DEPARTMENT OF HEALTH AND HUMAN SERVICES

Interim 3-010

MAR 06 1989

A.F. 43-293 FILE

The Honorable Jesse Helms
United States Senate
Washington, D.C. 20510

Dear Senator Helms:

This is to let you know that we have received your inquiry of February 23, 1989, addressed to Commissioner Young, concerning the importation of RU-486.

We have asked our specialists for their review and assistance. We will get back in touch with you as soon as possible.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
HFD-365w/ ——

R/D: ——:3/3/89
F/T:crw:3/6/89 — E--INTERIM)

Note to HFD-365 - Please prepare a response for the signature of Hugh C. Cannon.

APPEARS THIS WAY
ON ORIGINAL

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	FST	3/6						

FILE COPY

MIF 005601

JESSE HELMS
NORTH CAROLINA

United States Senate

WASHINGTON, DC 20510

February 23, 1989

Mr. Frank E. Young, M.D. Ph.D.
Commissioner
Food and Drug Adminstration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

It is my understanding that the FDA has issued a new policy allowing the importation of certain drugs currently unapproved by the FDA.

Under this new policy, will citizens and companies be allowed to import RU-486?

Kindest regards.

Sincerely,

Jesse Helms

JESSE HELMS:mjc

APPEARS THIS WAY
ON ORIGINAL

United States Senate

WASHINGTON, D.C. 20510

January 11, 1989

Director of Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

Enclosed is correspondence that I have received from [redacted] concerning the lack of birth control options for women. I would appreciate your expeditious attention to this matter.

Please respond directly to [redacted] However, for record purposes, please send a copy of your response to Janet McCracken of my staff.

Best regards.

Sincerely,

John Glenn

John Glenn
United States Senator

JG/jmm
Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005603

DEPARTMENT OF HEALTH AND HUMAN SERVICES

43-253 FILE
Request

The Honorable Brock Adams
United States Senate
Washington, D.C. 20510

FEB 17 1989

Dear Senator Adams:

This is in response to your letter of January 18, 1989, on behalf of _____ concerning the unapproved new drug, ~~RU-486.~~

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer On New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

We are ~~unable~~ to predict whether, or when, RU486 will be approved for marketing. You may assure _____ that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

5494

151 2-17-89

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-69	FST	2/17						

FILE COPY

MIF 005604

We hope these comments are helpful. If we can be of further service, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc: HFW-10(2)
R/D: ——— .2/16/89
F/T:cah:2/17/89(——— -RU486)

APPEARS THIS WAY
ON ORIGINAL

BROCK ADAMS
WASHINGTON

COMMITTEES:
APPROPRIATIONS
LABOR AND HUMAN RESOURCES
RULES AND ADMINISTRATION

United States Senate

WASHINGTON, D.C. 20510

January 18, 1989

Mr. Hugh C. Cannon
Food & Drug Administration
1555 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

Enclosed please find a copy of a request from my constituent, _____

I would appreciate it if you could address my constituent's inquiries concerning the potential availability of RU 486 to U.S. consumers.

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

Sincerely,

Brock Adams

BROCK ADAMS
United States Senator

BA/kw
Enclosure

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 1[illegible]9

The Honorable Lee H. Hamilton
House of Representatives
Washington, D.C. 20515

N.F. 43-263 FILE

Dear Mr. Hamilton:

This is in response to your letter of December 21, 1988, on behalf of _____, concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer On New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

We are unable to predict whether, or when, RU-486 will be approved for marketing. You may assure _____ that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

5414

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
OC	FST	1/13/89						

FILE COPY

MIF 005607

We hope these comments are helpful. If we can be of further service, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's Letter
Clinical Testing . . .
A Primer on New . . .

cc: HFW-10(2)
R/D: ——— :12/28/88
F/T:car:12/29/88(—— -RU486, ——

APPEARS THIS WAY
ON ORIGINAL

December 8, 1988

Congressman Lee H. Hamilton
Indiana 9th District
U.S. House of Representatives
Washington, DC 20515

Congressman Hamilton

I would like some information concerning the abortion pill. I want to know what it does, how it will be obtained, various side effects, and whether it will be made legal in the United States.

I appreciate the time being taken to collect this information.

Sincerely yours

/s/

Congress of the United States

House of Representatives

Washington, D.C.

DEC 21 1988 19.....

Sir:

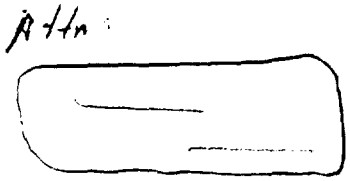
The attached communication is sent for your consideration. Please investigate the statements contained therein and forward me the necessary information for reply, returning the enclosed correspondence with your answer.

Yours truly,

CONGRESSMAN LEE H. HAMILTON
2187 RAYBURN BUILDING
WASHINGTON, D.C. 20515

M.C.

APPEARS THIS WAY
ON ORIGINAL



DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN

A.F. 113-253 FILE

The Honorable Donald W. Riegle, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Riegle:

This is in response to your letter of December 16, 1988, on behalf of _____, concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer On New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

We are unable to predict whether, or when, RU-486 will be approved for marketing. You may assure _____ that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
OCA	/ST	1/13/89						

FILE COPY

MIF 005611

We hope these comments are helpful. If we can be of further service, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's Letter
Clinical Testing . . .
A Primer on New . . .

cc: HFW-10(2)
R/D: ——— :12/28/88
F/T:car:12/29/88 ———-RU486)

APPEARS THIS WAY
ON ORIGINAL

Hon. Donald W. Riegle Jr.
SD-105
Washington D.C. ,20510

November 28,1988

Dear Senator Riegle,

Currently a graduating senior at Eisenhower High School in Shelby Township, I am concerned about the availibility of abortions in Michigan.

Over two hundred thousand women die every year from botched abortions, and the government has done little about this situation. Now that the government in Michigan has ended tax funded abortions, this number will increase greatly.

In an effort to reduce this number, scientists in Europe have discovered a drug that may help many women: RU-486 (Roussel-Uclaf). The pill RU-486 prevents the cells in the lining of the uterus from getting progesterone, without which the walls of the uterus break down, preventing the egg from ever implanting in the uterus. Taking this drug seems like a quicker, much more effective and less expensive way to solve the problem of unwanted pregnancy. The drug also may be used for breast cancer and ectopic pregnancies.

I would like to know why this drug is unavialable in the U.S.. It is legal in other countries, and there have been no reported problems as of yet.

Thank you for taking time to read my letter and I would appreciate a response.

Sincerely,

MIF 005613

DONALD W. RIEGLE, JR.
*MICHIGAN

COMMITTEES
BANKING, HOUSING, AND URBAN AFFAIRS
COMMERCE, SCIENCE, AND TRANSPORTATION
FINANCE
BUDGET

United States Senate

WASHINGTON, DC 20510

December 16, 1988

Mr. Hugh C. Cannon
Associate Commissioner
for Legislative Affairs
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Cannon:

Recently I was contacted by ———————— who expressed concern about a matter within your agency's jurisdiction. I am enclosing a copy of the constituent's correspondence for your information.

I would appreciate your response to the concerns raised in the attached letter. Please direct any questions or correspondence to Mr. Eric Phillips of my staff, at SD-182 Dirksen Senate Office Building, Washington, D.C. 20510.

