Sam Nunn
Georgia

United States Senate

WASHINGTON, D.C. 20510-1001

April 6, 1989

Please direct response to:
ATTN: Laura Johnson

Senator Sam Nunn
Suite 1700
75 Spring Street, S.W.
Atlanta, Georgia 30303

Tel: (404) 331-4811
(404) _____

(FTS) 242-4811
(FTS) _____

Food and Drug Administration
Congressional Liaison Office
5600 Fishers Lane
Rockvill, MD 20857

RE: _____

Attached is a communication within the area of your authority. 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.

Sincerely,

Sam Nunn

APPEARS THIS WAY
ON ORIGINAL

A. F. FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 28 1989

The Honorable Bob Graham
United States Senator
P.O. Box 3050
Tallahassee, Florida 32315

Dear Senator Graham:

This is in response to your letter of April 10, 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, 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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-7	FSt	4/28						

*U.S. GPO: 1988-216-488

MIF 005502

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)
F/D: ——— :4/20/89
F/T:vaj:4/26/89:(——— -RU486)
Re/T:vaj:4/27/89

APPEARS THIS WAY
ON ORIGINAL

BOB GRAHAM
FLORIDA

United States Senate

WASHINGTON, DC 20510

April 10, 1989

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

Dear Mr. Cannon:

Enclosed is a letter from [redacted]

I would appreciate your reviewing her inquiry and providing me with your comments. Please address your reply to my state office: Post Office Box 3050, Tallahassee, Florida 32315, Attention: Pat Grise'.

Your cooperation and assistance are greatly appreciated. I look forward to hearing from you soon.

With kind regards,

Sincerely,

Bob Graham

United States Senator

BG/pdg

Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005504

A. F. 89-123 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES Rousel

APR 28 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 inquiry of March 29, 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, 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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	FSt	4/28						

MIF 005505

*U.S. GPO: 1988-216-488

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)
F/D: ——— :4/20/89
F/T:vaj:4/25/89:(———RU486)
Re/T: vaj: 4/27/89

APPEARS THIS WAY
ON ORIGINAL

Sam Nunn
Georgia

United States Senate

WASHINGTON, D.C. 20510-1001

March 29, 1989

Please direct response to:
ATTN: Laura Johnson

Senator Sam Nunn
Suite 1700
75 Spring Street, S.W.
Atlanta, Georgia 30303

Tel: (404) 331-4811
(404) _____

(FTS) 242-4811
(FTS) _____

Food and Drug Administration
Congressional Lisison Office
5600 Fishers Lane
Rockville, Maryland 20857

RE: _____

Attached is a communication within the area of your authority. 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.

Sincerely,

Sam Nunn

APPEARS THIS WAY
ON ORIGINAL

[redacted] 43 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 28 1989

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

Dear Senator Riegle:

This is in response to your letter of April 13, 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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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 [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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	FSt	4/28						

MIF 005508

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)
F/D ——— :4/20/89
F/T:vaj:4/26/89:(———-RU486)
Re/T:vaj:4/27/89

APPEARS THIS WAY
ON ORIGINAL

March 14, 1989

The Honorable Donald Riegle, Jr.
U.S. Senate
1205 Dirksen Building
Washington, DC 20510

Dear Senator Riegle:

I am writing to urge you to oppose any attempts to restrict the Food and Drug Administration from further testing of the drug RU-486. This drug provides an alternative to surgical abortion. Although first trimester abortion is currently one of the safest surgical procedures performed in the United States, RU-486 decreases or eliminates many of the occasional complications which can occur with any kind of surgery.

American women ought to have access to the best possible health care, and this includes making sure the safest methods are available for all legal medical procedures. Please don't allow a vocal minority to deprive all women of advances in medical technology.

Sincerely,

DONALD W. RIEGLE, JR.
MICHIGAN

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS: Chairman
FINANCE
BUDGET

United States Senate

WASHINGTON, DC 20510

April 13, 1989

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 many constituents who expressed concern about a matter within your agency's jurisdiction. I am enclosing a copy of one of the letters for your information.

I would appreciate your response to the concerns raised in the attached letter. Please direct any questions or correspondence to Betty Cormier of my staff, at 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

MIF 005511

MICHIGAN REGIONAL OFFICES

WAYNE-MONROE
1850 McNamara Federal Bldg.
477 Michigan Ave.
Detroit, MI 48226

SOUTHEASTERN
Century Center Bldg., 3d Floor
30800 Van Dyke
Warren, MI 48093

EASTERN
Sabuco Bldg., Suite 910
352 S. Saginaw Street
Flint, MI 48502

CENTRAL
705 Washington Square Bldg.
109 W. Michigan Ave.
Lansing, MI 48933

WESTERN
Suite 716 Federal Bldg.
110 Michigan Ave., N.W.
Grand Rapids, MI 49503

NORTHERN-LOWER
308 Front Street
Traverse City, MI 49685

UPPER PENINSULA
Room 323, P.O. Bldg.
200 W. Washington
Marquette, MI 49855

A F FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 28 1989

The Honorable John J. Duncan, Jr.
House of ~~Represenatatives~~
Washington, D.C. 20515

Dear Mr. Duncan:

This is in response to your letter of April 11, 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.

