GLENN M. ANDERSON
32D DISTRICT, CALIFORNIA

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WASHINGTON, DC 20515-0532
TELEPHONE: (202) 225-6676

300 LONG BEACH BOULEVARD
(P.O. BOX 2349)
LONG BEACH, CA 90801-2349
TELEPHONE: (213) 437-7665

Congress of the United States
House of Representatives
Washington, DC 20515-0532

CHAIRMAN
PUBLIC WORKS AND TRANSPORTATION
CHAIRMAN, INVESTIGATION AND OVERSIGHT

- MEMBER, CONGRESSIONAL MARITIME CAUCUS
- MEMBER, CONGRESSIONAL HISPANIC CAUCUS
- MEMBER, HUMAN RIGHTS CAUCUS
- MEMBER, CONGRESSIONAL TRAVEL AND TOURISM CAUCUS
- MEMBER, ENVIRONMENTAL AND ENERGY STUDY CONFERENCE

PLEASE ADDRESS REPLY TO MY:
☐ WASHINGTON OFFICE
☐ LONG BEACH OFFICE

June 27, 1990

Mr. James Benson
Acting-Commissioner
U.S. Food and Drug Administration
Room 14-71
5600 Fishers Lane
Rockville, MD

Dear Mr. Benson:

Please find attached a copy of the letter I recently received from my constituent, [redacted]. Because his particular concerns fall within the jurisdiction of the FDA, I am forwarding this letter to you for the Administration's comments.

In advance, thank you for your attention to my request. I would ask that you please respond directly to my constituent. If you should have any questions or require additional information, please don't hesitate to contact me.

Sincerely,

GLENN M. ANDERSON
Member of Congress

GMA/wj
Enclosure

cc: [redacted]

APPEARS THIS WAY
ON ORIGINAL

HFA-224

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 29, 1990

FILE

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

Dear Mr. Wyden:

This is in response to your letter of May 24, 1990, regarding the Food and Drug Administration's (FDA) decision to issue an import alert on the unapproved abortifacient drug, RU-486.

Before responding to your specific questions, we would like to comment on our import policy in general and RU-486 specifically.

As you know, strictly interpreted, the Federal Food, Drug and Cosmetic Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States.

In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria outlined in our July 20, 1988 Pilot Guidances document are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public, which we stated in our June 9, 1989 response to Representative Robert Dornan. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses

safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with or policy guidance an the importation of unapproved drugs.

The responses to your specific questions are as follows:

Question 1: What evidence has the FDA gathered that indicates that RU-486 will be used without physician supervision?

Answer: Although we have no specific evidence or documentation that RU-486 would be used without physician supervision, this is a strong possibility given the nature of the drug's use and the history of misuse of abortifacients in general. We believe that since indiscriminate or unsupervised use could be hazardous to health, it is prudent public health policy to be concerned about this potential misuse.

Question 2: Why has the FDA not applied its physician supervision requirement to RU-486 when it might ensure that RU-486 would be used safely?

Answer: This is discussed in our response to Question 1. Also, it is significant to note that, because the user of the drug would, in all probability, not be under the care of a physician for a serious or life-threatening condition, we do not believe that the patient's statements about physician care that are required by our Policy Guidance document would provide sufficient assurance that the user would actually receive the drug under a physician's care.

Question 3: Why has the FDA issued an import alert based upon inquiries from the field that have not been made?

Answer: Infact, FDA has received verbal inquiries from the public that resulted from news stories that the drug would be available in France.

Question 4: What is the evidence of health or scientific risk that the Agency specifically used to issue the import alert for RU-486?

Answer: As stated above, we believe that the drug would be misused and, if used by laypersons without medical supervision, the potential side effects could be very hazardous, even life-threatening, to the patient. The carefully controlled distribution and use of the drug in France suggests that the French regulatory authorities have similar concerns.

I hope our comments and responses are helpful in the understanding of this issue. If we can be of any further assistance, please let me know.

Sincerely yours,

James S. Benson
Acting Commissioner
of Food and Drugs

APPEARS THIS WAY
ON ORIGINAL

FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 29 1990

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

Dear Mr. Wyden:

This is in response to your letter of May 24, 1990, regarding the Food and Drug Administration's (FDA) decision to issue an import alert on the unapproved abortifacient drug, RU-486.

Before responding to your specific questions, we would like to comment on our import policy in general and RU-486 specifically.

As you know, strictly interpreted, the Federal Food, Drug and Cosmetic Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States.

In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria outlined in our July 20, 1988 Pilot Guidances document are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public, which we stated in our June 9, 1989 response to Representative Robert Dornan. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses

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safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with or policy guidance an the importation of unapproved drugs.

The responses to your specific questions are as follows:

Question 1: What evidence has the FDA gathered that indicates that RU-486 will be used without physician supervision?

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Question 2: Why has the FDA not applied its physician supervision requirement to RU-486 when it might ensure that RU-486 would be used safely?

Answer: This is discussed in our response to Question 1. Also, it is significant to note that, because the user of the drug would, in all probability, not be under the care of a physician for a serious or life-threatening condition, we do not believe that the patient's statements about physician care that are required by our Policy Guidance document would provide sufficient assurance that the user would actually receive the drug under a physician's care.

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Question 4: What is the evidence of health or scientific risk that the Agency specifically used to issue the import alert for RU-486?

Answer: As stated above, we believe that the drug would be misused and, if used by laypersons without medical supervision, the potential side effects could be very hazardous, even life-threatening, to the patient. The carefully controlled distribution and use of the drug in France suggests that the French regulatory authorities have similar concerns.

I hope our comments and responses are helpful in the understanding of this issue. If we can be of any further assistance, please let me know.

