/other Doctors/Hospital's in various country's we are giving a purposal which as below:-

The selling price for Mifepristone tablet/dose will be same as prevailing in purchaser' country but they will get 15 to 25% discount in form of free products such as pregnancy test/Lh ovulation/FSH/OTHER cassette/strip and or tibolone / other o&g segment tablet/ capsule/injection.(In This regard we are sending our products list by SEPERATE E-MAIL)

please advise prevailing price of mifepristone in your country as well as how many tablet/dose you can buy at a time enabling us to give you our best (15 to >25% free product discount).If possiable please send us contact information of known O&G Doctors/hospital either in your country or in other country's AND ALSO CONTACT INFORMATION OF O&G DOCTORS ASSOCIATION IN YOUR COUNTRY/ANY OTHER COUNTRY'S.

looking forward to your reply
best regards
DILIP CHOUDHURY
DIVERSIFIED CORP.,
INDIA

Jacob W. Holler Family Medicine Center
885 South Avenue
Rochester, New York 14620
(716) 442-7470 Fax: (716) 442-8319

Danco Laboratories, LLC

VIA FACSIMILE: [redacted]

September 26, 2000

[redacted]

Center for Drug Evaluation
and Research
Food and Drug Administration
Woodmont Office Complex 2
1451 Rockville Pike
Rockville, MD 20852

Dear [redacted]

Further to your inquiries regarding [redacted] please be advised as follows:

- The Population Council has indicated, through Sandra P. Arnold, that they have had no relationship in any way with [redacted]
- Danco's [redacted] has also indicated that they have had no business dealings or relationship with [redacted]

Separately, the port of entry for importation of Danco's Drug Substance is [redacted] and Danco is amenable to notifying the FDA ahead of each importation. Please let me know how and to whom you wish us to provide this information.

Sincerely,

/dns

cc: Sandra P. Arnold – Population Council

This document constitutes trade secret and confidential commercial information exempt from public disclosure under **21 C.F.R. 20.61.** Should FDA tentatively determine that any portion of this document is disclosable in response to a request under the Freedom of Information Act, Danco Laboratories, LLC requests immediate notification and an opportunity for consultation in accordance with 21 C.F.R. 20.45. Contact telephone number is

MIFEPRISTONE NDA

STATUS

Brief Summary of Publicly Available Information

- The sponsor, The Population Council, Inc., initially submitted an NDA for Mifepristone (RU-486) in March 1996.

- The NDA contained the results of two large clinical trials performed in the European Union and preliminary data from an on-going U.S. trial in support of the indication: Medical termination of intrauterine pregnancy through 49 days' gestational age. (Pregnancy is dated from the first day of the last menstrual period).

- The NDA was reviewed on a 6-month regulatory clock, and issues were presented and discussed at an open advisory committee meeting in July 1996. The sponsor received an approvable letter on September 18, 1996, which conveyed the conclusion that the drug, used under specific conditions, was found safe and effective for the indication.

- The letter also outlined various deficiencies that required response before the application could be approved, including a list of chemistry and manufacturing controls requirements as well as label modifications and postmarketing surveillance commitments.

- The advisory committee discussion included recommendations for labeling, postmarketing surveillance, and a well-controlled distribution system for the drug. The committee also requested the opportunity to review the final U.S. study report once available.

Brief Summary of Non-Public Information

FACSIMILE TRANSMISSION RECORD

DIVISION OF PRESCRIPTION DRUG COMPLIANCE & SURVEILLANCE
OFFICE OF COMPLIANCE
CENTER FOR DRUG EVALUATION & RESEARCH
FOOD AND DRUG ADMINISTRATION
METROPARK NORTH I, HFD-330
7520 STANDISH PLACE, ROCKVILLE, MD. 20855

FAX #: 301-594-5998 PHONE #: 301-594-0101

DATE: 9/26/00 NUMBER OF PAGES 13

FROM:

TO:

FAX#: 4-6197 PHONE #:

COMMENTS:

Confidential

NOTE: THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone and return this document to us at the above address by mail. Thank you.

RDCLIST_ALL QUERY

Tradename:MIFEPRISTONE Rx/OTC:R

Firm: NDC:064877-0001 Status:DC 27-APR-1999 Owner:DRLS

Ingred:MIFEPRISTONE	100	%WW	0129613AA A

Drug Class	Package	Size	Type
	064877-0001-**	AS ORDERED	DRUM

*** NOTE ***
THIS SCREEN MAY CONTAIN TRADE SECRET INFORMATION. PLEASE TAKE CARE!!
> PRESS PF2 FOR DOSAGE, ROUTE & APPL INFO PRESS PF3 FOR MANUFACTURERS INFO <
Up/Down ARROWS MOVE THRU RECORDS, Return/Backspace MOVE THRU BLOCKS,PF4 EXITS.

<Replace>

Count: *1

NDCLIST_ALL QUERY

Tradename:MIFEPRISTONE Rx/OTC:R

Firm: NDC:064877-0001 Status:DC 27-APR-1999 Owner:DRLS

DOSAGE & ROUTE INFORMATION

DOSAGE CODE	DOSEFORM	ROUTE CODES	ROUTE FORM	APPLICATION NUMBER
313	NOT APPLIC	135	OTHER	

*** NOTE ***
THIS SCREEN MAY CONTAIN TRADE SECRET INFORMATION. PLEASE TAKE CARE!!
> PRESS PF2 FOR DOSAGE, ROUTE & APPL INFO PRESS PF3 FOR MANUFACTURERS INFO <
Up/Down ARROWS MOVE THRU RECORDS, Return/Backspace MOVE THRU BLOCKS, PF4 EXITS.

<Replace>

Count: *1

NDCLIST_ALL QUERY ------ MANUFACTURERS FOR NDC: 064877-0001
Tradename:MIFEPRISTONE

CFN	Lblcode	Shortname	Longname	State	Foreign
FCCH499	064877	SHANGHAI HUALIAN	SHANGHAI HUALIAN PHARMACEU		CH
	ADDRESS:MINLE RD PUDONG DEVELOPMENT AREA/SHANGHAI,				

Press Previous Screen to return to detail screen. For Help - Press CTRL K

Count: *1

<Replace>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DRUG PRODUCT LISTING

(In accordance with Public Law 92-387)

NAME AND ADDRESS OF FIRM
SHANGHAI HUALIAN PHARMACEUTICAL CO.,LTD.
370 JIANG WAN ROAD, WEST
SHANGHAI 200083, CHINA

LABELING REVISION
CHANGE OF
☐ RTE OF ADMIN ☐ INDICATION
☐ NAME / DOSE / STRENGTH
☐ OTHER (Specify)

[redacted] LI 156,027

NATIONAL DRUG CODE: LABELER [redacted] PRODUCT 66487700001

SEC | S | U | PRODUCT TRADE NAME OR CATALOG NAME
01 | MIFEPRISTONE | Mer Sop

FDA APPLICATION NO. [redacted]
REPORT DATE: MO 03 DA 25 YR 99
TYPES OF BUSINESS: [redacted] OTHER (Specify) [redacted] OTHER (Specify) HIZ
PRODUCT TYPE: [redacted] OTHER (Specify) IR
PRODUCT DISCONTINUED: OTHER (Specify) [redacted] APR 05 1999
BASIS OF CONCENTRATION: WHOLE NUMBERS 1 | DECIMAL | UNIT KG

DOSAGE FORM	ROUTES OF ADMINISTRATION	SEC	S	U	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
31313 5		03				** AS ORDERED	DRM
		03					
[redacted]		03					
MO YEAR MO YEAR MO YEAR		03					

NOTICE: This report is required by law (21 C.F.R. 207.30). Failure to report can result in misbranding for not more than one year or a fine of not more than $1,000, or both (FD&C Act, Section 303)

SEC	S	U	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC	AMOUNT: WHOLE NUMBER	DECIMAL	UNIT
05	A		MIFEPRISTONE	100		MGW
05						
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05						
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05						
05						
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05						

RECEIVED
MAY 03 1999
FIMB

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHUNT NAME
07			FEIC H4919	SHANGHAI HUALIAN PHARMACEUTICAL CO LTD		CHINA		
07				MINLEI ROAD PUDONG DEVELOPMENT AREA				
07				SHANGHAI 201419				

FORM FDA 2657 (10/93) PREVIOUS EDITION IS OBSOLETE

Original sent under separate

Food and Drug Administration
CDER/OIT/DDMS/IMT, HFD-095
5600 Fishers Lane
Rockville, MD 20857

Attn:

April 26, 1999

Re: LI 156027
Product: Mifepristone
Manufacturer: Shanghai HuaLian Pharmaceutical Co., Ltd.

Dear

This is in regard to our recent telephone conversation pertaining to the Drug Listing submission for Mifepristone manufactured by the Shanghai HuaLian Pharmaceutical Co., Ltd.

As indicated to you, Mifepristone is the Active Pharmaceutical Ingredient (API) involved in NDA 20-687 for Mifepristone Tablets, 200 mg. This NDA has been reviewed by the Agency and it is considered *"approvable"* pending an adequate response to some technical aspects pertaining to this submission (Agency letter of September 18, 1996, pertinent excerpt attached).

Therefore, please be so kind as to proceed with the pertaining Drug Listing as requested earlier.

Thank you for your attention.