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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-12	FSI	4/28						

*U.S. GPO: 1988-216-488

MIF 005512

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)
F/D: ——— 4/20/89
F/T:vaj:4/25/89:(——-RU486)
Re/T: vaj: 4/27/89

APPEARS THIS WAY
ON ORIGINAL

JOHN J. DUNCAN, JR.
2D DISTRICT, TENNESSEE

COMMITTEES:
PUBLIC WORKS AND TRANSPORTATION
AVIATION
SURFACE TRANSPORTATION
PUBLIC BUILDINGS AND GROUNDS
INVESTIGATIONS AND OVERSIGHT
REPUBLICAN TASK FORCE
ON HOUSING
CO-CHAIRMAN

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

April 11, 1989

506 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-4202
PHONE: (202) 225-5435

318 POST OFFICE BLDG.
KNOXVILLE, TN 37902-1806
PHONE: (615) 523-3772

200 E. BROADWAY
SUITE 419
FIRST AMERICAN BANK BLDG.
MARYVILLE, TN 37801-2404
PHONE: (615) 984-5464

COURTHOUSE
ATHENS, TN 37303-4297
PHONE: (615) 745-4671

Mr. Hugh Cannon
Director, Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Cannon:

Attached is a letter I have received from my constituent.

At your convenience, I would appreciate receiving a reply suitable for forwarding.

Yours truly,

JOHN J. DUNCAN, JR.
Member of Congress

JJD:ss

APPEARS THIS WAY
ON ORIGINAL

F 43-222 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES Rec'd

APR 28 1989

The Honorable Frank Horton
House of Represenatatives
Washington, D.C. 20515

Dear Mr. Horton:

This is in response to your letter of April 10, 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.

FILE COPY
MIF 005515

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	TSL	4/28						

*U.S. GPO: 1988-216-488

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)
F/D: [illegible] :4/20/89
F/T:vaj:4/25/89:([illegible] -RU486)
Re/T:vaj:4/27/89

APPEARS THIS WAY
ON ORIGINAL

Buck - FDA

3193-4

March 27, 1989

The Honorable Frank Horton
U.S. House of Representatives
Washington D.C. 20515

Dear Representative:

I am writing to urge you to strongly oppose any attempts to restrict in any manner the Food and Drug Adminstration from further testing of the drug known as RU 486. In fact, I urge you to strongly support extensive and expeditious testing. This drug provides an effective alternative to surgical abortion. Although first trimester abortion is currently one of the safest surgical procedures performed in the United States [4 times safer than a tonsillectomy and 20 times safer than childbirth], RU 486 decreases or eliminates many of the rare complications which can occur with any kind of surgery.

American women, in fact all women, ought to have access to the best possible health care, and this includes making sure the safest methods are available for all legal medical procedures. Please don't permit a small, but vocal minority deprive all women of access to advances in medical technology.

Sincerely,

FRANK HORTON
U.S. REPRESENTATIVE
29TH DISTRICT OF NEW YORK

COMMITTEES:
GOVERNMENT OPERATIONS
RANKING MINORITY MEMBER
POST OFFICE AND
CIVIL SERVICE
CHAIRMAN, NEW YORK BIPARTISAN
CONGRESSIONAL DELEGATION

WASHINGTON OFFICE:
2108 RAYBURN BUILDING
WASHINGTON, DC 20515
(202) 225-4916

RUBY G. MOY
ADMINISTRATIVE ASSISTANT

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

April 10, 1989

DISTRICT OFFICES:
314 KENNETH B. KEATING BUILDING
ROCHESTER, NY 14614
(716) 454-7490
FTS-963-6270

(TUESDAY ONLY)
WAYNE COUNTY COURT HOUSE
26 CHURCH STREET
LYONS, NY 14489
(315) 946-5996

307 METCALF PLAZA
144 GENESEE STREET
AUBURN, NY 13021
(315) 255-1125
FTS 953-2222

RIVERFRONT OFFICE BUILDING
OSWEGO, NY 13126
(315) 342-4688

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

Dear Frank:

I am writing to you on behalf of a constituent of mine, [redacted] regarding the testing of RU 486. I appreciate your interest in this important issue. I have enclosed a copy of [redacted] letter to me for your information.

I would greatly appreciate it if you could address the issue raised in [redacted] letter and inform me of any progress being made on the testing of RU 486. Please send your response to me directly.

Thank you in advance for your time and consideration. I look forward to your timely response.

With warmest personal regards,

Sincerely,

Frank Horton

FH:rmcc
Enclosure

APPEARS THIS WAY
ON ORIGINAL

United States Senate

WASHINGTON, D.C. 20510

April 4, 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 testing of the drug RU486. I would appreciate your expeditious attention to this matter.