Sincerely yours,

James S. Benson
Acting Commissioner
of Food and Drugs

APPEARS THIS WAY
ON ORIGINAL

101st Congress

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

May 24, 1990

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

Dear Mr. Benson:

The Subcommittee is reviewing FDA's issuance of the June 9, 1989, automatic detention import alert on RU 486. I am concerned that the FDA has taken the position that this alert is justifiable on the grounds of health and safety risks. After reviewing many FDA documents relating to this decision, I cannot find specific documentation in FDA records attesting to the health and safety risks of RU 486.

In fact, the FDA has issued inconsistent, contradictory statements with respect to RU 486. For example, the agency states in its July 20, 1988 Pilot Guidance for Release of Mail Importations that any unapproved drug -- including RU 486 -- may be released to a patient, if the patient affirms in writing that it is for their "own use and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product."

Yet, June 9, 1989, the Agency appears to take a different position on RU 486. In a letter to Rep. Robert Dornan, Dr. Frank Young simply assumes that patients will use RU 486 without physician supervision -- and cites this assumption as creating a health and safety problem which is grounds for barring its use.

The only criteria the the FDA has used in finding RU 486 unsafe, is that it would be used without physician supervision. It does not appear from a review of FDA's files that the Agency has any evidence indicating that RU 486 would, in fact, be used without such supervision.

The FDA is treating RU 486 differently than other unapproved drugs, without any evidence that this treatment is warranted. The FDA appears to have tossed aside its physician supervision requirement for unapproved drugs, so that it can block physician supervised personal use of RU 486.

Additionally, in a memo to you from your chief counsel,

[redacted] dated February 23, 1990, Ms. Porter indicates that "...because of the number of inquiries that the districts had received regarding its "legal status" in the United States, an import alert was required to clarify that the product was unapproved and, as such, was prohibited." Additional documents on file buttress this point. The handwritten cover page of the clearance record on the import alert, written by [redacted] reads:

"Do [sic] to numerous inquiries to OLA/HFC-1/IOB and districts on suitability for entry of abortifacient (RU 486) drugs under the Pilot Guidance for Release of Mail Importation for personal use, this import alert establishes the agency's position on this question. The alert establishes the agencies that this product is not to be released under the pilot guide and the product is not suitable for personal use without proper supervision by a physician."

However, in a letter from your Associate Commissioner for Legislative Affairs, Hugh Cannon, dated April 3, 1990, Mr. Cannon notes that "We have not been able to identify any correspondence or other documents from the field...regarding RU-486."

On the basis of my staff's review of FDA's policies on RU 486, I would like to ask the following questions:

1) What evidence has the FDA gathered that indicates that RU 486 will be used without physician supervision?

2) Why has the FDA not applied its physician supervision requirement to RU 486 when it might ensure that RU 486 would be used safely?

3) Why has the FDA issued an import alert based upon inquiries from the field that have not been made?

4) What is the evidence of health or scientific risk that the Agency specifically used to issue the import alert for RU 486?

I would appreciate a prompt, written response to the above questions by June 22, 1990.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

APPEARS THIS WAY
ON ORIGINAL

RW/gab

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date June 21, 1990

From Acting Commissioner of Food and Drugs

Subject RU-486, Request for Information from White House Domestic Policy Council Staff Member

To

Chief of Staff, Office of the Secretary

Through: ASH _____
ES _____

This is to inform you that on July 8, FDA staff received a telephone request from _____ of the White House Domestic Policy Council staff for one page of background information on the French abortifacient drug RU-486. I am attaching the information that was sent to _____ This paper was factually accurate as of June 8. On June 12, FDA received the IND it refers to.

James S. Benson

James S. Benson

Attachment

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ON ORIGINAL

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RU-486

- RU-486 is a drug that is approved for abortion in Europe. It is manufactured by the French drug firm Roussel UCLAF, and the firm holds a patent on the starting material for the drug.

- A New England Journal of medicine article reports an efficacy rate of 98.1% for early first trimester abortion using a single 600 mg dose of RU-486 followed (36 to 48 hours later) by an injection of 0.5 mg of the prostaglandin, sulprostone, while the efficacy rate with another prostagladin, gemeprost, (1 mg vaginal suppository) is 96.3%. Neither of these prostagladins is approved for marketing in the United States; however, three other prostaglandins have been approved, two of which are approved for second trimester abortions.

- FDA has two INDs for testing of RU-486 for abortifacient use, one of which is from the Population Council and is considered to be public knowledge. At this time, there is no abortifacient testing being done under these INDs.

- RU-486 is said to be strictly controlled in Europe. Sponsors of INDs for testing the anti-glucocorticoid properties of RU-486 have reported to FDA that they are unable to obtain the drug from Roussel UCLAF for at least one year.

- FDA has never received an application to market RU-486 in this country, and the agency has issued import "alerts" to detain any shipments of the drug that might enter the U.S. without an IND approved by FDA.

- While many states, including California, have statutes that permit experimental drug testing, since the only source of RU-486 is foreign, the drug would be in interstate commerce, and FDA would have primary jurisdiction over the development and approval of the drug in the U.S. Therefore, shipment from a foreign country to any state would be illegal if not done under an FDA IND.

- On June 7, the State of California received an IND for RU-486 testing as an abortifacient. The sponsor allegedly mailed INDs to California and to FDA at the same time; however, as of the afternoon of June 8 FDA had not received an IND.

- If FDA receives an IND and the data to support the IND submission are reasonable, the IND automatically goes into effect 30 days from submission unless FDA has scientific grounds to stop it.

- FDA is maintaining close communication on this matter with California officials.

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OCT 2 1990

The Honorable Ted Stevens
United States Senate
Washington, D.C. 20510

Dear Senator Stevens:

This is in response to your letter of October 3, 1990, on behalf of _____ concerning the unapproved new drug, RU-486.

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

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

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

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure _____ 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.