Sincerely,

Encl.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

4.13.99

Shanghai Hualian Pharmaceutical

X

We are returning copies of your FDA Form(s) 2657 submitted under the requirements of the Drug Listing Act of 1972 for the reason(s) indicated below:

Preliminary Requirements

- ☐ A separate Form FDA 2657 must be submitted for each product.
- ☐ Reporting firm's (submitter) name and/or address is missing from the form.
- ☐ Reporting firm's (submitter) name and /or address does not match our records.
- ☐ Reporting firm (submitter) is not registered. Please resubmit this form and all labeling for this product along with a completed Form FDA 2656 (Registration of Drug Establishment).
- ☐ Current label(s) and/or package insert(s) is/are missing.

Section 01

- ☐ Product trade name is missing.
- ☐ Labeler code is missing or incorrect. The labeler code must reflect that of the reporting firm.
- ☐ Product code is missing or incorrect. Please assign a product code according to your chosen NDC configuration.
- ☐ Product code belongs to a different product. Please assign a new product code.
- ☐ For finished dosage form prescription drugs, an FDA application number (NDA/ANDA) or an initial marketing date is required. Please fill in one or the other.
- ☐ Business and/or product type, and/or legal status is missing.

Section 03

- ☐ Package code, package size, and/or package type is missing.
- ☐ NDC configuration is incorrect. Product and package codes must be assigned as explained in 21 CFR 207.35(b).

Section 05

- ☐ Active ingredient(s), amount(s) and/or unit(s) is/are missing.

Section 07

- ☐ The actual manufacturer of the product is missing.
- ☐ Please indicate the actual site or firm establishment registration number (also known as the CFN) and/or the actual manufacturer's labeler code.
- ☐ Manufacturer in Section 07 is not registered. The manufacturer must be registered and/or list before this form can be processed.

See back page for additional comments.

Comments

- ☐ We are unable to determine from the attached Form(s) FDA 2657 the type of update and/or changes you are requesting. Please explain in more detail.
- ☐ Attached Form(s) FDA 2657 appears to be an update of an existing product. However, the original form(s) cannot be located. Please resubmit a copy of the originally submitted Form(s) FDA 2657 along with the appropriate label(s) and/or package insert(s).
- ☐ Manufacturer must submit Form FDA 2657 for this product before this form can be processed.

Other

- ☐ This product is not considered a drug and is not required to be listed with CDER. finished dosage
- ☐ Please provide name of approved drug product of which this is an active ingredient.

We request that you send the corrected form(s) and this letter within 20 working days to:

Food and Drug Administration
CDER/OIT/DDMS/IMT, HFD-095
5600 Fishers Lane
Rockville, MD 20857

If you need assistance, please contact _____

Enclosure(s)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DRUG PRODUCT LISTING

(In accordance with Public Law 92-387)

NAME AND ADDRESS OF FIRM
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SHANGHAI 200083, CHINA

LABELING REVISION
CHANGE OF
☐ SITE OF A ADMIN ☐ INDICATION
☐ NAME / DOSE / STR / INGR
☐ OTHER (Specify)

[redacted] LI 156,027

NATIONAL DRUG CODE: LABELER [redacted] PRODUCT 66487 aaa 1

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME
01			MIFEPRISTONE

FDA APPLICATION NO: .
REPORT DATE: MO 02 DA 25 YR 99
TYPES OF BUSINESS: [redacted] OTHER (Specify)
PRODUCT TYPE: [redacted] OTHER (Specify) HZ
SCHED: R
PRODUCT DISCONTINUED: OTHER (Specify) RECEIVED APR 05 1999
BASIS OF CONCENTRATION: WHOLE NUMBERS 1 DECIMAL UNIT KG

DOSAGE FORM	ROUTES OF ADMINISTRATION	SEC	S	U	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
3 1 3 1 3 5		03				** AS ORDERED	DIRM
		03					
[redacted]		03					
MO YEAR MO YEAR MO YEAR		03					
.		03					

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SEC	S	U	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME ETC.	AMOUNT: WHOLE NUMBER	DECIMAL	UNIT
05			A MIFEPRISTONE	100		% W/W
05						
05						
05						
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05						
05						

SEC	S	U	DATE OF ANY ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME
07			FCCH141519	SHANGHAI HUALIAN PHARMACEUTICAL CO LTD		CHINA		
07				MINLEI ROAD PUDONG DEVELOPMENT AREA				
07				SHANGHAI 201419				

PAGE 1 OF 1 PAGES

FORM FDA 2657 (8/94) PREVIOUS EDITION IS OBSOLETE.

MIF 005115

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

4.27.99

Shanghai Hualian Pharmaceutical

Bar Code #

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- ☐ Manufacturer must submit Form FDA 2657 for this product before this form can be processed.

Other

- ☐ This product is not considered a drug and is not required to be listed with CDER.
- ☐ NDA is not approved yet. Product is not in commercial distribution. Resubmit when NDA is approved.

We request that you send the corrected form(s) and this letter within 20 working days to:

Food and Drug Administration
CDER/OIT/DDMS/IMT, HFD-095
5600 Fishers Lane
Rockville, MD 20857

If you need assistance, please contact _____

Enclosure(s)

Food and Drug Administration
CDER/OIT/DDMS/IMT, HFD-095
5600 Fishers Lane
Rockville, MD 20857

Attn:

April 26, 1999

Re: LI 156027
Product: Mifepristone
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Thank you for your attention.

Sincerely,

Encl.

Fax Note 7671 Date 4/26 pages 5
To
Fax
From

What Do We Know about Induced Abortion in the United States

Induced Abortion Data:

- In 1996, a total of 1.22 million induced abortions were reported to CDC. At same year, a provider survey showed a slightly higher number, 1.37 million abortions performed, representing an abortion rate of 22.9 per 1,000 women aged 15-44 in the United States[1,2].
- Approximately one third of all abortions were performed at 7 or fewer weeks of gestation. Additional 20 percent were at 8 weeks of gestation[2].
- In 1996, approximately 4,200 medical abortions were performed and the remaining were surgical abortions[2].
- Four states, i.e. California, New York, Florida and Texas, accounted for about 50 percent of all abortions in the United States (Table 1)[2].

Who Seeks Abortion Service:

- Women aged 19 or younger obtained approximately 20 percent of all abortions while women aged 35 and older accounted for about 10 percent of the total[1].
- The abortion rate for black and Hispanic women were approximately 2-3 times the rates for white women even if white women account 60 percent of all abortions[1,2].
- Older women were more likely to obtain abortion earlier in pregnancy than were younger women[1].

Who Provides Abortion Service:

- In 1996, 78,910 physicians (MDs) were registered as family practice physicians and 38,424 as Ob/Gyns[3].
- In 2000, 12 percent of Ob/Gyns and 2 percent of family practice physicians routinely perform elective surgical abortions[4].
- In 1996, abortion services were provided in 2,042 facilities, including 703 hospitals, 452 abortion clinics, 417 other clinics and 470 physician offices[2].
- 22 percent of the facilities accounted for 80 percent of abortions performed in the United States[2].

Access to Abortion Service:

- Only 1 percent of abortions (14,070) was reported in nonmetropolitan counties, where 18 percent of women of reproductive age lived[2].
- Of the country's 320 metropolitan area, approximately one third (102) had no known abortion provider or had a provider that together reported fewer than 50 abortions[2].

Safety of Abortion Service:

- In 1992, 10 women died as a result of complication from legal induced abortion and the case fatality rate was 0.7 abortion-related deaths per 100,000 legal induced abortions[1].

Efficacy and Safety of Mifepristone:

- In US clinical trials, the success rate were 92 percent (762/827) in the 49 days group, 83 percent (563/678) in the 50-to-56 days group, 77 percent (395/510) in the 57-to-63 days group. In addition, approximately 51 percent of women in the study had a previous elective abortion and success rate tends to be lower among women who had previous elective abortions[5].
- Hospitalization, surgical interventions, and intravenous-fluid administration were reported for 2 percent of the women in the <49-days group and for 4 percent of those in each of the other groups, mostly due to excessive bleeding[5].
- Excessive bleeding necessitated blood transfusions in four women[5].

Safe and Effective Use of Mifepristone:

- In France, 80 percent of women who terminate their pregnancies before the seventh week choose the drug over surgical methods. Mifepristone accounts for 30 percent of all abortions in France[6].
- At Planned Parenthood of Greater Iowa, one of 17 sites that participated in US Mifepristone clinical trials, 80 percent (238/301) eligible patients choose Mifepristone when it was offered[7].
- 44 percent of Ob/Gyns and 31 percent of family practice physicians would be likely or very likely to prescribe Mifepristone after FDA's approval (Table 2)[4].
- 5 percent (106/2121) of US clinical trial participants failed to return for the last visit (visit 3)[5].

Reference

1. Koonin LM, Strauss LT, Chrisman CE, Montalbano MA, Bartlett LA and Smith JC. Abortion surveillance - United States, 1996, MMWR 1999;48(No. SS-4):1-52
2. Henshaw SK. Abortion incidence and service in the United States, 1995-1996. Family Planning Perspectives 1998;30:263-270.
3. American Medical Association. Physician Characteristics and Distribution in the US 1997/1998, Chicago, 1997.
4. KFF. Views of Women's Health Care Providers on Abortion: An Update on Mifepristone. The Henry J. Kaiser Family Foundation, Publication No. 3027, June 2000.
5. Spitz B, Bardin W, Benton L, Robbins A. Early pregnancy termination with mifepristone-misoprostol in the United States. N Engl J Med 1998;338:1241-7.
6. Abortion pill to be tested here. St. Louis Post-Dispatch, April 7, 1995 Pg 1A
7. Blinder V, Elul B and Winikoff B. Mifepristone-misoprostol medical abortion: who will use it and why? Am J Obstetrics and Gynecology 1998;179:

Table 2. Characteristics of Ob/Gyn and Family Practice Physicians participated in Kaiser Family Foundation's Survey (June 2000)

	Obstetricians and Gynecologist (n=566)	Family Practice Physician (n=201)
% aged 50 or less	52%	15%
% male	72%	86%
% solo practice	32%	54%
% rural practice site	15%	33%

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017

Sandra P. Arnold
Vice President, Corporate Affairs

July 26, 1996

Dr. David Kessler
Commissioner
US Food and Drug Administration
5600 Fishers Lane
Room 14-18
Rockville, Maryland 20857

Dear Dr. Kessler,

The Population Council would like to thank you and your associates at the FDA for the care with which the July 19th meeting of the Reproductive Health Advisory Committee to evaluate the safety and efficacy of mifepristone was planned and conducted. It has been a pleasure to work with the FDA staff members, and the meeting was testimony to the skill and effort that everyone put into it.