Please respond directly to _____. 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 005519

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 28 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 inquiry of April 6, 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, 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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	FSt	4/28						

*U.S. GPO: 1988-216-488

MIF 005520

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)
F/D: 4/20/89
F/T:vaj:4/25/89:(RU486)

APPEARS THIS WAY
ON ORIGINAL

Sam Nunn
Georgia

United States Senate

WASHINGTON, D.C. 20510-1001

April 6, 1989

Please direct response to:
ATTN: Laura Johnson

Senator Sam Nunn
Suite 1700
75 Spring Street, S.W.
Atlanta, Georgia 30303

Tel: (404) 331-4811
(404) _____

(FTS) 242-4811
(FTS) _____

Food and Drug Administration
Congressional Liaison Office
5600 Fishers Lane
Rockville, Maryland 20857

RE: _____

Attached is a communication within the area of your authority. 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.

Sincerely,

Sam Nunn

APPEARS THIS WAY
ON ORIGINAL

A. F. [illegible] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 28 1989

The Honorable Bill Grant
House of Represenatatives
Washington, D.C. 20515

Dear Mr. Grant:

This is in response to your letter of April 11, 1989, on behalf of your constituent 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 unable to predict whether, or when, RU-486 will be approved for marketing. You may assure your constituent 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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HAB	TST	4/28						

*U.S. GPO: 1988-216-488

MIF 005523

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)
F/D: ——— :4/20/89
F/T:vaj:4/25/89: ——— -RU486)
Re/T: vaj 4/27/89

APPEARS THIS WAY
ON ORIGINAL

BILL GRANT
2D DISTRICT, FLORIDA

PUBLIC WORKS AND
TRANSPORTATION COMMITTEE

SUBCOMMITTEES:
SURFACE TRANSPORTATION
WATER RESOURCES
PUBLIC BUILDINGS AND GROUNDS

GOVERNMENT OPERATIONS

SUBCOMMITTEES:
GOVERNMENT INFORMATION,
JUSTICE, AND AGRICULTURE
EMPLOYMENT AND HOUSING

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

WASHINGTON OFFICE:
ROOM 1331
LONGWORTH HOUSE OFFICE BUILDING
202-225-5235

DISTRICT OFFICES:
930 THOMASVILLE ROAD, SUITE 101
TALLAHASSEE, FL 32303
904-681-7434

1990-A SOUTH FIRST STREET
LAKE CITY, FL 32055
904-755-5657

POST OFFICE BUILDING #109
MARIANNA, FL 32446
904-526-3525

April 11, 1989

Mr. Hugh C. Cannon
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

Enclosed please find a letter I recently received from [redacted] regarding the testing of the drug RU-486 (Mifepristone).

I would appreciate you taking a moment to examine [redacted] correspondence and responding to her inquiry. If you have any questions or if there is anything I can do to help, I hope that you will please let me know.

With best wishes.

Sincerely yours,

Bill Grant
Member of Congress

BG/dag

Enclosure

APPEARS THIS WAY
ON ORIGINAL

AF 43-252 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES Renewal

APR 28 1989

The Honorable Lindy Boggs
House of Representatives
Washington, D.C. 20515

Dear Ms. Boggs:

This is in response to your letter of April 6, 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, 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.

9446

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-22	/S/	4/28						

MIF 005526

*U.S. GPO: 1988-216-488

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)
F/D: ——— :4/20/89
F/T:vaj:4/25/89:(~ -RU486)
Re/T:vaj:4/27/89

APPEARS THIS WAY
ON ORIGINAL

LINDY (MRS. HALE) BOGGS, M.C.
2D DISTRICT, LOUISIANA
COMMITTEES
APPROPRIATIONS
SELECT COMMITTEE ON CHILDREN, YOUTH, AND FAMILIES
(CHAIR, TASK FORCE ON CRISIS INTERVENTION)
NANCY McGEOWN
ADMINISTRATIVE ASSISTANT

Congress of the United States
House of Representatives
Washington, DC 20515-1802

WASHINGTON OFFICE
2353 RAYBURN BUILDING
WASHINGTON, DC 20515-1802
(202) 225-6636
DISTRICT OFFICE
1012 HALE BOGGS FEDERAL BUILDING
500 CAMP STREET
NEW ORLEANS, LA 70130-3385
(504) 589-2274

April 6, 1989

Mr. Hugh C. Cannon
Associate Commissioner for
Legislation and Information
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

I am enclosing for your consideration and review the attached, self-explanatory correspondence from _____ As you will note, they support the continued testing of RU-486.

It would be appreciated, after you have had an opportunity to look into the matter outlined in the attachment, if you would provide me with the necessary information for a response to this inquiry.

I look forward to hearing from you, and wish to thank you in advance for your courteous attention.

With kindest regards and best wishes,

Sincerely,

Lindy Boggs

Lindy (Mrs. Hale) Boggs, M.C.

LB:keb

Enclosure

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 28 1989

The Honorable Joseph R. Biden, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Biden:

This is in response to your inquiry of March 30, 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, 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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	FST	4/28						

*U.S. GPO: 1988-216-488

MIF 005529

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)
F/D :4/20/89
F/T:vaj:4/25/89:(-RU486)
Re/T:vaj:4/27/89

APPEARS THIS WAY
ON ORIGINAL

United States Senate

Washington, D. C., 3/30, *19*89

Respectfully referred to

Mr. Hugh C. Cannon
Associate Commissioner for
Legislative Affairs
Food and Drug Administration
1555 Parklawn Buiding
56[illegible] Fishers Lane
Rockville, MD 20857

Please address [redacted] concerns. In particular, are there any plans to restrict the testing of RU-486? Please dire response to:

The Honorable Joseph R. Biden,J
225 Russell Senate Office Bldg.
Washington, DC 20510

ATTN: David Snelbecker

T [illegible]kyou.