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ON ORIGINAL

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/S/

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*U.S. GPO: 1989-619-444

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

Enclosure
New Drug Development
in the United States

cc: HFW-10(2)
F/D: [redacted]:10/17/90
F/T: var:10/17/90
CONG-2586
[redacted] \DRUGS\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON APPROPRIATIONS
WASHINGTON, DC 20510-6025

October 3, 1990

Hugh C. Cannon, Associate Commissioner
Office of Legislative Affairs
Food & Drug Administration
Room 15-55, Parklawn Building
5600 Fishers Lane
Rockville, MD 20852

Dear Mr. Cannon:

Enclosed is a copy of a letter from [redacted] a constituent of mine who is interested in the drug RU486.

Any information you could provide that would address [redacted] concerns would be greatly appreciated.

Thank you for your help.

With best wishes,

Cordially,

Ted Stevens

TED STEVENS

Enclosure

APPEARS THIS WAY
ON ORIGINAL

FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 27 1990

The Honorable Steve Symms
United States Senator
207 Federal Building
Pocatello, Idaho 83201

Dear Senator Symms:

This is in response to your letter of November 30, 1990, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long

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permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance an the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
R/D: [redacted]12/18/90
R/T: var:12/18/90
F/D: [redacted]12/19/90
F/T; var:12/20/90
CONG-2922 No. 3387
([redacted],DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

STEVE SYMMS
IDAHO

United States Senate

WASHINGTON, DC 20510

November 30, 1990

Associate Comm. for Leg Affairs
Food and Drug Administration
Department of HHS
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner:

My office has been contacted by [redacted] inquiring why a cancer fighting drug, RU-486 from France, has been banned by the FDA.

In order that I might properly respond to my constituent, please furnish me a report on this matter. Your reply should be sent to the office indicated at the bottom of this letter.

Your prompt attention is appreciated.

Sincerely,

Steve Symms

STEVE SYMMS
United States Senator

SS/slg
Enclosure

APPEARS THIS WAY
ON ORIGINAL

#3371

PLEASE REPLY TO:

☐ IDAHO FALLS OFFICE
482 CONSTITUTION WAY
IDAHO FALLS 83402
(208) 522-9779

☑ POCATELLO OFFICE
207 FEDERAL BUILDING
POCATELLO 83201
(208) 236-6775

☐ TWIN FALLS OFFICE
401 2nd St., #108
TWIN FALLS 83301
(208) 734-2515

☐ BOISE OFFICE
BOX 1190
BOISE 83701
(208) 334-1776

☐ LEWISTON OFFICE
301 D STREET #103
LEWISTON 83501
(208) 743-1492

☐ MOSCOW OFFICE
105 FEDERAL BUILDING
MOSCOW 83843
(208) 882-5560

☐ COEUR D'ALENE OFFICE
305 FEDERAL BUILDING
COEUR D'ALENE 83814
(208) 664-5490

MIF 005718

RON WYDEN, OREGON
CHAIRMAN

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

101st Congress

United States House of Representatives
Committee on Small Business

Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

MINORITY MEMBERS
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SUBCOMMITTEE STAFF DIRECTOR
202-226-7787

PAUL RUSINOFF
MINORITY SUBCOMMITTEE PROFESSIONAL
STAFF MEMBER
202-226-8138

Grady Forrer
Counsel

OPENING STATEMENT
CHAIRMAN RON WYDEN

BEFORE THE
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

NOVEMBER 19, 1990

FEDERAL IMPORT BAN ON FRENCH DRUG RU 486:
IS THERE A REAL THREAT TO THE PUBLIC HEALTH?
HAS THE BAN CHILLED SIGNIFICANT MEDICAL RESEARCH?

Good morning. Today the Subcommittee on Regulation, Business Opportunities and Energy reviews the June 1989 decision of the U.S. Food and Drug Administration (FDA) to ban the importation of the French drug RU 486 for personal use. Specifically, the subcommittee will inquire into the effect the ban has had on American medical research and the approval of new drugs in the United States that may have multiple benefits.

Few recent drugs have generated as much interest as RU 486. The drug is considered a success in France as an alternative to surgical abortion. Many scientists now believe that the drug can successfully treat debilitating and life-threatening illnesses such as breast cancer, brain cancer, diabetes, and Cushing's Syndrome. According to published reports, both Western industrialized nations and the Third World, are now rushing to test RU 486 in various trials and in some case to distribute the drug to their fellow citizens.

But the response of U.S. health authorities to RU 486 has been markedly different -- and resistant. The FDA has banned the importation of the drug for personal use on the grounds that RU 486 is a health hazard threatening the "safety of the user."

What proof does the agency have to back up its conclusions about RU 486?

To answer this question, subcommittee staff spent almost a year investigating the FDA's documentary evidence. FDA files -- the legal foundation for the import ban -- are notable for what they contain, and for what they lack.

The Chair believes that the FDA's basis for restricting the personal importation of RU 486 is especially important for two reasons: First, the June 1989 decision is the first major policy statement on the part of the U.S. government as to how it views RU 486; Second, shortly after the FDA's decision critical research not related to abortion using RU 486 slowed down, or came to a halt.

Perhaps the best example of this research slow down involves the National Institutes of Health study for treatment of Cushing's Syndrome. This devastating, and sometimes fatal disease has responded remarkably to treatments using RU 486. NIH researchers will tell us today that this is nothing less than a medical breakthrough. They will also tell us that plans to expand their research and bring more Cushing's patients into this extraordinary program have been stymied because they cannot be assured of new supplies of RU 486.

FDA officials contend that there is no link, official or otherwise, between the winding down of non-abortion research with RU 486 and the import ban.

But the reality is we are losing the chance to do cutting edge medical research because the company that makes RU 486 is boycotting the United States for two reasons -- the arbitrary, political and unscientific RU 486 policies of the FDA, and the protests that have been promised from anti-abortion groups. The fact is the drug's manufacturer has made a business decision to use its supplies only in countries where government regulators will give them a fair shake.

The U.S. drug approval process, in the best of times, is a tortured exercise. At present, the FDA is under-funded, under-staffed and still reeling from the generic drug scandal. Given that RU 486 has been welcomed in other countries, its easy to see why from the standpoint of the company's self-interest they have steered clear of the United States.