We are of course quite pleased with the outcome. We also particularly appreciate your personal involvement in opening the meeting and participating actively throughout it. Thank you very much for devoting your time and effort to this issue and this meeting.

We are looking forward to our continuing interface with you and your associates as the remaining steps in the evaluation of the mifepristone New Drug Application are carried out.

Thank you once again.

Very truly yours,

Sandra Arnold

Telephone: (212) 339-0500 Telex: 9102900660 POPCO Facsimile: (212) 755-6052 Cable: POPCOUNCIL NEW YORK

This is a listing of documents sent to the Office of Legislation (OL) in response to a Congressional document request. I did not keep copies of the document.

DOCUMENT LISTING -- RU-486

DATE	FROM	TO	SUBJECT
11/03/88	Dr. Irving M. Spitz Population Council	Division of Metabolic & Endocrine Drug Products	Letter (and enclosures) in response to FDA's request for adverse reaction reports (ADRs) for IND
11/17/88	Dr. Irving M. Spitz		Letter (and enclosures) regarding ADRs.
11/19/90	Dr. Irving M. Spitz		Letter (and enclosures) regarding ADRs.
11/18/94	Dr. Irving M. Spitz	FDA	IND Safety Report
11/21/94	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
12/01/94	Dr. C. Wayne Bardin Population Council		Letter (and enclosures) regarding ADRs.
12/02/94	Dr. Irving Spitz	FDA	IND Safety Report
12/07/94	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
12/14/94	Dr. Fred Schmidt Population Council	FDA	IND Safety Report
12/20/94	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
01/18/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
01/23/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
02/07/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
02/10/95	Dr. Fred Schmidt	FDA	IND Safety Report
02/15/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
02/17/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.

DATE	FROM	TO	SUBJECT
02/17/95	Population Council	FDA	IND Safety Report
02/17/95	Dr. Fred Schmidt	FDA	IND Safety Report
02/24/95	Dr. Fred Schmidt	FDA	IND Safety Report
03/95	Sirkku Larsson	FDA	Final Clinical Report of Interruption of Early Pregnancy with RU-486 with Addition of a Prostaglandin (E_1), Gemeprost 24 Hours or 48 Hours after RU-486 Administration
03/03/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
03/06/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
03/09/95	Dr. Fred Schmidt	FDA	IND Safety Report
03/10/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
03/13/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
04/11/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
04/19/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
06/02/95	Dr. Fred Schmidt	FDA	IND Safety Report
06/07/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
06/07/95	Dr. André Ulmann		Tolerance of RU-486 during U.S. Studies
06/13/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
07/95	Roussel Uclaf	FDA	International Safety Report

DATE	FROM	TO	SUBJECT
07/18/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
07/25/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
07/28/95	Dr. Fred Schmidt	FDA	IND Safety Report
07/28/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
08/03/95	Dr. Fred Schmidt	FDA	IND Safety Report
08/04/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
08/08/95	Dr. Fred Schmidt	FDA	IND Safety Report
08/08/95	Dr. Fred Schmidt	FDA	IND Safety Report
08/09/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
08/10/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
08/15/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
08/25/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
09/01/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
09/21/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
10/04/95	Roussel Uclaf	FDA	Quarterly Safety Line Listing
11/02/95	Dr. C. Wayne Bardin		Letter (and enclosures) regarding ADRs.
01/04/96	Population Council	Dr. Stonier Hoechst Roussel LTD	Quarterly Safety Line Listings 10/1/95 through 12/31/95
04/12/96	Roussel Uclaf	FDA	Quarterly Safety Line Listings

DATE	FROM	TO	SUBJECT
06/20/96	Dr. Ann Robbins Population Council		Letter (and enclosures) regarding ADRs.
07/14/96	Dr. Ann Robbins	Division of Reproductive and Urologic Drug Products	Letter (and enclosures) regarding ADRs.
07/25/96	Dr. Ann Robbins	Div. of Reproductive and Urologic Drug Products	Letter (and enclosures) in response to FDA request for a summary of the international post-marketing surveillance data on the use of RU-486.
01/22/97	Clinical Investigations Branch	Dr. Elizabeth Aubeny Clinical Investigator Broussais Hospital	Letter (and 26 enclosures) that resulted from FDA's 6/26/96 inspection.
01/22/97		Dr. H. Quiquempois Clinical Investigator Center Hospitalier de Valenciennes	Letter (and 40 enclosures) that resulted from FDA's 07/01/96 inspection.
11/21/97	Dr. Fred Schmidt		Letter (and enclosures) regarding ADRs.
Undated			Spontaneous Notifications Reported to Roussel Uclaf 01/01/93 through 10/12/94
Undated	Population Council	FDA	Periodic Safety Update 06/01/95 through 11/30/95

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P00-19
September 28, 2000
FOR IMMEDIATE RELEASE

FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6250
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

FDA APPROVES MIFEPRISTONE FOR THE TERMINATION OF EARLY PREGNANCY

The Food and Drug Administration today approved mifepristone (trade name Mifeprex) for the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the last menstrual period.

Under the approved treatment regimen, a woman first takes 600 milligrams of mifepristone (three 200 milligram pills) by mouth. Two days later, she takes 400 micrograms (two 200-microgram pills) of misoprostol, a prostaglandin. Women will return for a follow-up visit approximately 14 days after taking mifepristone to determine whether the pregnancy has been terminated.

Because of the importance of adhering to this treatment regimen, each woman receiving mifepristone will be given a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side

-More-

effects can occur.

"The approval of mifepristone is the result of the FDA's careful evaluation of the scientific evidence related to the safe and effective use of this drug," said Jane E. Henney, M.D., Commissioner of Food and Drugs. "The FDA's review and approval of this drug has adhered strictly to our legal mandate and mission as a science-based public health regulatory agency."

FDA based its approval of mifepristone on data from clinical trials in the United States and France.

The labeling for mifepristone emphasizes that most women using the product will experience some side effects, primarily cramping and bleeding. Bleeding and spotting typically last for between 9 and 16 days. In about one of 100 women, bleeding can be so heavy that a surgical procedure will be required to stop the bleeding.

The drug's labeling also warns that it should not be used in women with the following conditions:

- Confirmed or suspected ectopic ("tubal") pregnancies
- Intrauterine device (IUD) in place
- Chronic failure of the adrenal glands

-More-

- Current long-term therapy with corticosteroids
- History of allergy to mifepristone, misoprostol or other prostaglandins
- Bleeding disorders or current anticoagulant (blood-thinning) therapy.

Under the terms of the approval, mifepristone will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding -- or they must have made plans in advance to provide such care through others.

To gather additional data about the use of mifepristone, the Population Council (sponsor of the product) has made a commitment to conduct postmarketing studies. These include a study comparing patient outcomes among physicians who refer their patients needing surgical intervention, compared to those who perform surgical procedures themselves; an audit of prescribers that will examine whether patients and their physicians are signing the patient agreement and placing it in the patient's

-More-

medical record, as required; and a system for surveillance, reporting and tracking rare ongoing pregnancies after treatment with mifepristone in the U.S.

Mifepristone, which was developed by a French pharmaceutical firm, was first approved for use in France in 1988. Since then, more than 620,000 European women have taken mifepristone in combination with a prostaglandin to terminate pregnancy. The drug has also been approved in the United Kingdom, Sweden, and other countries.

Mifepristone will be distributed in the U.S. by Danco Laboratories, LLC, New York, N.Y.

More detailed information about this product is available on FDA's website at http://www.fda.gov/cder/drug/infopage/mifepristone/

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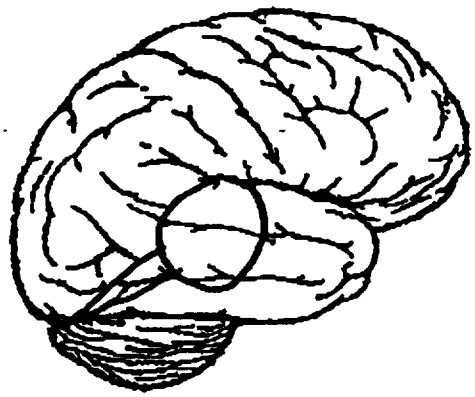

FACSIMILE TRANSMISSION
FROM

DEPARTMENT OF NEUROSURGERY
Phone:

DOB

Date: 10 Oct 92.

To:

Fax #: (602)

From: MD

Phone: ( )

Number of pages including this cover sheet: 7

Will discuss with you on the phone

Two maybe of interest

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 22, 1993

VIA FACSIMILE
LETTER TO THE EDITOR OF THE SAN FRANCISCO CHRONICLE:

Your column by Beverly Zakarian about RU-486 ("Open Forum," 1/11/93) reflected a widespread and fundamental misunderstanding of the policy of the Food and Drug Administration.