Joseph R. Biden, Jr.

APPEARS THIS WAY
ON ORIGINAL

U. S. S.

Form No. 3 16—45103-3 GPO

MIF 005531

Roussel-Uclaf
A.F. 43-253 MIF

January 18, 1990

Sterling Connecticut MW

Representative William H. (Nickerson)
35 Quail Road
Greenwich, CT 06831

Dear Mr. Nickerson:

This is in reply to your letter dated October 12, 1989, to Dr. Young, concerning RU-486, an abortifacient recently approved in France.

We regret we are unable to answer most of your questions; however, the following general information on RU-486 may be of interest to you.

RU-486 has not received FDA approval for marketing, although this drug is in clinical trials.

The Food and Drug Administration reviews drugs but does not test them. Drug sponsors, generally manufacturers, arrange for testing by experts, as well as shouldering the cost, and include the results in new drug applications.

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. In addition, the Federal Food, Drug, and Cosmetic Act contains no provision authorizing us to establish prices charged for drugs.

FDA's standards of safety and effectiveness for new drugs are high. The law requires them to be high because Congress did not feel that Americans should be subjected to exposure from unsafe or ineffective drugs instead of safe and effective ones to protect their health. It is too early to comment whether RU-486 will be found to be safe and effective for any condition under study.

We are enclosing a booklet that describes the new drug process in the United States.

5494

If we can be of further assistance in the future, please feel free to contact us.

Sincerely yours,

[redacted]

Division of Regulatory Affairs (HFD-365)
Office of Compliance
Center for Drug Evaluation and Research

cc:
HFD-1:0910-0077
HF-43:0904120
HFA-224
HFD-365/C
HFD-360/ —
——— :10/26/89
Init: ——— 10/27/89
F/T:leb:1/17/90:Doc #0767w
293-006-C2

APPEARS THIS WAY
ON ORIGINAL

State of Connecticut
HOUSE OF REPRESENTATIVES
STATE CAPITOL
HARTFORD, CONN. 06106

REPRESENTATIVE WILLIAM H. NICKERSON
ONE HUNDRED FORTY-NINTH DISTRICT

35 QUAIL ROAD
GREENWICH, CONNECTICUT 06831
TELEPHONE
CAPITOL: 240-8787
TOLL FREE: 1-800-842-8270

MEMBER
FINANCE COMMITTEE
TRANSPORTATION COMMITTEE

October 12, 1989

Commissioner Frank Young
Federal Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: RU486

Dear Commissioner Young:

I am writing to request information about RU486, a pill developed in France which induces abortions without surgery. I understand that this pill has been developed by the French drug company Roussel Uclaf and that 15% of abortions in France are now done by this pill.

What is the status of this pill in the U.S.? Has it been submitted to your agency for testing? If so, with what results? When do you think this might reach the U.S. market, and at what cost? Please provide me with any additional information necessary in order for me to be fully informed on the status of this pill in the U.S.

I look forward with thanks to your response.

Very truly yours,

William H. Nickerson

WHN:ep

293006-02

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 21 1989

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

Dear Senator Humphrey:

This is to let you know that we received your inquiry of November 29, 1989, addressed to Commissioner Young, regarding 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-364(2)

Note to HFD-364: Please prepare draft response for

R/D: :12/21/89
F/T: var:12/21/89
Int #12-04

PAB
1/17/90

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-10	[illegible]	12/21						

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

MIF 005535

[redacted]MPHREY
[redacted]IRE

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 [redacted] 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) 225-0483

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

Roussel UCLAF

DEPARTMENT OF HEALTH AND HUMAN SERVICES 43-253

DEC 18 1989

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

Dear Senator Lautenberg:

This is in response to your letter of November 1, 1989, on behalf of _____, concerning the unapproved 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.

Because the information in our files is considered confidential and not releasable under Freedom of Information regulations, we are unable to provide _____ with responses to his specific questions.

PAB 1/17/90

5 44.4

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-10	/S/	12/18						

/S/ 4/5

MIF 005537

We are unable to predict whether, or when RU-486 will be approved for marketing. Please be assured 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.

If we can be of any further assistance, 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: ——— 11/22/89
F/T:var:12/6/89(RU-486)
CTRL#11-070

APPEARS THIS WAY
ON ORIGINAL

August 26, 1989

Senator Frank Lautenberg
Washington, D.C.

Dear Senator Lautenberg,

I am writing in regard to the pharmaceutical drug designated RU486. The drug is of French origin and is produced by Roussel-UCLAF. It is useful for ending ectopic pregnancy, early non-surgical abortion, treatment of breast and prostate cancer and endometriosis.

The purpose of this letter is to ask you the status of the drug within the Food and Drug Administration. Is Roussel-UCLAF or their local affiliate Hoechst-Roussel Pharmaceuticals seeking U.S. registration? If they are, what stage in the registration process is the drug now? If it is in progress, assuming no delays, when is registration predicted?