Thank you for your attention to this matter.

Sincerely,

Donald W. Riegle, Jr.

DWR/epc

Enclosure

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FILE

APR 28 1988

The Honorable George Darden
House of Representatives
Washington, D.C. 20515

Dear Mr. Darden:

This is in response to your letter of April 11, 1988, on behalf of _____ concerning RU-486, an abortifacient developed in France.

As you know, RU-486 has not received the Food and Drug Administration's (FDA) approval for marketing although this drug is in clinical trials.

Before we will permit testing a drug in humans, the sponsor of the drug must provide us with information demonstrating that the drug is reasonably safe to administer to humans. The sponsor must also provide manufacturing and control data, a detailed protocol of study, and names and qualifications of investigators who will be performing the clinical trials. These requirements were met by the Population Council, New York, New York.

The Federal Food, Drug, and Cosmetic Act, which we administer, sets forth the criteria for approval of new drugs. Approval is based on submission of data collected during the course of an investigation which demonstrates the drug is safe and effective for the purpose of use.

We appreciate the concerns expressed by _____ Please assure him that approval of this, or any product, will only be granted if the safety and efficacy requirements mandated by law are satisfied.

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's Letter

cc: HFW-10(2) --RU-486)
RPD: _____ 4/23/88 _____
SET:cah:4/26/88 _____

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	4/28						

U.S. GPO 1986-169-089

MIF 005615

February 23, 1988

MAR 0 1 RECD

Representative George Darden
1330 LHOB
Washington D.C. 20515

Dear Mr. Darden

I am writting in concern of the new drug RU 486, which is going to be sold in France, China England and other such countries. This anti-abortion drug is known to have harmful side afects on women. It is also a useful drug, in that it can widen the birth canal to avoid Caesarean. However, I feel that this drug, RU 486, should not be sold in the U.S.. I would hope that you would support me on this issue.

2

GEORGE (BUDDY) DARDEN
7TH DISTRICT, GEORGIA

COMMITTEES:
ARMED SERVICES
SUBCOMMITTEES
RESEARCH AND DEVELOPMENT
READINESS
INTERIOR AND INSULAR AFFAIRS
SUBCOMMITTEES:
ENERGY AND ENVIRONMENT
PUBLIC LANDS
NATIONAL PARKS AND RECREATION

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

WASHINGTON OFFICE:
330 LONGWORTH BUILDING
WASHINGTON, DC 20515
(202) 225-2931

DISTRICT OFFICES:
376 POWDER SPRINGS STREET
MARIETTA, GA 30064
TELEPHONE: (404) 422-4480

301 FEDERAL BUILDING
ROME, GA 30161
TELEPHONE: (404) 291-7777

125 SOUTH MAIN STREET
LAFAYETTE, GA 30728
TELEPHONE: (404) 638-7042

April 11, 1988

Mr. Frank E. Young
Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Young:

Enclosed is a communication from one of my constituents within the area of your authority. Because of my desire to be responsive to all inquiries, your assistance is requested. I would appreciate your looking into this matter and providing me with a report so that I may further respond to my constituent.

Your findings and views, in duplicate form, along with the return of the enclosure will be greatly appreciated. Please direct your response to the attention of Amy Holley.

Sincerely,

George (Buddy) Darden
Member of Congress

GBD:alh
Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005617

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. RU-486 -4 FILE
43-153

APR 28 1988

The Honorable Alfonse M. D'Amato
United States Senator
304 Federal Building
100 State Street
Rochester, New York 14614

Dear Senator D'Amato:

This is in response to your letter of March 18, 1988, on behalf of _____, concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

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We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer On New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

We are unable to predict whether, or when, RU486 will be approved for marketing. You may assure _____ that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

3774

FILE COPY

151 4/28

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-2	151	4/28						

U.S. GPO 1986-169-089

MIF 005618

We hope these comments are helpful. If we can be of further service, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's Ltr
Clinical Testing . . .
A Primer on New . . .

cc: HFW-10(2)
R/D: ——— :4/20/88
F/T:cah:4/27/88(———-RU486)

APPEARS THIS WAY
ON ORIGINAL

MAR 4 18

March 3, 1988

Alfonse M. D'Amato
U. S. Senator
304 Federal Building
Rochester, New York 14614

Dear Senator D'Amato:

I have consistently supported your election, and am now am writing to you to enlist your help regarding **women's health care**.

An article appeared in the Albany TIMES-UNION under the headline **"ABORTION DRUG BLOCKED BY FEARS OF RIGHT-TO-LIFERS"** on Monday, February 22, 1988

The article says the drug, **RU486**, when combined with prostaglandin,is safer than surgical abortion; in fact, it so effective that it will eliminate the need for surgical abortion in the first trimester. It is expected to be approved for sale in France and China in March, and is expected to be marketed within a year in Sweden, the Netherlands and England.

Experts also say it may have a use in other situations, such as in widening the birth canal, which would enable many women to **avoid Caesarian sections**. It may also be useful in **treating some forms of breast cancer as well as endometriosis**, a leading cause of infertility.

However, Hoechst-Roussell Pharmaceuticals,Inc., of Somerville, New Jersey, which holds the rights to rights to market the drug in the United States, **has declined to ask for FDA approval**. The reason given is simple: economic survival.

The National Right to Life and other anti-choice groups have **threatened to boycott any company that introduces RU486** or any other abortion-inducing drug. Dr. Richard Glasgow, Education Director of National Right to Life, has said that NRL would organize a massive boycott of all the products of any company which did so, unless the drug was "the only one available for the treatment of a life threatening illness."

Because of these anti-choice people, women are being denied a safer, less expensive way to exercise their hard-won legal right to abortion. Indeed, experts predict that RU486 would eliminate abortion clinics, allowing first trimester abortions to be done by a woman's own gynecologist in the privacy of a routine visit.

I urge you to take whatever steps you can to see that this is treated as a health issue, not a moral or political one. We can not continue to jeopardize the lives and rights of women, in order to satisfy the beliefs of one special interest group.

Thank you for your much-needed support in this important matter.

Sincerely,

MIF 005620

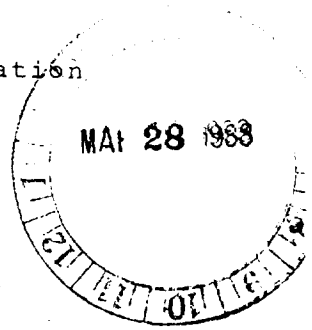
March 18, 1988

United States Senate

304 Federal Building
100 State Street
Rochester, NY 14614

Respectfully referred to:

Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852



To: Director
Re: _____

Because of the desire of this office to be responsive to all inquiries and communications, your consideration of the attached is requested. Your findings and views, in duplicate form, along with return of the enclosure, will be appreciated by

U.S.S.