The FDA has not obstructed import of the drug for medical research on its various potential uses. In fact, FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drugs applications (INDs).

Under the law, FDA is precluded in most cases from publicly discussing studies in progress under an IND. Your readers should know, however, that the National Institutes of Health, whose studies are public information, is using RU-486 in biochemical research and is investigating its potential for treatment of Cushing's disease and other serious conditions. Other RU-486 studies, for ailments that include several kinds of cancer, are being carried out by non-governmental entities.

All of this research uses RU-486 that has been imported legally and with FDA's approval under the IND process. The import alert on RU-486 relates only to illegal attempts to bring the drug into this country.

The basic obstacle to more widespread availability of RU-486 in the U.S. is not FDA, but the fact that the French manufacturer has declined to apply with the agency for the drug's approval.

Sincerely,

/s/

Carol R. Scheman
Deputy Commissioner for
External Affairs

9300320

MIF 005161

CAROL MOSELEY-BRAUN
ILLINOIS

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
JUDICIARY
SMALL BUSINESS

United States Senate

WASHINGTON, DC 20510-1303

July 28, 1993

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 615F
Washington, D.C. 20201

Dear Madam Secretary:

In January, President Clinton requested that the Department of Health and Human Services undertake an investigation of RU-486 and whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. The President also requested that the Department assess initiatives promoting the testing, licensing, and manufacturing of RU-486 within the United States.

I am requesting the status of these two activities. Thank you for your consideration.

Yours truly,

Carol Moseley-Braun
United States Senator

CMB:cmc

159158
TRACER

APPEARS THIS WAY
ON ORIGINAL

RECEIVED
AUG 5 2 46 PM '93
OFFICE OF
LEGISLATIVE AFFAIRS

30803004 2

MIF 005162

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 18 1995

The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

It has come to our attention that as a co-signator of the Citizen Petition regarding the Food and Drug Administration's (FDA) review of a new drug application for RU-486, you may not have received a response regarding the petition. The Agency did not respond to each of the petitioners individually. A formal response, however, was sent on March 20, 1995 to Mr. Gary Yingling, McKenna & Cuneo, who had filed the petition on behalf of the petitioners. For your information, we are enclosing a copy of that letter.

If you have any further questions about this matter, please contact _____ of my staff at _____

Sincerely,

/S/

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 20, 1995

Mr. Gary L. Yingling
McKenna & Cuneo
1575 Eye Street, N.W.
Washington, D.C. 20005

Dear Mr. Yingling:

We have received the petition you filed on February 28, 1995, regarding our review of a new drug application for mifepristone as an abortifacient. The petition has stated many concerns and considerations related to the safe and effective use of mifepristone as an abortifacient.

The Food and Drug Administration is prohibited from publicly disclosing the existence of an application unless its existence has been previously publicly disclosed or acknowledged (21 C.F.R. § 314.430(b)). However, if, and when, such an application is submitted to the Agency, please be assured that we will review it in accordance with the statutory criteria set forth in the Federal Food, Drug, and Cosmetic Act. As you know, such a review requires the Agency to review both the safety and effectiveness of the drug, among other factors.

Your petition has been provided to the Center for Drug Evaluation and Research for its information and consideration in its review of any application that may be submitted.

Please consider this in full response to your petition, docket number 95P-0054/CP 1.

Sincerely yours,

/S/

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

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DALLAS, TEXAS 75201
(214) 748-3700

BRUSSELS
AVENUE LOUISE 287, BOX 7
B-1050 BRUSSELS
BELGIUM
011 (322) 646-4810

February 28, 1995

By Hand Delivery

Dockets Management Branch (HFA-305)
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20852

CITIZEN PETITION

Petitioners, Hon. Thomas J. Bliley, Jr. (Chairman, Committee on Commerce); Hon. J. Dennis Hastert (Committee on Commerce); Hon. Cliff Stearns (Committee on Commerce, Committee on Veterans Affairs); Hon. Jack Fields (Committee on Commerce); Hon. Paul E. Gillmor (Committee on Commerce); Hon. Henry Hyde (Chairman, Committee on the Judiciary); Hon. Ed Bryant (Committee on the Judiciary, Committee on Agriculture); Hon. Bill Barrett (Committee on Economic and Educational Opportunities, Committee on Agriculture); Hon. Jim Talent (Committee on Economic and Educational Opportunities); Hon. Steve Largent (Committee on Science); Hon. Duncan Hunter (Committee on National Security); Hon. Mike Parker (Committee on the Budget); Hon. Jim Bunning (Committee on the Budget); Hon. John Murtha (Committee

on Appropriations); Hon. Barbara Vucanovich (Committee on Appropriations); Hon. Jim Lightfoot (Committee on Appropriations); Hon. Enid G. Waldholtz (Committee on Rules); Hon. Nick J. Rahall, II(Committee on Resources, Committee on Transportation and Infrastructure); Hon. Christopher H. Smith (Committee on International Relations. Committee on Veterans' Affairs); Hon. Andrea Seastrand (Committee on Science, Committee on Transportation and Infrastructure); Hon. Todd Tiahrt (Committee on National Security); Hon. Linda A. Smith (Committee on Resources, Committee on Small Business); Hon. Dan Coats (Committee on Labor and Human Resources); and the following individuals: Laurence M. Demers, M.D.; Camilla Hersh, M.D.; Donna J. Harrison, M.D.; Earle W. Lingle, Ph.D.; Eugene F. Diamond, M.D.; J. Walter Sowell, Ph.D.; and Joel Brind, Ph.D., hereby submit this citizen petition ("petition") under section 701 of the Federal Food, Drug, and Cosmetic Act ("the FDCA or Act"), 21 U.S.C. § 371 (1988 & Supp. V 1993), and its implementing regulations, 21 C.F.R. §§ 10.25 and 10.30 (1994). Petitioners specifically request that the Commissioner of the Food and Drug Administration ("the Commissioner") refuse to approve any new drug applications ("NDA") submitted pursuant to section 505(b) of the Act, 21 U.S.C. § 355(b) (1988), for RU 486 (mifepristone) for use as a pharmaceutical abortifacient.1/

1/ The comments submitted herein are limited to RU 486 as an abortifacient drug product. This petition does not, therefore, oppose or address in any manner the use of RU 486 in the treatment of diseases, such as breast cancer or meningiomas (brain tumors).

A. ACTION REQUESTED

Petitioners request that the Commissioner refuse to approve any NDA for RU 486 for use as a pharmaceutical abortifacient that does not contain adequate evidence that the drug has undergone nonclinical and clinical safety and effectiveness trials. The basis for petitioners' request is the statutory mandate of the Food and Drug Administration ("FDA") to withhold approval of any NDA that lacks sufficient data to establish that a drug is safe and effective for its intended use.[2/] Approval of any NDA that is devoid of the appropriate safety and effectiveness data would not only be an express violation of the FDCA, but also an arbitrary and capricious agency action.

Petitioners also are concerned that RU 486 could be approved in the United States ("U.S.") based largely on foreign data, with only limited safety data generated from studies conducted in the U.S. Because approval based on possibly invalid foreign data and limited safety data would expose patients to significant and unreasonable adverse health risks, petitioners respectfully request that FDA consider the following factors in reviewing any NDA for RU 486.

- Foreign data that has not undergone a validation review by FDA may be unreliable.
- Because of the gravity of the potential risks of RU 486, it is imperative that all safety concerns in the potential populations affected by RU 486 be adequately addressed by NDA-generated data.

2/ See FDCA § 505(d), 21 U.S.C. § 355(d).

- Adequate directions for use of RU 486 cannot be provided in approved product labeling, unless direct safety/effectiveness issues are sufficiently resolved and defined by reliable scientific research.

- Unlike treatment for Acquired Immunodeficiency Syndrome ("AIDS"), advanced metastatic refractory cancers or other severely debilitating life-threatening diseases, alternatives to the RU 486/prostaglandin ("RU 486/PG") abortion method are currently available in the U.S. Because alternative abortion methods exist, no novel or urgent medical situation is present that requires FDA to expedite review or approval of an NDA for RU 486 as an abortifacient.

- The availability of alternative abortion methods should be considered by FDA in performing a risk/benefit evaluation of RU 486 as an abortifacient.

In light of these considerations, petitioners specifically request that:

(1) FDA audit all foreign data submitted in support of any NDA for RU 486 as an abortifacient;

(2) No NDA for RU 486 as an abortifacient be approved by FDA unless the safety and efficacy concerns presented in this petition are adequately resolved:

(3) FDA not approve RU 486 in the absence of clinical and nonclinical data that fully evaluate the potential adverse effects on the health of women who take RU 486 and/or misoprostol and any children born after exposure to these drugs;

(4) FDA refrain from adjusting and/or expediting the NDA approval process for any NDA for RU 486 for such use;

(5) In the event that FDA determines that an NDA for RU 486 meets the stringent statutory and regulatory application requirements, the approved conditions for use should be strictly limited. In particular, the drug product's labeling should bear adequate directions for use, and complete contraindication, complication and adverse reaction information. In addition, the drug product should be accompanied by an approved patient package insert. The labeling further should provide that

administration of the drug must be limited to patients that are under the direct supervision and care of licensed physicians practicing in ambulatory care facilities or hospitals that meet the standards of the Joint Commission on Accreditation of Healthcare Organizations.