Since 80% of the people in the U.S. want women to have a choice in controlling or not controlling pregnancy, is it still possible for this administration to stifle the introduction of this product? I'm not comfortable in this matter because of the Bush administrations "anti-choice" position.

I would appreciate your help in determining the status of this drug.

Thank you,

MIF 005539

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

November 1, 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 43-252 FILE

Roussel-UCLAF

Your Case Number: #9262060012

The Honorable Strom Thurmond
United States Senate
Washington, D.C. 20510

NOV 03 1989

Dear Senator Thurmond:

This is in response to your letter of September 20, 1989, on behalf of [redacted], concerning the unapproved 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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-7a	/S/	11/3						11/3 /S/

MIF 005541

We are unable to predict whether, or when RU-486 will be approved for marketing. Please be assured 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.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
Clinical Testing . . .
A Primer on New . . .
cc: HFW-10(2)
R/D: _____ :10/17/89
F/T:var:10/23/89(RU-486): ——11/2/89
CTRL#10-024

APPEARS THIS WAY
ON ORIGINAL

STROM THURMOND
SOUTH CAROLINA
COMMITTEES

ARMED SERVICES
JUDICIARY
VETERANS' AFFAIRS
LABOR AND HUMAN RESOURCES

United States Senate

WASHINGTON, DC 20510

September 20, 1989

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

Dear Mr. Cannon:

Enclosed is a copy of correspondence I have recently received from _____ I believe you will find it self-explanatory.

Your reviewing this material and providing any assistance and/or information possible under the governing statutes and regulations will be greatly appreciated. Thank you for your attention in this matter, and I look forward to hearing from you soon.

With kindest regards and best wishes,

Sincerely,

Strom Thurmond

Strom Thurmond

ST/hk
Enclosure

Please include in your response case number # 9262060012

APPEARS THIS WAY
ON ORIGINAL

MIF 005543

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.

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. fIt 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
HFN-2	/S/	9/15						

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

MIF 005544

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: — 9/15/89
F/T: —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

Frederick S. Mayer, R.Ph.
President
Pharmacists Planning Service Inc.
200 Gate Five Road
P. O. Box 1336
Sausalito, California 94966

Dear Mr. Mayer:

This is in response to your letter of August 16, 1989, to former Associate Commissioner for Regulatory Affairs, Food and Drug Administration (FDA), requesting permission for Pharmacists Planning Service Inc. to become involved in the importation, via the mail system, and distribution in the United States of the abortifacient drug RU 486.

On June 6, 1989, FDA issued Import Alert #66-47 (enclosure) which calls for the automatic detention of all abortifacient drugs, including RU 486. FDA has concluded that unapproved products of this kind would be inappropriate for release under the personal importation policy. The intended use of such drugs could pose a risk to the safety of the user.

Sincerely yours,

/S/

Associate Commissioner
for Regulatory Affairs

Enclosure

bcc: ~~HFC-1~~ (#7736)
HFC-100
HFC-150
HFC-152
HFR-PA1
HFD-300

JRMay:rb 8-30-89

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
DFSR	/S/	8/30	HFC-3	/S/				
150	/S/	8/30						
100	/S/	8/31						

MIF 005547

3

A.F. 43-253 FILE
ROSSEL HCC AF
MAR 21 1990

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Dear Mr. Weiss:

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

As discussed with your staff, enclosed are documents related to RU-486 which have been identified thus far. Some of the enclosed documents are not releasable to the public under FDA's Freedom of Information regulations. Therefore we request the Subcommittee not publish or other wise make public any of the information contained in the enclosed documents. We would be happy to discuss with the Subcommittee staff the confidentiality of any specific document.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

cc: HFW-10(2)
F/D: ——— :3/19/90
F/T: var:3/19/90

APPEARS THIS WAY
ON ORIGINAL

4/4/90

5494

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFV12	/S/	3/29/90						
C:IN-2	/S/	3/29/90						

MIF 005548

A.F. [redacted] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 11 1989

The Honorable Owen B. Pickett
House of Representatives
Washington, D.C. 20515

Dear Mr. Pickett:

This is in response to your letter of March 20, 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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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 [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.

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-8	[illegible]	4/10						

FILE COPY

MIF 005549

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
"Clinical Testing . . ."
"A Primer on New . . ."
Constituent's letter

cc: HFW-10(2)
R/D: 4/4/89
F/T:wgr:4/10/89 .25:RU486)

APPEARS THIS WAY
ON ORIGINAL

MAR 1989

MAR 17 1989

DIRECT DIAL

The Honorable Owen B. Pickett
U. S. House of Representatives
Washington, D.C. 20515

Dear Owen:

I am writing to urge you to oppose any attempts to restrict the Food and Drug Administration from further testing of the drug RU-486. This drug provides an alternative to surgical abortion. Although first trimester abortion is currently one of the safest surgical procedures performed in the United States, RU-486 decreases or eliminates many of the occasional complications which can occur with any kind of surgery.

American women ought to have access to the best possible health care, and this includes making sure the safest methods are available for all legal medical procedures. Please don't allow a vocal minority to deprive all women of advances in medical technology.