As a result of FDA's RU 486 policies, anti-abortion politics, and the manufacturer's business decisions, Americans now suffering from horrible illnesses will not have the hope of cures they had before the import ban was imposed.

Americans with breast cancer and other dread diseases have become the innocent victims of this Administration's political brinkmanship with the pro-choice movement on abortion, and there will be needless suffering.

APPEARS THIS WAY
ON ORIGINAL

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 15 1991

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

Dear Mr. Pickett:

This is in response to your letter of November 27, 1990, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	/S/	1/7/91						/S/

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MIF 005721

personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria for the importation of an unapproved drug), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with or policy guidance an the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
R/D: ———— 12/18/90
R/T: var:12/18/90
F/D: ———— 12/19/90
F/T; var:12/20/90
CONG-2926 No. 3391
———\DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

OWEN PICKETT
2ND DISTRICT
VIRGINIA

CONGRESS OF THE UNITED STATES

HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

COMMITTEES
ARMED SERVICES
MERCHANT MARINE & FISHERIES

November 27, 1990

Mr. Hugh Cannon
Associate Commissioner
Food and Drug Administration
5600 Fisher's Lane, Room 1555
Rockville, Maryland 20857

Dear Mr. Cannon:

I am forwarding this correspondence to you for careful review on a subject of concern to my constituency. I would appreciate a timely response to this inquiry.

Thank you in advance for your attention to this matter.

With kindest regards, I am

Sincerely yours,

Owen Pickett

Owen Pickett
Member of Congress

OP:sbc

#3387

WASHINGTON OFFICE:
1204 LONGWORTH BUILDING
WASHINGTON, D.C. 20515
(202) 225-4215

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

NORFOLK OFFICE:
815 FEDERAL BUILDING
NORFOLK, VIRGINIA 23510
(804) 624-9124

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FILE

FEB 2 1991

The Honorable Phil Gramm
United States Senate
Washington, D.C. 20510

Dear Senator Gramm:

This is in response to your letter of January 15, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

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MIF 005725

*U.S.GPO:1988-0-213-062

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted]:1/30/91
F/T; var:2/19/91
CONG-3216 and No. 3736
' [redacted]\DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

December 14th, 1990

The Hon. Phil Gramm
Republican Sentor for the State of Texas
The United States Senate
Washington, D.C. 20510-4302

Dear Senator:

Having experienced extended chemotherapy for prostatic cancer, I am most concerned that RU486 cannot be imported from France; not, I understand, for use in experimental treatment, nor even for research purposes.

While I have no way of knowing whether RU486 would be of any value in my particular case, my oncologist has said that unless his research team can evaluate the chemical, he must necessarily withhold judgement. However, there is considerable evidence from the French research workers that RU486 does appear to be highly effective in a significant percentage of cases of breast cancer. As I am sure aware, the Food and Drug Administration will not allow the drug to be imported because of the fact that it can also be used to induce abortion; thus due to political pressure from Right to Life Groups, it is quite possible that there are women who are suffering from advanced stages of breast cancer, and who might at least be helped, if not actually cured by the use of RU486.

Do you not agree with me, Senator, that Congress should immediately investigate this matter and (a) require the FDA permit research to determine whether the chemical is a useful drug for treatment of a disease of epidemic proportions and (b) if proven useful, then controlled importation for treatment be permitted. The importation of RU486 should not be disallowed because of a secondary use, with which many people happen, with fanatical fervor to disagree ... and yet who seem to be prepared to allow many women to die, quite possibly unnecessarily, because of their obsession with its application as an abortive agent.

I shall be glad to know whether you, Sir, believe as I do, that this is a situation where the Director of the FDA should be reminded by the appropriate committees of Congress, that his Agency is required to be responsive to the virtual concensus within the medical profession, and that new and potentially valuable drug research not be inhibited by political pressure from organizations that represent only a highly visible minority; too many lives are at risk for that.

Sincerely,

MIF 005728

PHIL GRAMM
TEXAS

United States Senate

WASHINGTON, D. C. 20510-4302

January 15, 1991

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

Dear Sir:

The attached communication is submitted for your consideration, and to ask that the concerns voiced therein be addressed.

If you would advise me of your action in this matter and have the letter returned to me with your reply, I would appreciate it.

Senator Phil Gramm
370 Russell Senate Office Building
Washington, D.C. 20510

Attention: Jeff Hassmannn
224-0723

Yours respectfully,

PHIL GRAMM
United States Senator

PG:jsh

APPEARS THIS WAY
ON ORIGINAL

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 20 1991

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley:

This is in response to your letter of January 2, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Exec	/S/	2/20/91						

FILE

MIF 005730

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be 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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted]:1/30/91
F/T; var:2/19/91
CONG-3212 and No. 3732
[redacted] \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

United States Senate

WASHINGTON, D.C. 20510

January 2, 1991

Mr. James S. Benson
Acting Administrator
Food and Drug Administration
5600 Fishers Lane, Room 1547
Rockville, Maryland 20857

Dear Mr. Benson:

I have been contacted by a constituent, [redacted] regarding the use of the drug RU-486 in treating breast cancer.

I would appreciate any assistance you could provide pertaining to this matter. Please mark your return correspondence to the attention of Julie Bundt when responding to my office.

Thank you for your attention to my request.

Sincerely,

Chuck

Charles E. Grassley
United States Senator

CEG/jb

APPEARS THIS WAY
ON ORIGINAL

MIF 005733

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 20 1991

The Honorable Robert W. Kasten, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Kasten:

This is in response to your letter of January 4, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	[illegible]	2/20/91						

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MIF 005734

*U.S.GPO:1988-0-213-062

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be 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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted] 1/30/91
F/T; var:2/19/91
CONG-3222 and No. 3742
[redacted]\DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

ROBERT W. KASTEN, JR.
WISCONSIN

United States Senate

WASHINGTON, DC 20510-4902

January 4, 1991

Mr. Hugh C. Cannon
Legislative Affairs
Food & Drug Administration
5600 Fishers Lane - 1555
Rockville, Maryland 20857

Dear Mr. Cannon:

Please find enclosed correspondence I received from _____ Because of my desire to be responsive to the constituents in my state, I am referring this matter to you for your review.