B. STATEMENT OF GROUNDS

This petition concerns FDA's statutory obligation to approve only those NDAs that contain adequate evidence that the proposed drug is safe and effective for its intended use. Because there appear to be a number of unresolved safety and/or effectiveness questions associated with RU 486, FDA is statutorily obligated to withhold approval of any NDA for RU 486, a potentially harmful and toxic drug product.

1. FDA's Statutory Mandate

Specifically, section 505(b)(1)(A) of the FDCA requires that an applicant submit as part of an NDA, full reports of investigations that establish a drug is safe and effective for its intended use.[3/]

a) FDA May Only Approve An NDA That Demonstrates Drug Safety

Section 505(d) indirectly defines the necessary safety evidence to support approval of an NDA. This section provides, in relevant part, that FDA must refuse to approve any NDA that does not include: (1) "*adequate tests by all methods reasonably applicable* to

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3/ 21 U.S.C. § 355(b)(1)(A).

APPEARS THIS WAY
ON ORIGINAL

06 DEC 1995

The Honorable Tom A. Coburn
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in response to your letter of November 9, 1995, requesting information on the regulations limiting the release of confidential information to members of Congress.

Title 21 of the Code of Federal Regulations Section 20.87(c) states "that an individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public." Thus, unless an authorized request from a chairman of a committee or subcommittee of Congress acting pursuant to committee business requests information, the information provided to members of Congress is limited to that which a lay member of the community would have access to. Enclosed for your reference is a copy of the regulation cited above concerning disclosure to Congress.

If we can be of further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
cc: HFW-10 (2)
HFW-14
HFD-1
R/D: :11/30/95
Edit: 12/01/95
R/T: :12/4/95
F/T: :12/4//95
s:\wp\ \coburn
FDA Control No. 95-10410

APPEARS THIS WAY
ON ORIGINAL

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA
COMMITTEE ON COMMERCE
SUBCOMMITTEES
TELECOMMUNICATIONS AND FINANCE
HEALTH AND ENVIRONMENT
ENERGY AND POWER

Congress of the United States
House of Representatives
Washington, DC 20515–3602

511 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2701
(202) 225-3038 (FAX)

215 STATE STREET, SUITE 815
MUSKOGEE, OK 74401
(918) 687-2533
(918) 682-8503 (FAX)

November 9, 1995

Ms. Diane Thompson
Department of Health & Human Services
Food and Drug Administration
Rockville, MD 20857

Dear Ms. Thompson,

This is in response to your letter of September 18 regarding my inquiry about the development of a new "morning after" pill.

You stated that "under the Federal Food, Drug, and Cosmetic Act and its implementing regulations, we may not release any information about unapproved new drugs" and therefore "cannot provide the names of any such drugs under investigation, the type of research being conducted, etc."

I would like to know which specific regulations prevent release of this information. As a member of Congress, I think that is somewhat interesting that this information would be withheld.

Thank you for your attention to this matter. I look forward to your timely response.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress

APPEARS THIS WAY
ON ORIGINAL

issioner.

pt as provided in paragraph s section, the Commissioner is discretion, disclose part or Food and Drug Administra- rd that is otherwise exempt losure pursuant to subpart D art. The Commissioner shall his discretion to disclose such whenever he determines that losure is in the public inter- promote the objectives of the the agency, and is consistent rights of individuals to pri- property rights of persons in crets, and the need for the o promote frank internal pol- erations and to pursue its reg- ctivities without disruption.

Commissioner shall not make for public disclosure any at is:

empt from public disclosure to §20.61.

empt from public disclosure to §20.63.

hibited from public disclosure to 21 U.S.C. 331(j), 42 U.S.C. 12 U.S.C. 2631, or 18 U.S.C. 1905.

ontained in a Privacy Act System where disclosure would te a clearly unwarranted inva- ersonal privacy or is otherwise tion of 5 U.S.C. 552a(b), as ap- part 21, subpart G, of this chap- trictions on disclosure in the regulations).

iscretionary disclosure of a pursuant to this section shall the requirement that the record disclosed to any person who re- it pursuant to §20.21, but shall a precedent for discretionary re of any similar or related and shall not obligate the Com- er to exercise his discretion to any other record that is ex- om disclosure.

Disclosure required by court er.

ecords of the Food and Drug Ad- ation which the Commissioner termined are not available for disclosure, either in the form of lation published or cross-ref- l in this part or by a written de- ation pursuant to the procedure be made available for public disclosure in compliance with a final court order requiring such disclosure.

(b) Where the Food and Drug Administration record ordered disclosed under paragraph (a) of this section is a record about an individual that is not available for public disclosure under §20.63, the Food and Drug Administration shall attempt to notify the individual who is the subject of the record of the disclosure, by sending a notice to the individual's last known address.

(c) Paragraph (b) of this section shall not apply where the name or other personal identifying information is deleted prior to disclosure.

§20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§20.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by 21 U.S.C. 331(j), 21 U.S.C. 360(j)(c), 42 U.S.C. 263g(d) and 42 U.S.C. 2631(e) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the writ-

[47 FR 10804, Mar. 12, 1982, as amended at 59 FR 536, Jan. 5, 1994]

§20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 16, and 19 of this chapter or court proceedings, where the data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

§20.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

§20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in §20.64.

372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administratrion at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in §20.21 that such records shall be made available for disclosure to all members of the public.

§20.89 Communications with foreign government officials.

Communications with foreign government officials shall have the same status as communications with any member of the public, except that:

(a) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country, and trade secrets and confidential commercial or financial information obtained by such officials, which are

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 28 1995

The Honorable Tom A. Coburn
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in partial response to your letters of November 10, 1995, to Secretary Donna E. Shalala and Commissioner David A. Kessler, requesting copies of documents relating to the drug RU-486 (mifepristone). Due to the government shut-down, we are presently unable to ascertain if additional responsive documents exist. We will foward any additional documents to you or advise you otherwise, once we are able to do so.

As we explained to Mr. Roland Foster of your staff during a telephone conversation November 20, 1995, the enclosed documents are limited to those obtainable under the Freedom of Information Act. In a further discussion with Mr. Foster on December 21, 1995, we informed him that the Agency had received approximately 1200 consumer inquiries on RU-486, and approximately 75 congressional inquiries, primarily on behalf of constituents. We could provide all of this correspondence or examples. Mr. Foster asked that examples be provided at this time. We have, therefore, enclosed only examples of the general correspondence and congressional inquiries.

If you have any questions, or need further assistance, please let us know.

Sincerely,

/S/

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosures

APPEARS THIS WAY
ON ORIGINAL

DOCUMENTS IN RESPONSE TO REP. COBURN'S REQUEST ON RU-486 (FOI #93-47009)

OFFICE OF EXECUTIVE SECRETARIAT

1. Memorandum to Secretary, HHS, dated January 22, 1992, from President Clinton.

2. Letter to President Clinton, dated January 23, 1993, from ——— Response dated March 24, 1993, also included.

3. Letter to President Clinton, dated January 19, 1993, from ——— Response dated May 11, 1993, also included.

4. Letters to President Clinton and Secretary Shalala, dated September 27, 1993, from ——— Response dated December 3, 1993, also included.

5. Letters (10/6/93 from Dr. Ulmann and —— response) to Rep. Wyden from ———

6. Letter to Secretary Shalala, dated December 22, 1993, from Rep. Wyden.

7. Letter to Dr. Kessler, dated August 3, 1993, from Rep. Wyden. Response dated August 19, 1993, also included.

8. Letter to Secretary, HHS, dated December 5, 1990, from Rep. Wyden. Response dated December 5, 1991, also included.

9. Letter to Dr. Kessler, dated December 10, 1992, from Rep. Wyden. Response dated December 15, 1992, also included.

10. Letter to Mr. Lader, dated May 11, 1993, from Acting ASH. Incoming letter, dated March 31, 1993, also included.

11. Letter to Secretary Shalala, dated February 25, 1993, from Mr. Costikyan (representing Mr. Lader).

12. Letter to Secretary Shalala, dated May 12, 1993, from Mr.

Costikyan (representing Mr. Lader).

13. Letter to Mr. Costikyan, dated May 7, 1993, from Secretary Shalala and incoming letters to the Secretary.

14. Letter to Professor Hilger, dated February 3, 1993, from Dr. Kessler.

15. Letter to Dr. Kessler, dated April 15, 1993, from Professor Hilger.

16. Letter to Secretary Shalala, dated March 23, 1993, from Professor Hilger.

17. Letter to Dr. Jones, dated February 16, 1993, from Lou Sepersky, Chair, N.Y.C. Community Board No. 6.

18. Letter to David Dinkins, dated May 7, 1993, from Secretary Shalala. Incoming letter, dated January 22, 1993, from Dinkins also included.

19. Letter to _____ dated July 23, 1993, from _____ Incoming letter, dated May 20, 1993, also included.

20. Letter to Dr. Sakiz, dated January 22, 1993, from Dr. Kessler.

21. Letter to Dr. Kessler, dated December 17, 1992, from Dr. Sakiz.

22. Letter to Dr. Sakiz, dated December 14, 1992, from Dr. Kessler.

23. Letter to _____, dated May 5, 1993, from Alain Deslauriers.

24. Letter to Dr. Kessler, dated December 21, 1993, from Professor Hilger.

25. Letter to Dr. Ulmann, et al., dated January 22, 1993, from

26. Record of Telephone Conversation (1/25/93) between Dr. Ulmann and _____

27. Letter to Secretary Shalala, dated March 18, 1993, from Mr.

Sakiz.