Sincerely,

/s/

MIF 005551

OWEN B. PICKETT
2ND DISTRICT, VIRGINIA

1429 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4215

DISTRICT OFFICES:
815 FEDERAL BUILDING
200 GRANBY STREET
NORFOLK, VA 23510
(804) 624-9124

2710 VIRGINIA BEACH BOULEVARD
VIRGINIA BEACH, VA 23452
(804) 486-3710

COMMITTEES:
ARMED SERVICES
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RESEARCH AND DEVELOPMENT
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AND CRITICAL MATERIALS
MILITARY PERSONNEL AND COMPENSATION

MERCHANT MARINE AND FISHERIES
SUBCOMMITTEES:
MERCHANT MARINE
COAST GUARD AND NAVIGATION

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

March 20, 1989

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

Dear Dr. Young:

I have received the enclosed inquiry from one of my constituents in reference to a matter under your jurisdiction.

Any information you could provide that would help me respond to my constituent in an authoritative manner would be greatly appreciated.

With kindest regards, I am

Sincerely,

Owen B. Pickett
Member of Congress

OBP/gmm

APPEARS THIS WAY
ON ORIGINAL

MIF 005552

A.F. [illegible] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 11 1989

The Honorable Matthew F. McHugh
Member, United States
House of Representatives
Carriage House Terrace Hill
Ithaca, New York 14850

Dear Mr. McHugh:

This is in response to your letter of March 21, 1989, on behalf of [redacted]k, 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 [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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
[illegible]	(S)	4/11						

MIF 005553

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
"Clinical Testing . . ."
"A Primer on New . . ."
Constituent's letter

cc: HFW-10(2)
R/D: ———:4/4/89
F/T:wgr:4/10/89(—— 25:RU486)

APPEARS THIS WAY
ON ORIGINAL

CONSTITUENT INFORMATION FORM

DATE: 3/22/89

OFFICE: Ithaca

SALUTATION:

STAFF: Jean McPheeters

NAME:

COMMERCIAL TEL.#:

ADDRE

FTS TEL.#:

HOME PHONE: WORK PHONE:

S.S.#: V.A. CLAIM #:

NATURE OF CASE/REQUEST/COMMENT:

What is the FDA doing about approving / disapproving use of RU 486, the French contragestion pill.

Congress of the United States

House of Representatives

Washington, D.C.

March 21, 19 8

Congressional Liaison Office
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

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,

Matthew F. McHugh M. C.

Please reply to:

[redacted] HILL

Attn: Jean 607/273-1388

A.F. 22-252 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 11 1989

The Honorable Guy Vander Jagt
House of Representatives
Washington, D.C. 20515

Dear Mr. Vander Jagt:

This is in response to your letter of March 23, 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.

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
[illegible]	FST	4/11						

FILE COPY

MIF 005557

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
"Clinical Testing . . ."
"A Primer on New . . ."
Constituent's letter

cc: HFW-10(2)
R/D: 4/4/89
F/T:wgr:4/10/89(25:RU486)

APPEARS THIS WAY
ON ORIGINAL

March 14, 1989

The Honorable Guy Vander Jagt
House of Representatives
2409 Rayburn Building
Washington, DC 20515

Dear Representative Vander Jagt:

I am writing to urge you to oppose any attempts to restrict the Food and Drug Administration from further testing of the drug RU-486. This drug provides an alternative to surgical abortion. Although first trimester abortion is currently one of the safest surgical procedures performed in the United States, RU-486 decreases or eliminates many of the occasional complications which can occur with any kind of surgery.

American women ought to have access to the best possible health care, and this includes making sure the safest methods are available for all legal medical procedures. Please don't allow a vocal minority to deprive all women of advances in medical technology.

Sincerely,

151

GUY VANDER JAGT
9TH DISTRICT, MICHIGAN

2409 RAYBURN HOUSE OFFICE BUILDING
TELEPHONE (202) 225-3511

COMMITTEE
WAYS AND MEANS
SUBCOMMITTEES
TRADE
SELECT REVENUE MEASURES

ADMINISTRATIVE ASSISTANT
JAMES M. SPARLING, JR.

Congress of the United States
House of Representatives
Washington, DC 20515-2209

DISTRICT OFFICES
ROOSEVELT PARK
950 WEST NORTON AVENUE
MUSKEGON, MI 49441-4193
(616) 733-3131

31 WEST 8TH STREET
HOLLAND, MI 49423-3102
(616) 396-3849

124 NORTH DIVISION STREET
TRAVERSE CITY, MI 49684-2263
(616) 946-3832

March 23, 1989

Mr. Hugh C. Cannon
Associate Commissioner for
Legislation and Information
Food and Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

I was recently contacted by a constituent, [redacted] relative to the testing of a drug, RU-486, which, according to her letter, is an alternative to surgical abortion.

I have enclosed a copy of her correspondence detailing her views. Any information or comments you may be able to share with me relative to this situation would be greatly appreciated.

Thank you for your time and attention to this matter. I look forward to hearing from you in the near future.