I would like to request your assistance in evaluating the information provided. I would greatly appreciate your forwarding your findings in duplicate form to Manuel Bonilla, on my staff, at your earliest convenience.

Again, many thanks for your time and attention to this matter.

Best regards,

Robert W. Kasten, Jr.

RWK/meb
Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005737

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 15 1991

The Honorable David E. Skaggs
Member, United States
House of Representatives
9101 Harlan Street, Suite 130
Westminster, Colorado 80030

Dear Mr. Skaggs:

This is in response to your letter of January 9, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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MIF 005738

★U.S.GPO:1988-0-213-052

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

If we can be of any further assistance, please let us know. We hope the information provided will be helpful.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ———— :1/30/91
F/T; var:2/12/91
CONG-3202 No. 3723
————\DRUGS\STDRU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

DAVID E. SKAGGS
2ND DISTRICT, COLORADO

1709 LONGWORTH BUILDING
WASHINGTON, DC 20515
(202) 225-2161

9101 HARLAN STREET, SUITE 130
WESTMINSTER, COLORADO 80030
(303) 650-7886

UNITED STATES
HOUSE OF REPRESENTATIVES

PUBLIC WORKS AND
TRANSPORTATION COMMITTEE

SCIENCE, SPACE, AND
TECHNOLOGY COMMITTEE

SELECT COMMITTEE ON CHILDREN,
YOUTH, AND FAMILIES

WHIP AT LARGE

January 9, 1991

Mr. Hugh Cannon
Assoc. Commissioner, Leg. Affairs
Food and Drug Administration
U.S. Dept. of Health/Human Services
5600 Fishers Lane
Rockville, Maryland 20859

Dear Mr. Cannon:

I am writing in behalf of ——— who contacted my office requesting assistance. I have enclosed a copy of his letter.

I would appreciate your looking into this for me. Please respond to my Colorado office.

Sincerely yours,

David Skaggs

David E. Skaggs

DES:eeg
Enclosure

APPEARS THIS WAY
ON ORIGINAL

A.I. ——— FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 14 1991

Marvin Z. Schreiber, M.D.
770 Boylston Street, 11G
Boston, Massachusetts 02199

Dear Dr. Schreiber:

This is in reply to your recent inquiry to the Food and Drug Administration requesting a copy of the November 19, 1990 testimony regarding RU-486.

As requested, we are enclosing a copy of the above mentioned correspondence and a copy of our response.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure

cc:HFW-10(2)
HFI-35 (F91-003896 ——— and enclosures)
R/D: ——— for —— :2/13/91
F/T:vaj:2/13/91:(val:f ———

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

*U.S. GPO: 1989-624-403

MIF 005742

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Statement

of

Ronald Chesemore

Associate Commissioner for Regulatory Affairs

Food and Drug Administration

Public Health Service

Department of Health and Human Services

BEFORE THE

Subcommittee on Regulation, Business Opportunities and Energy

Committee on Small Business

U.S. House of Representatives

November 19, 1990

Mr. Chairman:

I am pleased to be here today to discuss with the Subcommittee the Food and Drug Administration's (FDA) activities related to the unapproved new drug RU-486.

I am Ronald Chesemore, Associate Commissioner for Regulatory Affairs. I am accompanied by Dr. Solomon Sobel, Director of our Division of Metabolism and Endocrine Drug Products and Sandra Barnes of our General Counsel's office.

As you know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. Studies have been conducted on the treatment uses of this drug including brain tumors, breast cancer, Cushing's syndrome, and other types of cancer. This drug is the subject of an import alert which means that if observed coming into the country either through the mail or with individual persons, it will be detained by FDA field personnel and U.S. Customs Service officials. I should make the distinction, however, that with respect to the importation of unapproved drugs, those drugs under an investigational new drug application (IND) can be imported for research purposes, but individuals cannot import an unapproved drug for personal use unless it meets certain criteria. In the case of RU-486, importation for research for any therapeutic use could occur if an approved IND exists.

New Drug Approval Process

Before discussing issues related to RU-486 in more detail, I would like to describe for the record the procedures by which a new drug is brought to the market in this country. As you know, under the provisions of the Federal Food, Drug, and Cosmetic Act, FDA has the responsibility to monitor the use of investigational new drugs by allowing clinical studies to proceed, if appropriate, and to review the scientific data supporting a marketing application.

In order to start testing of investigational drugs in humans, an Investigational New Drug application (IND) must be filed with FDA by the drug's sponsor, usually a drug firm. The IND must contain information adequate to demonstrate that it is reasonably safe to test the drug or drugs in human subjects, including drug composition, manufacturing controls data, the results of animal testing, information on the training and experience of investigators, and a plan for the clinical investigation. In addition, FDA requires that informed consent be obtained to protect the rights and safety of human subjects. The clinical protocol content of that informed consent document must be approved by a local ethics committee known as an Institutional Review Board.

Clinical testing under an IND to develop adequate data to approve drugs for general marketing, whether done by the pharmaceutical company, an academic institution, or the National Institutes of Health, is normally divided into three sequential phases. It is 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 ultimately if a drug is safe and effective for widespread marketing for use by the general public.

Phase 1 is the initial introduction of an investigational therapy into humans to determine safety. Phase 1 studies are intended to assess the safety of the drug with an emphasis on identifying toxicities associated with varying doses, and to determine how the drug is distributed and degraded by the body. Phase 1 studies often include fewer than 100 volunteers (patients) and may take as long as one to two years to complete.