Form #2

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FILE

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 3, 1989, on behalf of _____ concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer on New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

It is also important to point out that FDA does not actually do the clinical testing of drugs before they are marketed. Pharmaceutical manufacturers, the National Institutes of Health, and other research institutions across the country carry out programs to identify, develop and test drugs. It is FDA's responsibility to review and analyze the results of the testing to determine if a drug is safe and effective for widespread marketing for use by the general public

/S/

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW(B)	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005622

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
TRANSPORTATION, CHAIRMAN
COMMERCE, JUSTICE, STATE AND JUDICIARY
DEFENSE
FOREIGN OPERATIONS
VA, HUD AND INDEPENDENT AGENCIES

COMMITTEE:
BUDGET

COMMITTEE:
ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEES:
SUPERFUND, OCEAN AND WATER PROTECTION, CHAIRMAN
ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

United States Senate
WASHINGTON, DC 20510

August 3, 1989

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from _____

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

☐ 717 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

United States Senate

WASHINGTON, D.C. 20510

May 25, 1989

Director of Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

Enclosed is correspondence that I have received from _____ concerning the drug RU 486. I would appreciate your expeditious attention to this matter.

Please respond directly to Ms. Barnhart. However, for record purposes, please send a copy of your response to Janet McCracken of my staff.

Best regards.

Sincerely,

John Glenn

John Glenn
United States Senator

JG/jm
Enclosure

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Gantz P. Fascell
House of Representatives
Washington, D.C. 20515

MAY 23 1989

Dear Mr. Fascell:

This is in response to your inquiry of April 24, 1989, on behalf of several of your constituents, concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

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We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer On New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

We are unable to predict whether, or when, RU-486 will be approved for marketing. You may assure your constituents that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

We hope these comments are helpful. If we can be of further service, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc: HFW-10(2)
R/D: 5/17/89
F/T:crw:5/19/89:(RU486)

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW10	FST	5/22						

FILE COPY

MIF 005626

*U.S.GPO:1988-0-213-052

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. FILE

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 3, 1989, on behalf of [redacted] concerning the unapproved new drug, RU-486.

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/S/ /S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-18	/S/	9/18						

*U.S. GPO: 1989-619-660

MIF 005627

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 43-222 FR

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 3, 1989, on behalf of _____ concerning the unapproved new drug, RU-486.

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/S/

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005629

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

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Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. FILE

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

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/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-19	/S/	9/18						

/S/

*U.S. GPO: 1989-619-669

MIF 005631

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

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Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
TRANSPORTATION, CHAIRMAN
COMMERCE, JUSTICE, STATE AND JUDICIARY
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United States Senate

WASHINGTON, DC 20510

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ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

August 3, 1989

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from _____.

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

☐ 717 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F.

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

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/S/

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005634

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure ——— that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: ——— :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
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COMMERCE, JUSTICE, STATE AND JUDICIARY
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United States Senate
WASHINGTON, DC 20510

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ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

August 3, 1989

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The Food and Drug Administration
Parklawn Building
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Rockville, New Jersey 20857

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With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

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WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 43-233 FH

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 3, 1989, on behalf of [redacted] concerning the unapproved new drug, RU-486.

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/S/ /S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-18	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005637

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

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Hugh C. Cannon
Associate Commissioner
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2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEES:
APPROPRIATIONS
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COMMERCE, JUSTICE, STATE AND JUDICIARY
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SUBCOMMITTEES:
SUPERFUND, OCEAN AND WATER PROTECTION, CHAIRMAN
ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

United States Senate

WASHINGTON, DC 20510

August 3, 1989

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Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

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WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FYLI

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

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/S/ /S/ 9/14

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-12	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005640

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Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] 8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)
CTRL #8-162

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
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SUBCOMMITTEES:
TRANSPORTATION, CHAIRMAN
COMMERCE, JUSTICE, STATE AND JUDICIARY
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United States Senate
WASHINGTON, DC 20510

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COMMITTEE:
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HELSINKI COMMISSION

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FRL:tdb
Enclosure

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ON ORIGINAL

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WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
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☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 73-22 FILE

SEP 22 1989

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United States Senate
Washington, D.C. 20510

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4463

/S/

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-18	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005643

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Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted].8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEES:
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COMMERCE, JUSTICE, STATE AND JUDICIARY
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United States Senate

WASHINGTON, DC 20510

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ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

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FRL:tdb
Enclosure

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ON ORIGINAL

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WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
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(201) 645-3030

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. FILI

SEP 22 1989

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/S/ /S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-18	/S/	9/18						

*U.S. GPO: 1989-619-669

MIF 005646

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Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

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COMMERCE, JUSTICE, STATE AND JUDICIARY
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United States Senate

WASHINGTON, DC 20510

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SUPERFUND, OCEAN AND WATER PROTECTION, CHAIRMAN
ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

August 3, 1989

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from _____

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

☐ 717 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FH

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 3, 1989, on behalf of _____, concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

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We are enclosing reprints, "Clinical Testing for Safe and Effective Drugs" and "A Primer on New Drug Development," that describe in more detail the requirements for new drug clearance in the United States.

It is also important to point out that FDA does not actually do the clinical testing of drugs before they are marketed. Pharmaceutical manufacturers, the National Institutes of Health, and other research institutions across the country carry out programs to identify, develop and test drugs. It is FDA's responsibility to review and analyze the results of the testing to determine if a drug is safe and effective for widespread marketing for use by the general public.

/S/

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	/S/	9/18						/S/

FILE COPY

*U.S. GPO: 1989-619-669

MIF 005649

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted]:8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
TRANSPORTATION, CHAIRMAN
COMMERCE, JUSTICE, STATE AND JUDICIARY
DEFENSE
FOREIGN OPERATIONS
VA, HUD AND INDEPENDENT AGENCIES

United States Senate

WASHINGTON, DC 20510

COMMITTEE:
BUDGET

COMMITTEE:
ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEES:
SUPERFUND, OCEAN AND WATER PROTECTION, CHAIRMAN
ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

August 3, 1989

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from _____

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

☐ 717 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FILE

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 3, 1989, on behalf of _____ concerning the unapproved new drug, RU-486.

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/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-18	/S/	9/15						

/S/

*U.S. GPO: 1989-619-669

MIF 005652

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure ——— that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: ——— 8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)

APPEARS THIS WAY
ON ORIGINAL

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
TRANSPORTATION, CHAIRMAN
COMMERCE, JUSTICE, STATE AND JUDICIARY
DEFENSE
FOREIGN OPERATIONS
VA, HUD AND INDEPENDENT AGENCIES

United States Senate

WASHINGTON, DC 20510

COMMITTEE:
BUDGET

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SUBCOMMITTEES:
SUPERFUND, OCEAN AND WATER PROTECTION, CHAIRMAN
ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

August 3, 1989

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

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WASHINGTON, DC 20510
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☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

A.F. _____ FILE

SEP 22 1989

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

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It is also important to point out that FDA does not actually do the clinical testing of drugs before they are marketed. Pharmaceutical manufacturers, the National Institutes of Health, and other research institutions across the country carry out programs to identify, develop and test drugs. It is FDA's responsibility to review and analyze the results of the testing to determine if a drug is safe and effective for widespread marketing for use by the general public.