With all good wishes,

Sincerely,

Guy Vander Jagt
Member of Congress

GVJ:ljh
Enclosure

APPEARS THIS WAY
ON ORIGINAL

United States Senate

WASHINGTON, D.C. 20510

March 17, 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 testing of drug RU-486. I would appreciate your expeditious attention to this matter.

Please respond directly to _____ 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

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 —— :--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 005562

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 _____ concerning the lack of birth control options for women. I would appreciate your expeditious attention to this matter.

Please respond directly to _____ 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 005564

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.

5194

151
2-17-89

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-9	JST	2/17						

FILE COPY

MIF 005565

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

I.F. 43-253 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.

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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 _____ 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.

FILE COPY

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

MIF 005568

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/

MIF 005570

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

MIF 005571

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN

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

A.F. 13-263 FILE

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.

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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 _____ 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.

MIF 005572

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
CRA	ftf	1/13/89						

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 unaviaiable 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,

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) 4/23/88 --RU-486)
HFT:cah:4/26/88

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-10	/S/	4/28						

U.S. GPO 1986-169-089

MIF 005576

February 23, 1988

MAR 0 1 [illegible]

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

MIF 005577

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

April 11, 1988

WASHINGTON OFFICE:
1330 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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. Roussel-Uclaf FILE
43-253

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.

5774

FILE COPY

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

151 4/28

U.S. GPO 1986-169-089

MIF 005579

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 1988

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,

/s/

MIF 005581

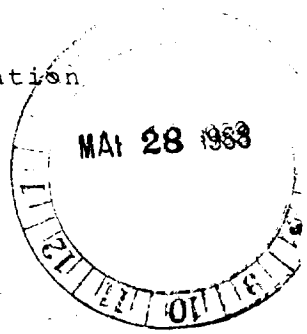
March 18, 1988

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

MIF 005582

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 005583

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

Frederick S. Mayer, R.Ph.
President
Pharmacists Planning Service Inc.
200 Gate Five Road
P. O. Box 1336
Sausalito, California 94966

Dear Mr. Mayer:

This is in response to your letter of August 16, 1989, to former Associate Commissioner for Regulatory Affairs, Food and Drug Administration (FDA), requesting permission for Pharmacists Planning Service Inc. to become involved in the importation, via the mail system, and distribution in the United States of the abortifacient drug RU 486.

On June 6, 1989, FDA issued Import Alert #66-47 (enclosure) which calls for the automatic detention of all abortifacient drugs, including RU 486. FDA has concluded that unapproved products of this kind would be inappropriate for release under the personal importation policy. The intended use of such drugs could pose a risk to the safety of the user.

Sincerely yours,

/S/

Associate Commissioner
for Regulatory Affairs

Enclosure

bcc: ~~HFG-1~~ (#7736)
HFC-100
HFC-150
HFC-152
HFR-PA1
HFD-300

JRMay:rb 8-30-89

8/31/89

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
DFSR	/S/	8/30	HFC-3	/S/				
150	/S/	8/30						
100	/S/	8/31						

MIF 005586

3

A.F. 43-253 FILE
ROSSEL HCC AF
MAR 21 1990

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Dear Mr. Weiss:

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

As discussed with your staff, enclosed are documents related to RU-486 which have been identified thus far. Some of the enclosed documents are not releasable to the public under FDA's Freedom of Information regulations. Therefore we request the Subcommittee not publish or other wise make public any of the information contained in the enclosed documents. We would be happy to discuss with the Subcommittee staff the confidentiality of any specific document.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

cc: HFW-10(2)
F/D: ——— :3/19/90
F/T: var:3/19/90

APPEARS THIS WAY
ON ORIGINAL

4/4/90

5919

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	3/20/90						
OCIN-2	/S/	3/20/90						

FILE COPY

MIF 005587

A.F. [illegible] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 11 1989

The Honorable Owen B. Pickett
House of Representatives
Washington, D.C. 20515

Dear Mr. Pickett:

This is in response to your letter of March 20, 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.

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 [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.

MIF 005588

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-10	[illegible]	4/10						

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
"Clinical Testing . . ."
"A Primer on New . . ."
Constituent's letter

cc: HFW-10(2)
R/D: 4/4/89
F/T:wgr:4/10/89 .25:RU486)

APPEARS THIS WAY
ON ORIGINAL

MAR 1989

MAR 17 1989

DIRECT DIAL

The Honorable Owen B. Pickett
U. S. House of Representatives
Washington, D.C. 20515

Dear Owen:

I am writing to urge you to oppose any attempts to restrict the Food and Drug Administration from further testing of the drug RU-486. This drug provides an alternative to surgical abortion. Although first trimester abortion is currently one of the safest surgical procedures performed in the United States, RU-486 decreases or eliminates many of the occasional complications which can occur with any kind of surgery.

American women ought to have access to the best possible health care, and this includes making sure the safest methods are available for all legal medical procedures. Please don't allow a vocal minority to deprive all women of advances in medical technology.