The second phase of IND testing usually involves the first controlled clinical studies in patients to evaluate the effectiveness of the drug for a particular indication and to

determine common short-term side effects. Phase 2 studies typically involve a few hundred patients. After Phase 2 studies are completed, the drug's sponsor usually has learned much about the drug's safety and effectiveness, and larger studies involving several thousand patients are conducted as Phase 3 studies. These Phase 3 studies generally are intended to verify the initial study results in broader populations, and to collect enough information to support marketing approval.

Once Phase 3 testing is completed, the sponsor submits the test results to FDA in the form of a New Drug Application (NDA). FDA's medical officers, pharmacologists, chemists, and statisticians review the application in parallel to determine if the sponsor's data demonstrate that the drug is safe and effective for the claimed indication. In certain instances, a drug may be brought before an expert Advisory Committee to the FDA in order to seek their advise on a new product. If it is determined that safety and effectiveness have been demonstrated, the drug is approved for marketing for that indication.

The above describes our process for approving new drugs. However, an import alert does not impact this process.

APPEARS THIS WAY
ON ORIGINAL

Importation of Unapproved New Drugs

Strictly interpreted, the Federal Food, Drug, and Cosmetic Act prohibits the importation of any drug product that has not been approved for use in this country. However, FDA has for many years exercised its enforcement discretion to allow the importation of small amounts of drugs for the personal use of patients, provided they do not pose unreasonable or significant safety risks, and their use will not be commercialized. The intent of FDA's personal importation policy is to guide FDA field personnel on how to use enforcement discretion. FDA's personal importation policy is contained in the Pilot Guidance issued in July 1988 and in chapter 9-71 of FDA's Regulatory Procedures Manual. I would like to submit copies of these documents for the record.

Specifically, the policy provides that FDA will use its discretion to allow entry of certain unapproved drug products that are carried or mailed into this country if they meet the following criteria:

- the quantity of the drug or other product demonstrates that the product is intended for personal use - generally, not more than a 3-month supply for one person;

- the product is intended to treat a serious condition for

which no treatment is commercially available in this country;

- there is no known promotion or commercialization of the product;

- the product does not pose unreasonable safety risks to the patient; and

- the patient confirms that the product is for his or her personal use, and provides the name and address of a practicing physician who will be responsible for his or her treatment (or provides evidence that the product is needed to continue treatment begun in a foreign country).

On a case by case basis, the above criteria are considered in determining whether FDA will allow entry of certain unapproved drug products. It should be noted that discretion has also been used to allow importation of unapproved drugs where the intended use of the drug is appropriately identified, the use is not for treatment of a serious condition, and the drug is not known to represent a significant health risk. This is meant to apply, for example, to a traveller who develops an upper respiratory tract infection and reenters the United States with a remedy purchased abroad.

In those instances where the Agency has determined that importation of a drug product is not appropriate, it may advise its district offices by issuing an import alert. An import alert means that the discretion allowed under the personal importation policy is not appropriate and FDA field personnel are directed to detain and refuse entry of a certain product under specified circumstances. Currently, there are 58 import alerts covering various human drugs and classes of drugs.

FDA may choose to issue an import alert under certain circumstances including:

- the personal importation of a product that appears to create either a direct or indirect risk to the public health; or

- the promotion of unapproved foreign products; or

- the repeated importation of products that constitute a health fraud.

IMPORT ALERT ON RU-486

The approval and availability of RU-486 as an abortifacient

when used in conjunction with a prostaglandin in France has resulted in a great deal of publicity in this country. This has in turn generated a significant number of inquiries to the Agency from the public and the Congress about the status of RU-486 in the United States, and whether or not it should be imported into this country under our existing personal importation policy.

As you know, the use and distribution of RU-486 together with a prostaglandin in France are carefully controlled. The drugs are available only in certain clinics where patients can be closely monitored. Patients are required to make several trips to the clinic where RU-486 and the prostaglandin, an ancillary drug essential to the effectiveness of RU-486, are administered under the supervision of a physician. Once the patient receives RU-486, she is allowed to leave the clinic but must return 2 - 3 days later so that the she can receive the prostaglandin. After the patient is observed for several hours to determine that no complications have arisen, she is allowed to leave the clinic. The patient then must return to the clinic after several days for further observation.

Since neither RU-486 nor either of the two prostaglandins used in France is approved in this country, FDA has not evaluated their safety and effectiveness nor evaluated what controls might be appropriate in this country to ensure their safe use.

Although FDA can regulate the conditions of use for investigational drugs covered by an IND, no such controls would be in place to ensure safe use of these products if they were imported for personal use outside the IND procedures.

We, therefore, became concerned that the publicity regarding the availability of these drugs overseas might create a demand in this country, which could in turn foster importation of these unapproved drugs leading to unsupervised use and/or clandestine distribution. We recognize that importation may not be accomplished easily because of the limited availability of RU-486 in France. We believe, however, that it was appropriate to issue an import alert for these unapproved new drugs, given our responsibility to protect the public health. We also took this action because, as an abortifacient, RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists, a primary consideration in the development and implementation of our personal importation policy. Nor could the Agency conclude that RU-486 and the prostaglandins, as they might be used, posed no significant health risks. The Agency was concerned that because of the intended use of RU-486, potential users might well not be under the care a physician.

In addition, to be optimally effective, as I mentioned, RU-486 must be used in conjunction with a prostaglandin. Prostaglandins are potent drugs that themselves can cause serious adverse events. Indiscriminate or unsupervised use could be hazardous to the patient's health because of the risk of serious adverse effects such as excessive uterine bleeding, severe nausea, vomiting, and weakness, which might require prompt medical intervention.

Consequently, the import alert, which pointed out that use of RU-486 posed unacceptable safety risks to the American public, was issued on June 9, 1989, and alerted FDA field offices to detain all unapproved abortifacient drugs, including RU-486. I would also like to submit a copy of that alert for the record.