/S/

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
R/D: [redacted] :8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)
CTRL# 8-163

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-62	[illegible]	9/18						

*U.S. GPO: 1989-619-669

MIF 005656

FRANK R. LAUTENBERG
NEW JERSEY

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
TRANSPORTATION, CHAIRMAN
COMMERCE, JUSTICE, STATE AND JUDICIARY
DEFENSE
FOREIGN OPERATIONS
VA, HUD AND INDEPENDENT AGENCIES

United States Senate

WASHINGTON, DC 20510

COMMITTEE:
BUDGET

COMMITTEE:
ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEES:
SUPERFUND, OCEAN AND WATER PROTECTION, CHAIRMAN
ENVIRONMENTAL PROTECTION
WATER RESOURCES, TRANSPORTATION AND INFRASTRUCTURE

HELSINKI COMMISSION

August 3, 1989

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

☐ 717 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEP 22 1989

The Honorable Bob Stump
House of Representatives
Washington, D.C. 20515

Dear Mr. Stump:

This is in response to your letter of August 3, 1989, on behalf of [redacted] of [redacted] concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

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It is also important to point out that FDA does not actually do the clinical testing of drugs before they are marketed. Pharmaceutical manufacturers, the National Institutes of Health, and other research institutions across the country carry out programs to identify, develop and test drugs. It is FDA's responsibility to review and analyze the results of the testing to determine if a drug is safe and effective for widespread marketing for use by the general public.

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-2	/S/	9/16						/S/

*U.S. GPO: 1989-619-669

MIF 005658

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituents Ltr
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2) ES/PHS CCU
R/D: [redacted]:8/30/89:vaj:9/15/89
F/T:vaj:9/15/89:(val:ru486.mdg)
CTRL *8-324

APPEARS THIS WAY
ON ORIGINAL

Congressman Bob Stump
211 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Stump:

We urge you to oppose any attempts to restrict the Food and Drug Administration from further testing of the drug RU-486, the drug which has the potential for providing an alternative to surgical abortion.

Although we do not agree with your position on surgical abortion, we do respect your views about it. We believe that RU-486 may be an acceptable alternative for many of the opponents of legal abortion, and a reasonable compromise for most of the persons on both sides of the volatile abortion issue, which, as you well know, threatens to tear this country apart during the coming months and years.

We strongly believe that RU-486 should be fully tested by the F.D.A. without political intervention.

Respectfully,

Congress of the United States
House of Representatives
Washington, D.C. 20515

August 3 1989

Congressional Liaison

REF: attached correspondence

Sir:

The attached communication is sent for your consideration. Please investigate the statements contained therein and forward me the necessary information for reply, returning the enclosed correspondence with your answer.

Yours truly,

BOB STUMP, M.C.
Third District, Arizona

PLEASE RETURN TO:
211 Cannon House Office Bldg.
Washington, D.C. 20515
ATTN: D. Dunn T24457
TRACER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 43-202 FILE

SEP 21 1989

The Honorable Sam Nunn
United States Senator
Suite 1700
75 Spring Street, S.W.
Atlanta, Georgia 30303

Dear Senator Nunn:

This is in response to your letter of August 15, 1989, on behalf of [redacted] concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFM12	/S/	9/18						

/S/

/S/

*U.S. GPO: 1989-619-669

MIF 005662

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new product as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .

cc:HFW-10(2)
F/D: [redacted] :9/15/89
F/T:vaj:9/18/89:(val:nunn.ru4)
CTRL #9-025

APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON ARMED SERVICES
WASHINGTON, DC 20510-6050

August 15, 1989

Mr. Hugh C. Cannon
Associate Commissioner for Legislative Affairs
Congressional Liaison Office
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

I recently received the enclosed constituent inquiry. Because of my desire to be responsive to all inquiries, I would appreciate your looking into this matter and providing me with a report so that I may further respond to my constituent.

Your kind assistance is greatly appreciated.

Sincerely,

Sam Nunn

Sam Nunn

Enclosure

SN/lkj

PLEASE REPLY TO:
75 Spring Street, S.W.
Suite 1700
Atlanta, Ga. 30303
Attn: Laura Johnson

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 43-22 FI

R

SEP 21 1989

The Honorable Lloyd Bentsen
United States Senator
961 Federal Building
Austin, Texas 78701

Dear Senator Bentsen:

This is in response to your inquiry of August 14, 1989, on behalf of [redacted] concerning RU-486, an abortifacient developed in France.

As you know, RU-486 has not received the Food and Drug Administration's (FDA) approval for marketing although this drug is in clinical trials.

Before we will permit testing a drug in humans, the sponsor of the drug must provide us with information demonstrating that the drug is reasonably safe to administer to humans. The sponsor must also provide manufacturing and control data, a detailed protocol of study, and names and qualifications of investigators who will be performing the clinical trials. These requirements were met by the Population Council, New York, New York.

The Federal Food, Drug, and Cosmetic Act, which we administer, sets forth the criteria for approval of new drugs. Approval is based on submission of data collected during the course of an investigation which demonstrates the drug is safe and effective for the purpose of use.

We appreciate the concerns expressed by [redacted] Please assure her that approval of this, or any product, will only be granted if the safety and efficacy requirements mandated by law are satisfied.

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

/S/

Enclosure
Constituent's Ltr

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-22	/S/	9/18						

/S/

*U.S. GPO: 1989-619-669

MIF 005665

June 12, 1989

Honorable Senator Benson
U.S. Senate
Washington, D.C. 20510

Dear Senator Benson:

There are reports that the FDA is planning to bring the drug RU 486, commonly known as the abortion drug, into the United States without proper studies. Please Sir , DON'T ALLOW THIS.
I have been a nurse anesthetist for 35 years, and I keep abreast of the types of drugs that are put upon the market.

Again I plead with you not to let down your vigil, of doing what is best for our people's health. This drug has so many bad features it will be a real problem for us all.

Sincerely,

[redacted]

LLOYD BENTSEN
TEXAS

COMMITTEES:
FINANCE
COMMERCE, SCIENCE, AND TRANSPORTATION
JOINT ECONOMIC
JOINT COMMITTEE ON TAXATION

United States Senate

WASHINGTON, DC 20510

August 14, 1989

Dr. Frank E. Young
Commissioner
Food and Drug Administration
Parklawn Building
Rockville, Maryland 20857

Dear Commissioner Young:

I recently received the enclosed constituent inquiry, and I would very much appreciate your providing me with any pertinent information you might have regarding the matter.

Your kind assistance is greatly appreciated.

Sincerely,

Lloyd Bentsen

Lloyd Bentsen

Enclosure

PLEASE REPLY TO:

961 Federal Building
Austin, Texas 78701
ATTN: Tony Knutson

APPEARS THIS WAY
ON ORIGINAL

Ru-486 Documents as Requested by Weiss March 1990

May 5, 1989	Letter from Rep. Dornan, re: RU-486 status (2 Pages)
April 17, 1989 referral date	Draft letter Commis/ to Senator Helms(9 Pages)
June 6, 1989	Import Alert (1 Page)
June 9, 1989	Letter Young/Rep. Dornan, response to 5/5/89 letter (6 Pages)
March 31, 1989	——— clearance record, Alert, (10 Pages)
May 24, 1989	Draft ——— ——— ltr. to Dornan (9 Pages)
May 2, 1989	Letter Helms/FYoung, response to 2/23/89 ltr. (6 Pages)
April 10, 1986	Letter /Humphrey (14 Pages)
May 2, 1986	Letter /Humphrey, signed (2 Pages)
August 13, 1986	Letter Dornan/ —— (4 Pages)
June 6, 1989	Import Alert (2 Pages)
No Date	Customs Regulations 19 CFR 12.40 (4 Pages)
September 29, 1986	Confidential Memo, IND's for RU-486, by ———
August 6, 1986	Clearance form and ltr. Dornan/ ——— (1 Page) and (2 Pages)
August 13, 1986	Letter Dornan/ —— (2 Pages)
October 7, 1986	Options Memo ——— with FAX covers (2 Pages)
May 6, 1987	——— resp. to Lautenberg (1 Page)
April 4, 1987	" " (1 Page)
April 13, 1987	Letter Lautenberg/Commissioner (1 Page)
May 5, 1987	Draft ltr. Cannon resp. Lautenberg (2 Pages)