Sincerely,

/s/

MIF 005590

WEN B. PICKETT
2ND DISTRICT, VIRGINIA

1429 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4215

DISTRICT OFFICES:
815 FEDERAL BUILDING
200 GRANBY STREET
NORFOLK, VA 23510
(804) 624-9124

2710 VIRGINIA BEACH BOULEVARD
VIRGINIA BEACH, VA 23452
(804) 486-3710

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

COMMITTEES
ARMED SERVICES
SUBCOMMITTEES
RESEARCH AND DEVELOPMENT
SEAPOWER AND STRATEGIC
AND CRITICAL MATERIALS
MILITARY PERSONNEL AND COMPENSATION

MERCHANT MARINE AND FISHERIES
SUBCOMMITTEES
MERCHANT MARINE
COAST GUARD AND NAVIGATION

March 20, 1989

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

Dear Dr. Young:

I have received the enclosed inquiry from one of my constituents in reference to a matter under your jurisdiction.

Any information you could provide that would help me respond to my constituent in an authoritative manner would be greatly appreciated.

With kindest regards, I am

Sincerely,

Owen B. Pickett
Member of Congress

OBP/gmm

APPEARS THIS WAY
ON ORIGINAL

MIF 005591

A.F. [illegible] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 11 1989

The Honorable Matthew F. McHugh
Member, United States
House of Representatives
Carriage House Terrace Hill
Ithaca, New York 14850

Dear Mr. McHugh:

This is in response to your letter of March 21, 1989, on behalf of [redacted]rk, 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 [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.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
[illegible]	(S)	4/11						

MIF 005592

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
"Clinical Testing . . ."
"A Primer on New . . ."
Constituent's letter

cc: HFW-10(2)
R/D: [redacted]:4/4/89
F/T:wgr:4/10/89([redacted] 25:RU486)

APPEARS THIS WAY
ON ORIGINAL

CONSTITUENT INFORMATION FORM

DATE: 3/22/89

OFFICE: Ithaca

SALUTATION:

STAFF: Jean McPheeters

NAME:

COMMERCIAL TEL.#:

ADDRE

FTS TEL.#:

HOME PHONE: WORK PHONE:

S.S.#: V.A. CLAIM #:

NATURE OF CASE/REQUEST/COMMENT:

What is the FDA doing about approving / disapproving use of RU 486, the French contragestion pill.

Congress of the United States

House of Representatives

Washington, D.C.

March 21, 19 8

Congressional Liaison Office
Food and Drug Administration
1555 Parklawn Building
5[illegible] Fishers Lane
Rockville, MD 20857

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,

Matthew F. McHugh M. C.

Please reply to:

[illegible] E HILL

Attn: Jean 607/273-1388

A.F. 22-252 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 11 1989

The Honorable Guy Vander Jagt
House of Representatives
Washington, D.C. 20515

Dear Mr. Vander Jagt:

This is in response to your letter of March 23, 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.

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.

MIF 005596
FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-8	FST	4/11						

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
"Clinical Testing . . ."
"A Primer on New . . ."
Constituent's letter

cc: HFW-10(2)
R/D: ——— 4/4/89
F/T:wgr:4/10/89(——— 25:RU486)

APPEARS THIS WAY
ON ORIGINAL

March 14, 1989

The Honorable Guy Vander Jagt
House of Representatives
2409 Rayburn Building
Washington, DC 20515

Dear Representative Vander Jagt:

I am writing to urge you to oppose any attempts to restrict the Food and Drug Administration from further testing of the drug RU-486. This drug provides an alternative to surgical abortion. Although first trimester abortion is currently one of the safest surgical procedures performed in the United States, RU-486 decreases or eliminates many of the occasional complications which can occur with any kind of surgery.

American women ought to have access to the best possible health care, and this includes making sure the safest methods are available for all legal medical procedures. Please don't allow a vocal minority to deprive all women of advances in medical technology.

Sincerely,

/s/

GUY VANDER JAGT
9TH DISTRICT, MICHIGAN

2409 RAYBURN HOUSE OFFICE BUILDING
TELEPHONE (202) 225-3511

COMMITTEE
WAYS AND MEANS
SUBCOMMITTEES
TRADE
SELECT REVENUE MEASURES

ADMINISTRATIVE ASSISTANT
JAMES M. SPARLING, JR

Congress of the United States
House of Representatives
Washington, DC 20515-2209

DISTRICT OFFICES
ROOSEVELT PARK
950 WEST NORTON AVENUE
MUSKEGON, MI 49441-4193
(616) 733-3131

31 WEST 8TH STREET
HOLLAND, MI 49423-3102
(616) 396-3849

124 NORTH DIVISION STREET
TRAVERSE CITY, MI 49684-2263
(616) 946-3832

March 23, 1989

Mr. Hugh C. Cannon
Associate Commissioner for
Legislation and Information
Food and Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

I was recently contacted by a constituent, [redacted] relative to the testing of a drug, RU-486, which, according to her letter, is an alternative to surgical abortion.

I have enclosed a copy of her correspondence detailing her views. Any information or comments you may be able to share with me relative to this situation would be greatly appreciated.

Thank you for your time and attention to this matter. I look forward to hearing from you in the near future.

with all good wishes,

Sincerely,

Guy Vander Jagt
Member of Congress

GVJ:ljh
Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005599

United States Senate

WASHINGTON, D.C. 20510

March 17, 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 testing of drug RU-486. I would appreciate your expeditious attention to this matter.

Please respond directly to _____ 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