In summary, we continue to believe that use of our discretion to permit importation of unapproved RU-486 under the Agency's import policy is not appropriate. We believe that our decision to restrict the importation of RU-486 is sound from a public health standpoint and is consistent with our policy on personal importation of unapproved drugs.

We are aware of the American Medical Association's Resolution, adopted at its annual House of Delegates meeting in June 1990, supporting "the legal availability of RU-486 for appropriate research and, if indicated, clinical practice." In my

presentation, I described the process by which clinical research with RU-486 could proceed. We have placed no barriers in the way of research and can supply ample documentation of this fact to the Committee in executive session. It is, however, incumbent upon a sponsor to initiate the request to begin studies by submitting an application to FDA. The Agency is committed to maintaining the scientific integrity of FDA's new drug testing and approval process carried out under the existing laws enacted by the Congress.

We would be pleased to answer any questions you may have.

MARVIN-ZACH SCHREIBER, M.D., D.M.D.

770 BOYLSTON STREET 11G • BOSTON, MA. 02199 • (617) 267-1016

BOSTON UNIVERSITY • SCHOOL OF LAW (J.D. '91) • SCHOOL OF PUBLIC HEALTH (M.P.H. '91)

TO: FREEDOM OF INFORMATION OFFICE

FAX: (301) 443-1719 THIS PAGE ONLY

Please send copies of the transcripts from hearings held regarding RU-486 in November, 1990. I believe the hearings were before a subcommittee of the House Small Business Committee. I would also appreciate transcripts of any more recent hearings that may have been held.

Thank you,

Marvin Z. Schreiber, M.D., D.M.D.

91-3896

RECEIVED

FEB 11 1991

FDA FOI Staff (HFI-35)

MIF 005755

A.F. _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 01 1991

The Honorable John Barton
Member, United States
House of Representatives
809 University Drive East
Suite 222
College Station, Texas 77840

Dear Mr. Barton:

This is in response to your letter of December 27, 1990, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

/S/

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-8	/S/	2/1/91						

FILE COPY

MIF 005756

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ———— :1/30/91
F/T; var:1/31/91
CONG-3138 No. 3645
————\DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

JOE BARTON
6TH DISTRICT, TEXAS

HOME OF THE
SSC
NATIONAL LABORATORY

1225 LONGWORTH BUILDING
WASHINGTON, DC 20515-4306
(202) 225-2002

DEPUTY WHIP

COMMITTEE ON
ENERGY AND COMMERCE

SUBCOMMITTEES
ENERGY AND POWER
COMMERCE, CONSUMER PROTECTION
AND COMPETITIVENESS

Congress of the United States
House of Representatives
Washington, DC 20515-4306

December 27, 1990

Dr. Frank E. Young
Commissioner
Food and Drug Administration
1555 Park Lawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

Enclosed is information from [redacted] concerning the prohibiting of the import of the French drug RU 486.

I would appreciate any information and/or assistance you could provide in regard to this matter.

Please direct any correspondence concerning this inquiry to my College Station district office, 809 University Drive East, Suite 222, College Station, Texas 77840.

Thank you for your interest and consideration.

Sincerely,

Joe Barton
Member of Congress

JB/th

BRYAN/COLLEGE STATION OFFICE:
809 E. UNIVERSITY, SUITE 222
COLLEGE STATION, TX 77840-2116
(409) 846-1985

CONROE OFFICE:
300 WEST DAVIS, SUITE 507
CONROE, TX 77301-2803
(409) 760-2291

ENNIS OFFICE:
303 WEST KNOX, SUITE 101
ENNIS, TX 75119-3942
(214) 875-8488

FORT WORTH OFFICE:
3509 HULEN, SUITE 103
FORT WORTH, TX 76107-6811
(817) 737-7737

A.F. [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 30 1991

The Honorable Alfonse D'Amato
United States Senator
Seven Penn Plaza, Suite 600
370 Seventh Avenue
New York, New York 10001

Dear Senator D'Amato:

This is in response to your letter of January 2, 1991, on behalf of [redacted] concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual /S/

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-12	/S/	2/1/91						

FILE COPY

★U.S.GPO:1988-0-213-052

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony
cc: HFW-10(2)
F/D: [redacted] :1/30/91
F/T; var:1/31/91
CONG-3142 No. 3649
([redacted] \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

Ronald Chesemore
Associate Commissioner for
Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Chesemore,

I write to you to ask that the FDA import ban on RU-486 be lifted, so that the scientific and medical community, and ultimately cancer patients, can have the benefit of its use in treating cancer.

The FDA must protect the interests of all the American people. Free and open research in the treatment of cancer must continue. Lives are at stake.

Sincerely yours,

/S1

ALFONSE M. D'AMATO
NEW YORK

SUITE 600
SEVEN PENN PLAZA
370 SEVENTH AVENUE
NEW YORK, NEW YORK 10001
(212) 947-7390

United States Senate

WASHINGTON, DC 20510

January 2, 1991

TO: Congressional Relations
Food and Drug Administration
5600 Fisher Lane
rockville, MD 20852

FROM: Alfonse M. D'Amato
United States Senator

Because of the desire of this office to be responsive to all inquiries and communications, your consideration of the attached is requested.

PLEASE TRY TO RESPOND WITHIN 4 WEEKS OF YOUR RECEIPT OF THIS REQUEST. YOUR FINDINGS AND VIEWS, IN DUPLICATE, ALONG WITH THE RETURN OF THIS MEMO, WILL BE APPRECIATED.

SEND ALL CORRESPONDENCE ON THIS MATTER DIRECTLY TO MY NEW YORK CITY OFFICE, SEVEN PENN PLAZA, SEVENTH AVENUE, SUITE 600, NEW YORK, NEW YORK, 10001.

Thank you.