July 23, 1987	Letter/Cover JCWilke NRLC/FYoung, followup to meeting, Letter /FDA:6/24/87 (4 Pages)
March 31, 1989	Handwritten memos, [redacted] drafting alert (7 Pages)
January 12, 1990	Letter [redacted] 'Hamilton (New Republic)
June 1989	Import Alert 66-42 (2 Pages)
February 23, 1990	Memo Benson re:Ru-486 (2 Pages)
June 6, 1989	Import Alert 66-47 (2 Pages)
March 31, 1989	Clearance Record, re: import alert [redacted] (4 Pages)
No Date	Example of various responses to Ru-486 inquiries (8 Pages)
No Date	Tracking info and notes (5 Pages)
February 2, 1990	[redacted] Fax, draft congressional (12 pages)
February 21, 1990	Note (1 Page)
February 22, 1990	Interoffic Memo , [redacted] (1 Page)
February 13, 1986	Letter Humphrey/ (3 Pages)
May 2, 1986	Letter Humphrey/ (3 Pages)
June 12, 1987	Memo /FDA (4 Pages)

APPEARS THIS WAY
ON ORIGINAL

March 31, 1989	Clearance Record, ——— (4 Pages)
October 6, 1986	Fax request ——— / (7 Pages)
December 27, 1989	Memo ——— / , request for info. on import policy (4 Pages)
Deceber 11, 1989	Regulatory Procedures Manual, coverage of Personal Importations (8 Pages)
August 29, 1989	Memo /RFDD's and DD's, re: guidance for responding to quest. on personal import policy (5 Pages)
August 1, 1988	Import Alert: Unapproved new drugs (5 Pages)
No Date	Desperation-Drugs-Hope-Quakery (4 Pages)
May 31, 1989	Letter / re: pilot guidance (2 Pages)
No Date	Draft letter / re: pilot guide (2 Pages)
April 7, 1989	Letter / re: policy guidance for unapproved drugs (2 Pages)
No Date	Memo of Telecon, between :/
October 17, 1988	Letter / (2 Pages)
July 20, 1989	Letter / (2 Pages)
October 13, 1989	Letter / (2 Pages)
October 11, 1989	Letter / (2 Pages)
July 14, 1989	Letter /
October 12, 1989	Letter request for info. Ru-486 Young/. (cover and page)
May 2, 1989	Letter Helms/Young re: Ru-486 and the import of it w/policy guidelines (16 pages)

Various Dates Sent over by Blumberg	Draft re: Import alert 66-47, handwritten notes, Ltr. 1/19/90 Benson/Dingell, Ltr. Nelson/ , Import Alert 66-B13, Import Alert 6/6/89, Import Alert 66-47, Draft alert 56008H, clerance record 5/31/89, Draft alert 56008H, Import alert bulletin 66-B13 (22 page)
July 31, 1987	Letter Bentsen/Cannon re: Ru-486, clinical study, w/ draft, and inc.(7 Pages)
September 12	Fax Transmission / ; Dornan/ (3 Pages)
Septembe 11, 1986	Fax Transmissioner /
December 16, 1986	Radio TV Reports, Inc. re: Abortion pill (7 Pages)
January 6, 1987	Executive Correspondence, Wh response to constituent re: pornography and Ru-486 Ltr. (7 Pages)
May 18, 1987	Washington Drug Ltr. (2 Pages)
June 17, 1987	Ltr. Humphrey/Cannon re: investigationl drugs
July 13, 1987	Washington Drug Ltr.
July 31, 1987	Ltr. Bentsen/Cannon response to consituent re: Ru-486 w/inc (4 Pages)
December 5, 1988	Ltr. Humphrey/Cannon re:abortifacient potential
October 12, 1988	Congressional record S15633
November 10, 1988	Interim ltr. #10-142 Humphrey/Cannon (2 Pages)
Novermber 7, 1988	Newsletter Vol. 30, No. 44 (6 Pages)
October ~~29~~, 1988	Ltr. Young/Humphrey (2 pages)
September 26, 1988	Improt Alert 66-B13
December 28, 1987	Ltr. Humphrey/Cannon Re: Warning labels for drugs w/ abort. potentil
September 23, 1987	Ltr. Cochran/Cannon w/inc (4 Pages)

September 2, 1987	Ltr. Boschwitz/Cannon w/inc (5 Pages)
August 24, 1987	Interim ltr. Humphrey/Cannon
December 12, 1989	Note to w/attachments, fax / w/reply material (6 Pages)
November 3, 1989	Ltr. Thurmond/Cannon w/inc (4 Pages)
September 21, 1989	Ltr. Bentsen/Cannon w/inc (4 Pages)
February 28, 1986	Ltr. Humphrey/Cannon w/inc (3 Pages)
May 6, 1987	Ltr. Lautenberg/Cannon w/inc (3 Pages)
July 25, 1986	Ltr. Quayle/Cannon (2 Pages)
October 31, 1989	Ltr. Doty/Cannon w/icn (3 Pages)
October 17, 1989	Remark page
September 1989	Commissioner's briefing book table of contents
Septembr 1989	Chronolgy of contacts w/Humphrey " " Update on RU486 and beast cancer
June 15, 1989	Ltr. Hamilton/Cannon w/inc (5 Pages)
June 6,1989	Improt Alert 66-47 (2 Pages)
April 7, 1989	Ltr. Cooper/Cannon w/inc (3 Pages)
February 17, 1989	Ltr. Farrell/Cannonw/inc (4 Pages)
Jan. 23-2, 1989	Summary Cong. Activities
January 13, 1989	Ltr. Riegle/Cannon w/inc (4 Pages) Ltr. Hamilton/Cannon w/inc (4 Pages)
September 11	PHS Correspondence sheet
July 31, 1986	The American Colege of OB/GYN report (14 Pages)
June 6, 1986	Ltr. Proxmire/Cannon (2 Pages)
May 13, 1986	Ltr. Lautenberg/Cannon (2 Pages)
April 30, 1986	Ltr. Gramm/Cannon (2 Pages)
April 17, 1986	Ltr. /Humphrey
April 2, 1986	Fax Transmission (cover and 2 Pages)

February 28, 1986	Ltr. Humphrey/Cannon w/inc and draft (9 Pages)
February 28, 1986	Ltr. humphrey/Cannon w/inc and draft (9 Pages)
No Date	Coverage mail importations in personal baggae (2 Pages)

ROUSSEL - MEM

DEPARTMENT OF HEALTH AND HUMAN SERVICES 43-253

A.F. ril

MAR 02 1990

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Mr. Wyden:

This is in response to your February 28, 1990 letter to Acting Commissioner Benson, requesting documents related to RU-486.

Enclosed are the documents identified by your staff on their visit to our office on February 27. Responses to the additional requests for information noted in your letter will be forwarded separately.