28. Letter to Mr. Sakiz, dated March 4, 1993, from [redacted]

29. Letter to Dr. Kessler, dated May 15, 1992, from [redacted]

30. Letter to [redacted] dated July 31, 1992, from Mr. R.H. Forey, British Embassy.

31. Letter to Ms. Margaret Catley-Carlson, dated May 18, 1994, from [redacted]

32. Note to Dr. Kessler, dated April 19, 1994, from Mr. Lester Hyman.

33. Letter to Secretary Shalala, dated May 19, 1994, from Ms. Eleanor Smeal.

34. Note to Dr. Kessler, dated May 20, 1994, from Lester S. Hyman.

35. Letter to [redacted], dated May 20, 1994, from Eleanor Smeal.

36. Letter to Dr. Edouard Sakiz, dated June 9, 1994, from [redacted]

37. Letter to Dr. Kessler, dated May 25, 1994, from Dr. Edouard Sakiz.

38. Letter to Secretary Shalala, dated May 19, 1994, from Eleanor Smeal.

39. Letter to Mrs. Judie Brown, dated June 13, 1994, from [redacted]

40. Letter to Dr. Kessler, dated June 3, 1994, from Mrs. Judie Brown.

41. Letter to [redacted] dated May 19, 1994, from Pascal Chevit, M.D.

42. Letter to Secretary Shalala, dated June 8, 1994, from Marie Bass.

43. Letter to Secretary Shalala, dated May 30, 1994, from Dr. Edouard Sakiz.

OFFICE OF REGULATORY AFFAIRS

1. Note to _____ (HFC-100) and _____ (HFC-101), from _____ w/attachments.

2. Letter to Ronald Miller, dated March 24, 1994, from Marvin A. Blumberg.

3. Letter to Rep. Ron Wyden, dated December 15, 1992, from _____

4. Letter to Dr. Kessler, dated December 10, 1992, from Rep. Ron Wyden.

5. Letter to Dr. Kessler, dated July 15, 1992, from Rep. Ron Wyden.

6. Letter to Rep. Loren Leman, dated March 10, 1992, from _____ w/attachments.

7. Memorandum to Joseph Hayes, dated October 9, 1992, from Joseph L. McCallion.

8. E-mail to _____ dated December 9, 1993, from Marvin Blumberg.

9. Letter to Dr. Kessler, dated December 29, 1992, from Frederick S. Mayer, PPSI.

10. Letter to Mr. Laventurier, dated November 8, 1989, from _____

11. Letter to Dr. Victor Bauer, dated December 29, 1992, from Frederick S. Mayer.

12. Letter to Mr. Sakiz, dated December 29, 1992, from Frederick S. Mayer.

13. Letter to Mr. Sakiz, dated August 10, 1989, from Frederick S. Mayer.

14. Letter to Mr. Mayer, dated September 27, 1989, from Donald R. Thorsen.

15. Letter to Dr. Bauer, dated August 16, 1989, from Mr. Mayer.

16. Letter dated, August 11, 1993, to Cooper from Beil.

17. Memorandum to [redacted] et.al., dated November 2, 1993, from Malcolm Frazier, Director, State Information Branch.

18. Memo from [redacted] Dir., Div. of Federal-State Relations, ORO/FDA, regarding Talk Paper on RU-486, dated February 25, 1993.

19. Letter to [redacted] from Lawrence Lader, Pres. ARM.

PHILADELPHIA DISTRICT OFFICE

1. Import Alert #66-47, Automatic Detention.

2. Telephone Log - Public Affairs Office.

OFFICE OF CHIEF COUNSEL

1. Civil Action No. CV-92-3161 - Reply Memorandum in Support of Defendants' Motion to Dismiss.

2. Civil Action No. CV-92-3161 - Memorandum in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Motion for Summary Judgment.

3. Civil Action No. CV-92-3161 - Response to Plaintiff's Supplemental Brief.

4. Civil Action No. CV-92-3161 - Declaration of [redacted] M.D.

5. Civil Action No. CV-92-3161 - Memorandum in Support of Defendants' Motion to Dismiss.

6. Civil Action No. CV-92-3161 - Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Dismiss.

7. CV-92-3161 - Plaintiff's Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment and Reply Memorandum in Support of Plaintiff's Motion for Summary Judgment.

8. CV-92-3161 - Plaintiff's Supplemental Brief.

9. Letter to the Clerk of the Court, dated September 5, 1995, from Simon Heller, The Center for Reproductive Law and Policy.

OFFICE OF COMPLIANCE

1. Letter dated January 13 ,1993, from [redacted]
2. Letter dated December 3, 1993, from [redacted]
3. Letter to Secretary Shalala, dated September 27, 1993,
4. Letter dated January 14, 1994, from [redacted]
5. Letter to FDA, dated November 2, 1993.
6. Facsimile transmittal to Dr. Andre Ulmann, Ph.D., dated March 17, 1995, from [redacted]
7. Letter dated March 16, 1995, from [redacted]

OFFICE OF LEGISLATIVE AFFAIRS

1. Testimony by Dr. Kessler, dated May 16, 1994.
2. Letter to Rep. Ron Wyden, dated June 16,1995, from Diane E. Thompson, w/attachment.
3. Letter to Rep. Ron Wyden, dated February 8, 1994, from Secretary Shalala.
4. Letter to Rep. Ron Wyden, dated January 19, 1993, from [redacted]
5. Facsimile transmittal to [redacted] dated December 8, 1992, from Steve Jenning.
6. Letter to Rep. Ron Wyden, dated August 7, 1992, from [redacted]
7. Letter to Rep. Ron Wyden, dated July 28, 1992, from [redacted]
8. Letter to Rep. Ron Wyden, dated July 24, 1992, from [redacted], w/attachment.
9. Letter to Rep. Ron Wyden, dated June 12, 1992, from [redacted]

10. Letter to Rep. Ron Wyden, dated January 22, 1992, from ——

11. Document transmittal to ———— , dated August 26, 1993, from Dris Kiser.

12. Letter to Dr. Kessler, dated May 24, 1993, from ——

13. Memorandum of Meeting, dated March 2, 1993.

14. Letter to the Editor of the San Francisco Chronicle, dated January 22, 1993, from Carol R. Scheman.

15. Remarks by the President during signing of Presidential Memoranda, dated January 22,1 993, w/attachments.

16. Letter to Dr. Kessler, dated December 17, 1992, from Dr. Sakiz.

17. Letter to Mr. Miyoshi, dated June 29, 1992, from Dr. Kessler.

18. Memorandum to Subcommittee on Regulation, Business Opportunities, and Energy, dated January 6, 1992, from Acting Associate Commissioner for Legislative Affairs, w/attachment.

19. Import Alert Format.

20. Memo regarding RU-486 Hearing, dated July 31, 1992.

21. Witness list from Rep. Wyden regarding Hearing before Subcommittee on Regulation, Business Opportunities, and Energy, dated July 28, 1992.

22. Opening Statement by Rep. Wyden, dated July 28, 1992.

23. Testimony by Rep. Patricia Schroeder, dated July 28, 1992.

24. Testimony by J. David Grow, dated July 28, 1992.

25. Testimony by ———— dated May 8, 1992.

26. Memorandum to ———— , dated February 24, 1993, from

CENTER FOR DRUG EVALUATION AND RESEARCH

1. "Dear Colleague" letter, dated January 14, 1992, from Alan Cranston, w/attachment.

2. Current French Label (characteristics) for RU-486, dated May 8, 1992.

3. Transcript of John McLaughlin's "One on One," with Dr. Kessler, dated December 11, 1992.

4. HHS Fact Sheet: Mifepristone (RU-486)- Brief Overview, dated May 16, 1994, w/attachment.

5. News releases by The Population Council, dated May 16, 1994 and October 27, 1994.

6. Letter to Dr. Kessler, dated December 29, 1994, from American Life League, Inc.

7. Testimony by Center for Reproductive Law and Policy, dated July 28, 1992.

8. Testimony by the American Medical Association, dated November 19, 1990.

9. HHS News: "Roussel Uclaf donates U.S. Patent Rights for RU-486," dated May 16, 1994.

10. News Release from San Francisco General Hospital, dated May 3, 1994.

11. "Dear Colleague" letter, dated November 9, 1990, from The Alan Guttmacher Institute, w/attachments..

OFFICE OF WOMEN'S HEALTH

1. News Release from Americans United for Life, dated February 28, 1995.

2. Report of the Antioprogestin Drug Conference, December 6-7, 1991.

3. Letter to ———— dated January 3, 1992, from Dr. Ulmann.

4. Letter to ———————— from Lawrence Lader.

5. Letter to Dr. Kessler, dated July 15, 1992, from Judie Brown, Pres., American Life League, Inc.

6. Petition of Resolve to the President, dated August 31, 1992.

7. Letter to [redacted] dated December 18, 1992, from [redacted]

8. Letter to Secretary Shalala, dated January 22, 1993, from David Dinkins.

9. Workshop on Antiprogestins: Assessing the Science, April 13-14, 1993.

10. News Release from the Institute of Medicine, dated September 7, 1993.

11. Civil Action - Complaint.

12. Letter to Mr. Miyoshi, dated June 29,1 992, from Dr. Kessler.

13. Comparison of First Trimester Abortion Procedures, w/attachment.

14. FDA Talk Paper, February 25, 1993.

15. Facsimile transmittal of "Science Held Hostage" transcript, dated September 8, 1992.

16. Import Alerts - Drugs.

17. Letter from [redacted] dated January 14, 1994.

18. Unclassified Fax message from [redacted] dated July 31, 1992, to [redacted]

19. Letter to [redacted] dated October 6, 1992, from [redacted]

DOCKETS MANAGEMENT BRANCH

1. Letter to Mr. Gary L. Yingling, dated March 20, 1995, from [redacted]

2. Citizen's Petition dated February 28, 1995, to FDA.

3. Comments received on petition.

APPEARS THIS WAY
ON ORIGINAL

CORRESPONDENCE

1. Examples of general correspondence.

2. Examples of congressional responses.

APPEARS THIS WAY
ON ORIGINAL

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA
COMMITTEE ON COMMERCE
SUBCOMMITTEES
TELECOMMUNICATIONS AND FINANCE
HEALTH AND ENVIRONMENT
ENERGY AND POWER

Congress of the United States
House of Representatives
Washington, DC 20515–3602

WASHINGTON, DC 20515
(202) 225-2701
(202) 225-3038 (FAX)
215 STATE STREET, SUITE 815
MUSKOGEE, OK 74401
(918) 687-2533
(918) 682-8503 (FAX)

November 10, 1995

SPECIAL

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

As a Member of the House Commerce Committee's Subcommittee on Health and the Environment in the House, I write to request copies of documents in the possession of the Department of Health and Human Services relating to the drug known as RU 486 (mifepristone), developed by the company Roussel Uclaf SA.