Some of the enclosed documents contain confidential information and, as such, are not releasable to the public under the Food and Drug Administration's Freedom of Information regulation. Therefore, we request that the Subcommittee not publish or otherwise make public any of the information contained in the enclosed documents. We would be glad to discuss with the Subcommittee staff the confidentiality of any specific document.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures
Documents requested

cc: HFW-10(2)

R/D: —:2/28/90
F/T: var:3/1/90 -

3-15-90
PAB

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-14	/S/	3/2/90						

*U.S. GPO: 1989-619-669

MIF 005674

101st Congress

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

February 28, 1990

James A. Benson
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Benson:

I would appreciate you sending the documents which my staff requested earlier today, when they visited your Rockville offices.

In addition, I would like the following information, which was not accessible to my staff at that time:

1) A list of any and all abortifacients which have been approved by the FDA.

2) Copies of all correspondence from your field offices regarding RU 486.

3) Copies of all correspondence between the FDA and U.S. Customs regarding RU 486.

Your prompt attention to this matter is deeply appreciated.

With warm regards,

Sincerely,

Ron Wyden

RON WYDEN
Chairman

RW/gab

cc: Hugh C. Cannon

APPEARS THIS WAY
ON ORIGINAL

RON WYDEN
OREGON
3D DISTRICT

2452 RAYBURN BUILDING
WASHINGTON, DC 20515
(202) 225-4811

500 NE MULTNOMAH, SUITE 250
PORTLAND, OR 97232
(503) 231-2300

Congress of the United States
House of Representatives

ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEES
HEALTH AND THE ENVIRONMENT
TELECOMMUNICATIONS AND FINANCE
OVERSIGHT AND INVESTIGATIONS

SMALL BUSINESS COMMITTEE
CHAIRMAN,
SUBCOMMITTEE ON REGULATION,
BUSINESS OPPORTUNITIES AND ENERGY

SELECT COMMITTEE ON AGING
HEALTH AND LONG-TERM CARE
SUBCOMMITTEE

CO-CHAIRMAN,
FORESTRY 2000 TASK FORCE

February 27, 1990

James A. Benson
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Benson:

I would appreciate you sending the documents which my staff requested earlier today, when they visited your Rockville offices.

In addition, I would like the following information, which was not accessible to my staff at that time:

1) A list of any and all abortifacients which have been approved by the FDA.

2) Copies of all correspondence from your field offices regarding RU 486.

3) Copies of all correspondence between the FDA and U.S. Customs regarding RU 486.

Your prompt attention to this matter is deeply appreciated.

With warm regards,

Sincerely,

Ron Wyden

RON WYDEN
Member of Congress

RW/gab

cc: Hugh C. Cannon

Withdrawn & replaced by Chairman letter

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 43-253 FILE
Rossel - UCCHF

The Honorable Gordon J. Humphrey
United States Senate
Washington, D.C. 20510

MAR 02 1990

Dear Senator Humphrey:

This is in further response to your letter of November 29, 1989, regarding the development of the drug, RU-486.

Although we wish to be fully responsive to your inquiries regarding Investigational New Drug (IND) applications, we are prevented by provisions of Title 21, Code of Federal Regulations (21 CFR) from revealing confidential commercial and trade secret information to the public, including Members of Congress (21 CFR 4.87 and 314.430). With that restriction in mind, we are providing you with as much information as possible.

According to our regulations, we can neither confirm no deny the existence of an IND unless it is sponsored by a Federal agency or has been previously acknowledged by the sponsor. Therefore, we can confirm that the Population Council has an active Investigational New Drug application to study the use of RU-486 as an abortifacient, but we are not permitted to comment on the status of any investigations under that IND. We regret that we cannot respond to your question as to whether a pharmaceutical company has applied for an IND for RU-486.

Regarding your question about the possibility of approval of a New Drug Application (NDA) based on foreign studies, we have the following comments. Our regulations do permit approval of NDAs based solely on foreign studies if those studies meet the following conditions: (a) the data are applicable to the U.S. population and U.S. medical practice, (b) the studies have been performed by clinical investigators of recognized competence, and (c) the validity of the data can be confirmed (21 CFR 314.106[b]).

The FDA is not funding any research on RU-486; we have no information on funding activities of other Federal agencies. The FDA routinely coordinates all of its import activities with the United States Custom Service. We have alerted our field personnel as to the status of RU-486, most recently in 1989

3/9/90

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Ola	/S/	3/1/90						

(51) 3/28

MIF 005677

when FDA issued an Import Alert (copy enclosed) which specifically prohibits the private importation of RU-486 into the United States. Commercial importation of RU-486 has never been allowed.

We hope this is helpful to you. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure
Importation Alert

cc: HFW-10(2)
HFD-365
HFD-500
HFD-510(Uterine Acting Agents)
HFD-510
R/D: HFD-510: :1/5/90
concur: 1/5/90
Revised: 2/1/90
Init: :1/29/90
:1/9/90
:2/5/90
R/T: var:2/6/90
F/T: var:2/16/90
CRTL #12-045

APPEARS THIS WAY
ON ORIGINAL

GORDON J. HUMPHREY
NEW HAMPSHIRE

531 HART SENATE OFFICE BUILDING
(202) 224-2841
FAX NUMBER
(202) 224-1353
NEW HAMPSHIRE TOLL FREE NUMBER
1-800-852-3714

COMMITTEES
JUDICIARY
FOREIGN RELATIONS
ENVIRONMENT AND PUBLIC WORKS

United States Senate

WASHINGTON, DC 20510

November 29, 1989

Dr. Frank E. Young
Commissioner
Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857

Dear Dr. Young:

I appreciated the opportunity to meet with you last month regarding RU-486. As you know, I have been greatly concerned about the development of this product for use as an abortifacient in this country.

I would like to follow-up on our meeting with several more specific questions. I am particularly interested in the status of the Population Council's application for the testing of RU-486 as well as the implications for which it is being studied. I would also like information on the _____ hospital study, especially the name of the holder of the application under which the study is being conducted, the status of the study and the purpose of the study.

With regard to these above mentioned studies, have any adverse events been observed? As I understand it, malformed babies have been reported in 15 to 20 percent of the cases, women have experienced significant changes in their blood flow rate and RU-486 can, in fact, be life-threatening to both the woman and the fetus.

In addition to these studies, has any pharmaceutical company applied for an Investigational New Drug Application? Would data from foreign studies be adequate for approval of RU-486 in the U.S. or would studies have to include data from studies in this country? Further, is the Federal government funding any research on RU-486 abroad?

Finally, what is the FDA doing to assure that RU-486 is not being imported into the U.S.? Does the FDA coordinate with U.S. Customs in this area?

I thank you for your cooperation.

Sincerely,

Gordon J. Humphrey, USS

ONE EAGLE SQUARE
CONCORD, NH 03301
(603) 225-0453

157 MAIN STREET
BERLIN, NH 03570
(603) 752-2600

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Ted Weiss
Chairman, Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

This is in further response to your letter of March 8, 1990, requesting documents related to RU-486.

The additional enclosed documents have been located in our files.

In accordance with the Departmental policy relative to the disclosure of patient identifying information, the enclosed documents have been purged of such information. However, the names of the physicians or other health providers have remained unpurged. Even so, we would like to emphasize our concern for the privacy of physicians or other health care providers who have reported adverse drug reactions.