I understand that the Population Council has an active investigational new drug application (IND) to use RU 486 for abortion. Several reports have appeared which indicate extensive communications between representatives of the Clinton administration and private companies and organizations, including the Population Council, concerning the future availability of RU 486 for use as an abortion pill in the United States. These reports, together with issues raised in a Citizens' Petition on RU 486 recently submitted to the FDA, have generated serious concern for public safety and the integrity of the drug approval process. Consequently, I am requesting that you provide the following information:

1) Any and all written or recorded communications, including electronic or telephonic communications, to or from the persons listed below relating to RU486 from January 1, 1992 up to the present (i.e., up until the time the document search is conducted).

When used in the above request, the word "communication" includes, but is not limited to: correspondence, electronic mail, memoranda, notes of conversations, notes of meetings, copies of the calendars of meetings, and telephone logs and message slips. It also includes all communications which do not specifically mention RU 486 but which may relate to its possible approval by FDA for use as an abortifacient (eg., communications relating to the acceptability of foreign data in the drug approval process). For each such communication, please indicate the date of the communication, the names and the professional or organizational affiliations of all persons involved or present, the locations of meetings, and the offices within the Department from which the communications were obtained. Also, please indicate which communications, if any, are confidential and may not be disclosed to the public.

This request includes all communications sent to or by the following persons from January 1, 1992 up to the present:

President Clinton, Mrs. Clinton, and White House staff
Other administration officials or personnel
Edouard Sakiz, Dr. Andre Ulmann, and other officers, employees, or representatives of Roussel Uclaf
Margaret Catley-Carlson, Dr. Wayne Bardin, and other officers, employees, and representatives of the Population Council
David A. Grimes, M.D.
Daniel R. Mishell, M.D.
Suzanne Poppema, M.D.
Officers, employees and representatives of the following companies and organizations:
Hoechst AG of Frankfurt, Germany
Hoechst Celanese Corporation of Somerville, New Jersey
Hoechst-Roussel Pharmaceuticals of Somerville, New Jersey
Rhone-Poulenc of Paris
Schering AG of Berlin, Germany
G.D. Searle Company of Skokie, Illinois
Upjohn Company of Kalamazoo, Michigan
Gynopharma, Inc. of Somerville, New Jersey
Cabot Medical Corporation of Langhorne, Pennsylvania
Aurora Medical Services of Seattle, Washington
Fund for the Feminist Majority
Planned Parenthood Federation of America
Reproductive Health Technologies Project
National Abortion Federation
National Abortion and Reproductive Rights Action League (formerly the National Abortion Rights Action League)
Oregon Science Health University of Portland, Oregon
Center for Reproductive Law and Policy
National Organization for Women
Women's Issues Network

2) Any and all documents relating to the implementation of President Clinton's January 22, 1993, memorandum for you as Secretary of Health and Human Services regarding the importation of RU 486.

In this memorandum, the President asked you to take the following three actions:

a) "promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption;"

b) "immediately take steps to rescind Import Alert 66-47" if the "FDA concludes that RU-486 meets the criteria for the personal use importation exemption;" and

c) "promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 and other antiprogestins."

When used in the above request, the word "document" includes, but is not limited to: internal and external documents of the Department of Health and Human Services, documents prepared by persons or offices outside the Department (including documents prepared by non-governmental persons, organizations, or companies), correspondence, electronic mail, memoranda, notes of conversations, notes of meetings, copies of the calendars of meetings, and telephone logs and message slips. It also includes all documents which do not specifically mention RU 486 but which may relate to its possible approval by FDA for use as an abortifacient (eg., criteria for the acceptance of foreign data, etc.). For each such document, please indicate the date of the document, the author or authors of the document, the persons to whom it was given or sent, and the offices within the Department from which the documents were obtained. Please separate the documents in this second request into three categories based on which of the three actions requested by the President the documents address. Again, please indicate which communications, if any, are confidential and may not be disclosed to the public.

Thank you for your attention to this inquiry. A similar request for documents has been submitted to Dr. Kessler at the Food and Drug Administration. I look forward to receiving the information by December 1, 1995. If you foresee any difficulty in fulfilling this request by that date, please notify me immediately. Roland Foster on my staff will be available to work with you on this.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress

SPECIAL

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY - 7 1993

APPEARS THIS WAY
ON ORIGINAL

[redacted]

Dear [redacted]

This is in response to your letters regarding the drug RU-486 (mifepristone). I appreciate your sharing the information on Larry Lader's efforts related to the Chinese version of RU-486 and of his concerns regarding the continued availability of Cytotec.

As you may know, President Clinton has directed me to study the issues surrounding the availability of RU-486 in the country, including initiatives that can be undertaken to promote the drug's testing and licensing in this country. In addition, the President directed an assessment of whether there is sufficient evidence to exclude qualification of RU-486 for importation under the Food and Drug Administration's (FDA) personal use importation policy. If the assessment shows that the drug qualifies for importation, the import alert would be rescinded. The FDA is an active participant in this ongoing evaluation.

On February 24, senior representatives from FDA and Roussel-Uclaf met to discuss the scientific and medical issues involved in the submission of a marketing application. Although Roussel-Uclaf asserted at the meeting that RU-486 should be made available in the United States, the firm emphasized the importance of finding a way to achieve that goal without its direct involvement.

FDA is fully prepared to review an investigational new drug or marketing application for mifepristone (as with any other drug), if one is submitted, based on established legal and scientific criteria. Thus, if your client wishes to submit an investigational new drug application for testing the Chinese version of mifepristone in the United States, FDA is prepared to review the application and to provide advice on the extent of testing that would be required for marketing approval.

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Thank you again for writing. I also appreciate your kind words of encouragement.

Sincerely,

Donna E. Shalala

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

WRITER'S DIRECT DIAL NUMBER
(212) 373-3332

March 12, 1993

Honorable Donna E. Shalala
Secretary
U.S. Department of Health
and Human Services
200 Independence Avenue, S.W.
Room 615F
Washington, D.C. 20201

Dear Donna:

A piece of information has come to my attention which I think I should bring to yours. The RU 486 treatment requires the use of a drug called Cytotec as part of the treatment. It is an essential part. Cytotec is manufactured by Searle, which is a subsidiary of Monsanto.

Larry Lader has been advised that Monsanto has decided to remove Cytotec from the market. The result of that would be to make RU 486 unusable.

I understand there is legislation which bars removal from the market of a drug which is important for public health purposes. I suggest that Cytotec is such a drug and, if it is, that the government should be interested in whether or not the report of its withdrawal from the market is accurate and take some steps to prevent it from happening.

Certainly, the report is worth inquiry.

T54498
TRACER

[redacted]

Honorable Donna E. Shalala

APPEARS THIS WAY
ON ORIGINAL

Kindest personal regards.

Sincerely,

[redacted]

FEB 2 7 1996

The Honorable John Ashcroft
United States Senate
Washington, D.C. 20510-2504

Dear Senator Ashcroft:

This is in response to your letter of February 2, 1996, asking to be notified when a New Drug Application (NDA) for RU-486 is filed with the Food and Drug Administration (FDA).

We appreciate your interest in matters related to the safety and efficacy of this product. Our regulations, however, prohibit us from disclosing the existence of an NDA unless this information has been publicly acknowledged by the sponsor of the application. As you may know, The Population Council, a non-profit research organization based in New York, has been licensed by the French manufacturer, Roussel-Uclaf, to develop RU-486 for marketing in the United States. You may wish to contact them for further information. They can be reached at (212) 327-8717.

If we can be of any further assistance, please contact us.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
HFW-14
R/D: :2/12/96
F/T: :2/24/96 (RU-486.NDA)
Control No. 96-920

APPEARS THIS WAY
ON ORIGINAL

MIF 005191

JOHN ASHCROFT
MISSOURI

e-mail:john_ashcroft@ashcroft.senate.gov

United States Senate

WASHINGTON, DC 20510-2504

February 2, 1996

Dr. David A. Kessler
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Inquiry into Filing of New Drug Application

Dear Dr. Kessler:

In light of the health and safety issues, including concerns about efficacy, regarding the use of RU-486 (mifepristone), I would like to be notified if and when any New Drug Application (NDA) is filed for, or in relation to, RU-486.

Thank you for your attention to this matter.