Some of the enclosed documents contain confidential information and, as such, are not releasable to the public under the Food and Drug Administration's Freedom of Information regulations. Therefore, we request that the Subcommittee not publish or otherwise make public any of the information contained in the enclosed documents. We would be glad to discuss with the Subcommittee staff the confidentiality of any specific document.

Sincerely yours,

PAB

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

cc: Wayne Cimmons
Minority Staff Member

cc: HFW-10(2)
HFW-1
HFW-2

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

*U.S. GPO: 1989-619-669

MIF 005680

HFD-365

R/D: :3/30/90
F/T: var:4/2/90

APPEARS THIS WAY
ON ORIGINAL

RU 486 DOCUMENT as REQUESTED
by WEISS MARCH 1990

IND	Vol. 5.1	Tablets	Population Council
IND	Vol. 1.1	Tablets	Population Council
IND	Vol. 2.1	Tablets	Population Council
IND	Vol. 1.1	Tablets & IM	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	Population Council
IND	Vol. 2.1	Tablets	Population Council
IND	Vol. 3.1	Tablets	Population Council
IND	Vol. 3.2	Tablets	Population Council
IND	Vol. 4.1	Tablets	Population Council
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]
IND	Vol. 1.1	Tablets	[redacted]

APPEARS THIS WAY
ON ORIGINAL

March 21, 1990	Routing Slip ————
No Date	Example ltr. Correspodent/ ——— RU-486
No Date	Example ltr. Correspodent, ——— RU-486
March 21, 1990	Routing Slip ———— RU-486 (3 Pages)
February 17, 1990	Washington Post "Politics and RU-486"
February 21, 1990	Note ———— RU-486 Import Alert (14 Pages)
February 21, 1990	Note ———— Import Policy: Unapproved drugs (4 Pages)
June 6, 1987	Note Commissioner Young/ Briefing Package for meeting w/ (8 Pages)
No Date	Adress List for Ru-486 INDs
September 26, 1986	INDs for RU486 Mifepristone
Various	Example ltrs./response RU-486
February 27, 1989	Pre-IND RU-486 PPH Memorandum of meeting
May 28, 1987	Ltr./Response ———— 'HFN-1 and HFN-800
July 31, 1986	The American College of Obstericians and Gynecologist
April 20, 1982	Washington Post clipping

APPEARS THIS WAY
ON ORIGINAL

/S/

ONE HUNDRED FIRST CONGRESS

Congress of the United States

House of Representatives

HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE
COMMITTEE ON GOVERNMENT OPERATIONS
RAYBURN HOUSE OFFICE BUILDING, ROOM B-372
WASHINGTON, DC 20515
(202) 225-3648
FAX NO. 225-3382

March 8, 1990

James S. Benson, Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Benson:

As part of the subcommittee's ongoing review of the Federal role in contraceptive development and availability, I am writing to request the following information regarding RU 486:

All documents, including, but not limited to letters, memoranda, articles, internal or draft documents, minutes of meetings, and notes from conversations. This request includes hard copies of any information that is maintained in electronic or other non-paper formats.

Thank you in advance for your cooperation. I would appreciate receiving these materials by March 23, 1990. If you have any questions about this request, please contact Dr. Diana Zuckerman of the subcommittee staff.

Sincerely,

Ted Weiss

TED WEISS
Chairman

TW:DZ

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 02 1990

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Mr. Wyden:

This is in further response to your February 28, 1990 request for documents related to RU-486.

As you requested, we have enclosed a list of the Food and Drug Administration's (FDA) Approved Uterine-Acting Drugs (abortifacients). We have also included copies of FDA advisory committee meetings in 1978 and 1980 which contains discussions of estrogen for post-coital contraception; a May 1973 FDA Drug Bulletin discussing post-coital contraceptive use of DES; and a January 1975 Federal Register notice about labeling of DES for that use. We have not been able to identify any correspondence or other documents from the field or between FDA and United States Customs regarding RU-486.

For your information, we have also enclosed a Memorandum to the Assistant Secretary of Health from the Acting Commissioner regarding RU-486 dated March 10, 1990.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

4/12/90

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-12	/S/	4/2/90						

*U.S. GPO: 1989-619-669

MIF 005685

cc: Anthony Powell
Ranking Minority Staff Member

cc:all
HFW-10(2)
HFW-1
HFW-2
HFD-365

R/D: :3/24/90
F/T: var:4/2/90
WYDENREQ.MDG)
DOC-#3

APPEARS THIS WAY
ON ORIGINAL

MAJORITY MEMBERS
RON WYDEN, OREGON
CHAIRMAN

ELIOT L. ENGEL, NEW YORK
JIM OLIN, VIRGINIA
MICHAEL R. McNULTY, NEW YORK

101st Congress

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

MINORITY MEMBERS
WM. S. BROOMFIELD, MICHIGAN
MELTON D. HANCOCK, MISSOURI
JOEL HEFLEY, COLORADO

STEVE JENNING
SUBCOMMITTEE STAFF DIRECTOR
202-225-7797

ANDREW POWELL
MINORITY SUBCOMMITTEE PROFESSIONAL
STAFF MEMBER
202-225-6135

February 28, 1990

James A. Benson
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Benson:

I would appreciate you sending the documents which my staff requested earlier today, when they visited your Rockville offices.

In addition, I would like the following information, which was not accessible to my staff at that time:

1) A list of any and all abortifacients which have been approved by the FDA.

2) Copies of all correspondence from your field offices regarding RU 486.

3) Copies of all correspondence between the FDA and U.S. Customs regarding RU 486.

Your prompt attention to this matter is deeply appreciated.

With warm regards,

Sincerely,

Ron Wyden

RON WYDEN
Chairman

RW/gab

cc: Hugh C. Cannon

APPEARS THIS WAY
ON ORIGINAL

MODEL LETTER FOR USE IN GENERAL MAIL IMPORTATIONS

Exhibit X9-71-1

(LETTERHEAD)

A mail shipment of an article from a foreign country addressed to you is being detained at the U.S. Post Office. All products of this kind must meet the requirements of the Federal, Food, Drug, and Cosmetic Act or other laws enforced by the U.S. Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles. The product addressed to you does not appear to comply with the law.

Please read the enclosed Notice of Detention and Hearing carefully since it explains why FDA believes that the product sent to you is in violation. The Notice does not in any manner accuse you of violating any law.

If you have a good reason to believe that the product does comply with the law and wish to discuss it with us, you may come personally to this office or write to us within the time limit shown on the Notice.

If you do not wish to claim this shipment, you may disregard the Notice and the shipment will be returned to the sender without cost to you. The shipment will be returned automatically if we do not hear from you within the time limit shown on the Notice.

Sincerely yours,

Enclosure:

APPEARS THIS WAY
ON ORIGINAL

April 26, 1990

FOI Services, Inc.
12315 Wilkins Avenue
Rockville, MD 20852

Our Reference: F90-7903
Your Reference: 85104

Dear Requester: A. F. _____ FILE

Reference is made to your Freedom of Information request of March 1, 1990 for a copy of the current Quality Assurance Profile (QAP) and the Establishment Inspection Report (EIR) for the most recent inspection of Roussel UCLAF, Compeigne, France.

Enclosed is a copy of the most recent EIR dated 4/14-15/86.

You will receive a separate response to your request for the QAP because it has been assigned to another agency office.

Certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request to the following address:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, Maryland 29857

Should the Agency then deny this information, you have the right to appeal such denial. Any letter of denial will explain how to make this appeal.

The following charges will be included a monthly invoice:
Reproduction $.60; Search $5.00; Review $5.00; Total $10.60.

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Freedom of Information Staff (HFI-35).

Sincerely,

_____

Policy and Guidance Branch, HFD-323
Division of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research
Telephone: _____

cc:
HFD-300/RF
HFD-320/RF
HFD-323/FOI
HFD-323/ ———
HFA-224
HFD-19
HFI-35
F9079104.WCC

APPEARS THIS WAY
ON ORIGINAL

HFD-323	/S/	4/26/90			
"		4/27/90			

DEPARTMENT OF HEALTH AND HUMAN SERVICES AF FIL

MAY 17 1990

The Honorable Howell Heflin
United States Senate
Washington, D.C. 20510

Dear Senator Heflin:

This is in response to your letter of April 19, 1990, on behalf of [redacted] concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA the NDA is either approved or not approved; upon approval the drug may be marketed.

We are enclosing a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

6/7/90

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Horton	/S/	5/16/90						

/S/

FILE COPY

MIF 005691

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Constituent's letter
New Drug Development in
the United States

cc: HFW-10(2)
F/D: [redacted] :5/9/90
F/T: var:5/11/90
CONG-594
[redacted] \DRUGS\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

[redacted]

OFFICE OF SENATOR HEFLIN
1990 MAR 27 AM 10:52

Senator Howell Heflin
United States Senate
Washington, D. C. 20510

Dear Senator Heflin,

The obvious solution to the seriously divisive abortion issue is to make the medication RU 486 available to the American public. I urge you and the Congress of the United States to everything possible to make this drug available to all women in this country and around the world.

Sincerely,

[redacted]

MIF 005693

HOWELL HEFLIN
ALABAMA

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON ENERGY AND NATURAL RESOURCES
COMMITTEE ON THE JUDICIARY
SELECT COMMITTEE ON ETHICS

☐ 728 SENATE HART BUILDING
WASHINGTON, DC 20510-0101
(202) 224-4124

United States Senate

WASHINGTON, DC 20510-0101

STATE OFFICES:

☐ 355 FEDERAL BUILDING
1800 FIFTH AVENUE NORTH
BIRMINGHAM, AL 35203
(205) 731-1500

☐ 113 ST. JOSEPH STREET
437 U.S. COURTHOUSE
MOBILE, AL 36602
(205) 432-7715

☐ FEDERAL COURTHOUSE, B-29
15 LEE STREET
MONTGOMERY, AL 36104
(205) 265-9507

☐ 105 MAIN STREET
P.O. BOX 228
TUSCUMBIA, AL 35674
(205) 381-7060

April 19, 1990

Hugh C. Cannon
Assoc. Commissioner for Legis. Affairs
Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

I have been contacted by one of my constituents, _____ describing his proposal to resolve the abortion issue. A copy of his correspondence is attached for your reference.

I would be most appreciative if you would provide me with information on this matter in order that I may share it with my constituent.

With kindest regards, I am

Sincerely,

Howell Heflin

HH/llw

Enclosure(s)

APPEARS THIS WAY
ON ORIGINAL

MIF 005694

A.F. _____ MLE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 29 1990

The Honorable Frank R. Lautenberg
United States Senate
Washington, D.C. 20510

Dear Senator Lautenberg:

This is in response to your letter of August 16, 1990, on behalf of _____ concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA the NDA is either approved or not approved; upon approval the drug may be marketed.

It is also important to point out that FDA does not actually do the clinical testing of drugs before they are marketed. Pharmaceutical manufacturers, the National Institutes of Health, and other research institutions across the country carry out programs to identify, develop and test drugs. It is FDA's responsibility to review and analyze the results of the testing to determine if a drug is safe and effective for widespread marketing for use by the general public.

We are enclosing a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

11 SEP 1990 /S/

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-20	/S/	8/29						

FILE COPY

MIF 005695

*U.S. GPO: 1989-619-669

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Constituent's letter
New Drug Development in
the United States

cc: HFW-10(2)
R/D: [redacted] :8/27/90
R/T: var:8/28/90
F/D: [redacted] :8/28/90
Init: [redacted] :8/29/90
F/T: var:8/29/90
CONG-1759
([redacted] DRUGS\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

July 13, 1990

Sen. Frank Lautenberg
717 Hart Senate Off. Bldg.
Washington, DC 20510

Dear Senator Lautenberg:

RU-486 is safe, effective and Legal in France. Please advocate its testing and potential distribution in the U. S. The more options there are to choose from, the better chances we have for informed decisions.

Sincerely yours,

/S/

ZDOENERGY ZFWS ZINTERIOR ZNJHEALTH ZSTATE

****

Comments: ____

JRK

FRANK R. LAUTENBERG
NEW JERSEY

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HELSINKI COMMISSION

United States Senate

WASHINGTON, DC 20510

August 16, 1990

Office of the Commissioner
The Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, New Jersey 20857

Dear Commissioner:

I am enclosing a copy of a letter I have received from _____

Please provide any information you might have regarding this issue in order that I might be able to respond to my constituent's inquiry. Please return the enclosed correspondence with your report and mark the envelope to the attention of Tom Dosh.

With best wishes,

Sincerely,

Frank R. Lautenberg

FRL:tdb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

REPLY TO:

☐ 717 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-4744

☐ ONE GATEWAY CENTER SUITE 1510
NEWARK, NEW JERSEY 07102
(201) 645-3030

☐ THREE COOPER PLAZA
SUITE 408 SOUTH
CAMDEN, NEW JERSEY 08103
(609) 757-5353

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

A.F. 42-253 FILE

Memorandum

Date August 10, 1990

From Acting Commissioner of Food and Drugs

Subject RU-486 Import Alert

To Assistant Secretary for Health

At the "dry run" for the Secretary's briefing on contraceptives on August 2, you requested a memorandum explaining FDA's import alert on the French abortifacient drug RU-486. The following paragraphs deal with FDA's import policy in general and our RU-486 policy in particular.

Strictly interpreted, the Federal Food, Drug and Cosmetic Act prohibits the import of any product that is unapproved for use in this country. However, in response to requests from desperately ill patients and their representatives, FDA has for many years exercised its discretion to allow the importation of small amounts of drugs and other products for personal use, provided they do not pose significant or unreasonable safety risks and are not commercialized.

The RU-486 import alert, which was initiated last summer, was based on a conclusion that the RU-486 regimen (which includes a prostaglandin that is also unapproved in this country) could present an unreasonable safety risk because its intended use makes it likely that it would be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health.

In addition, because RU-486 is not proposed for treatment of a serious (life threatening) condition, yet poses a safety risk, FDA did not regard the drug as a proper candidate for importation under the Agency's personal importation policy. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial reasons.

APPEARS THIS WAY
ON ORIGINAL

We believe that because of these concerns, the import alert for this drug should be continued, except in circumstances where an approved IND is in effect. This is consistent with the memoranda we sent you on April 24 and May 29 on this subject, and with the discussion at our meeting with you on June 11.

I hope this information is helpful. Let me know if you have any further questions.

/S/

for James S. Benson

APPEARS THIS WAY
ON ORIGINAL