Sincerely yours,

John Ashcroft

JDA/aeb

APPEARS THIS WAY
ON ORIGINAL

96-920

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 12 2000

The Honorable Louise M. Slaughter
House of Representatives
Washington, D.C. 20515-3228

Dear Ms. Slaughter:

Thank you for the letter of March 27, 2000, co-signed by thirty-four of your colleagues, expressing your views concerning the new drug application (NDA) of the drug product, mifepristone, (French brand name - RU486). This NDA, sponsored by the Population Council of New York City, is currently pending before the Food and Drug Administration (FDA or the Agency).

On February 18, 2000, FDA issued a second "approvable" letter concerning the Population Council's NDA for mifepristone. A copy of the Agency's Talk Paper explaining this action is enclosed. An approvable letter is one of several actions the Agency can take during the drug approval process. Such letters are a formal communication to the sponsor, informing them in detail, of the remaining information that must be submitted to complete an application. As explained in the Talk Paper, under the requirements for FDA set out in the Prescription Drug User Fee Act, the Agency has a six-month goal for acting on information submitted in response to an original action. The February 2000 approvable letter was the Agency's response to that requirement.

FDA regulations, 21 CFR § 20.61, prevent the Agency from discussing any information about a pending NDA that has not been made public by the sponsor. Please be assured that the Agency is aware of your concerns on this matter and is acting as expeditiously as possible to process the application within the requirements of the law.

We trust this responds to your concerns. If we may be of further assistance, please contact us again. A similar letter has been sent to all co-signers of the letter.

Sincerely,

/S/

for Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

APPEARS THIS WAY
ON ORIGINAL

bcc: HFW-10
HFW-1
HFW-14
R/D: ———— :3/30/00
Rev: ——— :3/31/00
Cleared: ———— :3/31/00
Edits: ——— :4/3/00
Edits: ——— 4/4/00
F/T:frw:4/4/00:(G:\WP\ ——— .00-2187.doc)
Control No.:00-2187

APPEARS THIS WAY
ON ORIGINAL

COMMITTEE ON RULES
SUBCOMMITTEE
RULES AND ORGANIZATION
OF THE HOUSE

CAUCUS FOR WOMEN'S ISSUES

CONGRESSIONAL ARTS CAUCUS
CHAIR

DEMOCRATIC LEADERSHIP
VICE CHAIR: RESEARCH

WHIP-AT-LARGE

CONGRESS OF THE UNITED STATES
LOUISE M. SLAUGHTER
28TH DISTRICT, NEW YORK

2347 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, D.C. 20515-3228
202/225-3615

DISTRICT OFFICE:
3120 FEDERAL BUILDING
100 STATE STREET
ROCHESTER, NY 14614-1309
716/232-4850
TTY 716/454-4805

E-mail: louseny@mail.house.gov
web: http://www.house.gov/slaughter/

March 27, 2000

The Honorable Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Room 1471
Rockville, Maryland 20857

Dear Dr. Henney,

We are writing to you to express our concern about the delays in the Food and Drug Administration's (FDA) review of mifepristone (RU-486) and to request additional information about the status of the review.

It has been almost four years since FDA made its initial determination that the submission for RU-486 was approvable. During that time, there have been delays due to problems with finding a company willing to manufacture the drug, a situation likely exacerbated by the activities of anti-abortion protestors. While some of these previous delays were clearly outside FDA's control, we are disappointed with the agency's recent decision to once again find that the submission is only "approvable."

America's women are best served when we provide them access to the greatest number of options to make optimal reproductive health choices. It is critical that once all the technical issues are resolved, that FDA approve RU-486 as expeditiously as possible.

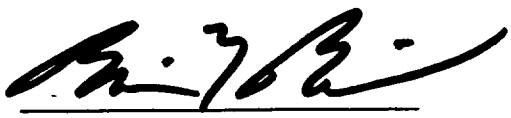
Thank you for your attention to this matter. We know that you share our commitment to making this important drug available as quickly as possible, and we look forward to receiving your response.

Sincerely,

Louise M. Slaughter
Member of Congress

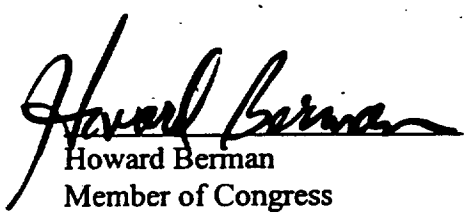
Neil Abercrombie
Member of Congress

No. 00-2187



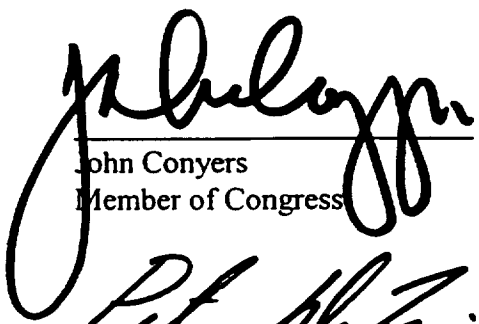
Brian Baird
Member of Congress

Tammy Baldwin
Member of Congress



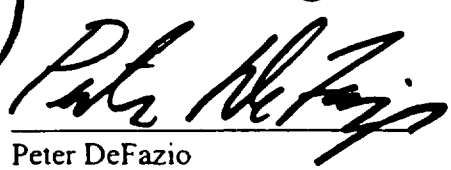
Howard Berman
Member of Congress

Michael Capuano
Member of Congress

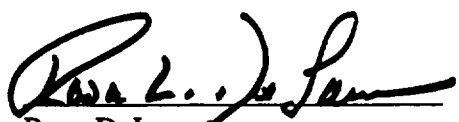


John Conyers
Member of Congress

Elijah Cummings
Member of Congress

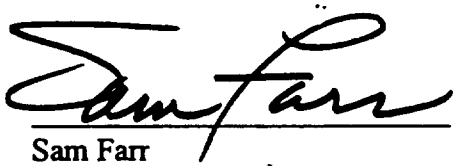


Peter DeFazio
Member of Congress

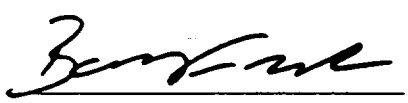


Rosa DeLauro
Member of Congress

Lane Evans
Member of Congress



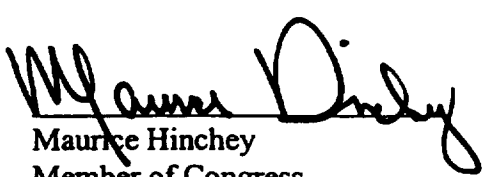
Sam Farr
Member of Congress



Barney Frank
Member of Congress

Sam Gejdenson
Member of Congress

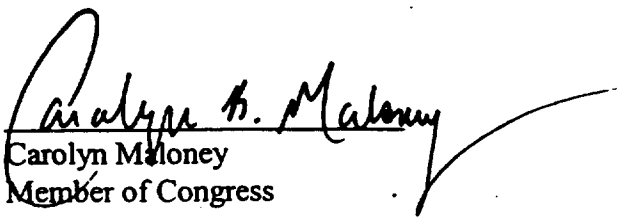
Gene Green
Member of Congress



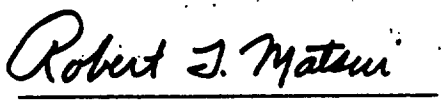
Maurice Hinchey
Member of Congress

Rush Holt
Member of Congress

Nancy Johnson
Member of Congress

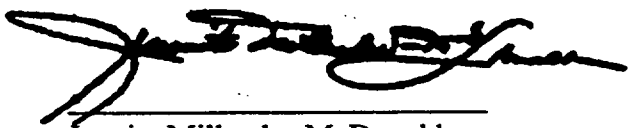


Carolyn Maloney
Member of Congress



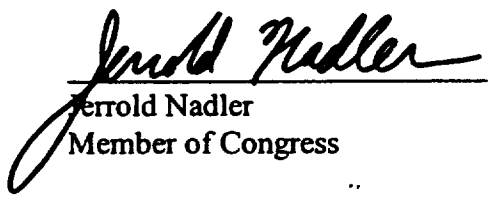
Robert Matsui
Member of Congress

Jim McDermott
Member of Congress

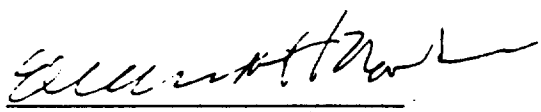


Juanita Millender-McDonald
Member of Congress

Constance Morella
Member of Congress

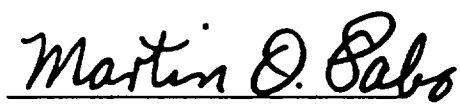


Jerrold Nadler
Member of Congress



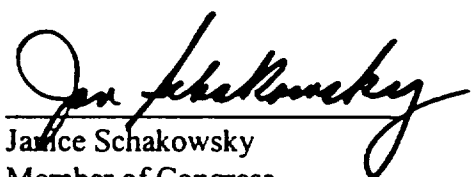
Eleanor Holmes Norton
Member of Congress

Lynn Rivers
Member of Congress

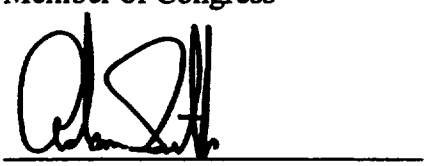


Martin Sabo
Member of Congress

Bernard Sanders
Member of Congress



Janice Schakowsky
Member of Congress



Adam Smith
Member of Congress

John Tierney
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Edolphus Towns
Member of Congress

Mark Udall
Member of Congress

Henry Waxman
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Lynn Woolsey
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