APPEARS THIS WAY
ON ORIGINAL

A.r. _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 25 1991

The Honorable Dante B. Fascell
House of Representatives
Washington, D.C. 20515

Dear Mr. Fascell:

This is in response to your letter of December 21, 1990, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug and Cosmetic Act (FDC), 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 a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States

/S/

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-2	/S/	1/25/91						

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

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
R/D: [redacted]:1/18/91
R/T: var:1/22/91
F/D: [redacted]:12/23/91
F/T; var:1/23/91
CONG-3114 No. 3607
[redacted],DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

DANTE B. FASCELL
19TH DISTRICT, FLORIDA

FOREIGN AFFAIRS COMMITTEE
CHAIRMAN

ARMS CONTROL, INTERNATIONAL
SECURITY AND SCIENCE SUBCOMMITTEE
CHAIRMAN

SELECT COMMITTEE ON NARCOTICS
ABUSE AND CONTROL
MEMBER

Congress of the United States

House of Representatives

Washington, DC 20515

CHARLES R. O'REGAN
ADMINISTRATIVE ASSISTANT

COMMISSION ON SECURITY AND
COOPERATION IN EUROPE
MEMBER

NORTH ATLANTIC ASSEMBLY
CHAIRMAN
HOUSE DELEGATION

CANADA—UNITED STATES
INTERPARLIAMENTARY GROUP
MEMBER, U.S. DELEGATION

December 21, 1990

Mr. Hugh C. Cannon, Associate Commissioner
for Legislative Affairs
Food and Drug Administration
5600 Fisher's Lane, Room 1555
Rockville, Maryland 20857

Dear Mr. Cannon:

Enclosed is a copy of correspondence from one of my constituents.

It would be greatly appreciated if you would accord the comments in the letter every consideration and provide me with a report on the matter.

Many thanks for your assistance.

Sincerely,

Dante B. Fascell

DANTE B. FASCELL
Member of Congress

DBF/RT

Enclosure

APPEARS THIS WAY
ON ORIGINAL

H.F.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 1991

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

Dear Senator Bentsen:

This is in response to your letter of February 7, 1991, on behalf of [redacted] concerning the unapproved new drug, RU-486.

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

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

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

We are unable to predict whether, or when RU-486 will be approved for marketing. We can assure you 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 005769

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-10	/S/	3/12/91						

*U.S.GPO:1988-0-213-062

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

Enclosure
New Drug Development in
the United States

cc: HFW-10(2)
F/D: [redacted] 3/11/91
F/T: var:3/12/91
3464 No. 4024 [redacted] \DRUGLTR\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

LLOYD BENTSEN
TEXAS

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

United States Senate

WASHINGTON, DC 20510-4301

February 7, 1991

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

Dear Commissioner Kessler:

I recently received the enclosed constituent inquiry, and I would very much appreciate your providing me with any pertinent information you might have regarding the matter, or any assistance you might be able to give in routing it to the proper authorities.

Your kind consideration is greatly appreciated.

Sincerely,

Lloyd Bentsen

Lloyd Bentsen

Enclosure

PLEASE REPLY TO:

961 Federal Building
Austin, Texas 78701
ATTN: Rosa Castano

APPEARS THIS WAY
ON ORIGINAL

#4024

A.F. _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 1 1991

The Honorable Peter J. Visclosky
House of Representatives
Washington, D.C. 20515

Dear Mr. Visclosky:

This is in response to your letter of February 11, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-2	/S/	3/13/91						

FILE COPY

*U.S.GPO:1988-0-213-062

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be 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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted] :3/11/91
F/T; var:3/12/91
CONG-3477 and No. 4040
([redacted] \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

COMMITTEES:
PUBLIC WORKS AND TRANSPORTATION
INTERIOR AND INSULAR AFFAIRS
CONGRESSIONAL STEEL CAUCUS
WHIP-AT-LARGE

WASHINGTON, DC 20515
(202) 225-2461

215 WEST 35TH AVENUE
GARY, IN 46408
TTY-TDD SERVICE AVAILABLE
(219) 884-1177

CITY HALL, LOWER LEVEL
100 EAST MICHIGAN BOULEVARD
MICHIGAN CITY, IN 46360
(219) 873-1435
(219) 873-1436

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

February 11, 1991

Mr. Hugh C. Cannon
Commissioner, Legislative Affairs
Food and Drug Administration
Health & Human Services Department
200 Independence Avenue, S. W.
Washington, D.C. 20201

Re: [redacted]

Dear Mr. Cannon:

Please find enclosed a copy of the correspondence submitted to my office by my constituent, [redacted]

[redacted] has written due to the availability of the drug RU 486. [redacted] is seeking additional information regarding the availability of this drug in the United States and also identifying any research programs involving this drug. I would appreciate your review of the circumstances involved and any efforts which can be taken to address her concerns.

Please feel free to contact my staff assistant, Paula Sheets, at the Gary District office should you have any questions or comments pertaining to this request.

Thank you for your kind attention.

Sincerely,

Peter J. Visclosky
Member of Congress

PJV/pws

Enclosures (2)

APPEARS THIS WAY
ON ORIGINAL

MIF 005775

A.T. [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 07 1991

The Honorable Tom Coleman
House of Representatives
Washington, D.C. 20515

Dear Mr. Coleman:

This is in response to your inquiry of February 13, 1991, on behalf of [redacted] concerning RU-486, an abortifacient developed in France.

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

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

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

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
F/D: [redacted] :2/19/91
F/T; var:3/4/91
CONG-3380 NO. 3931
([redacted] DURGLTR\STOPRU.486)

MIF 005776
FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	3/7/91						

★U.S.GPO:1988-0-213-052

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 04 1991

The Honorable John McCain
United States Senate
Washington, D.C. 20510

Dear Senator McCain:

This is in response to your letter of February 5, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug, and Cosmetic Act (FDC), 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 a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-18	/ST	2/25/91						

FILE COPY

★U.S.GPO:1988-0-213-062

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

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Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ———— 2/15/91
F/T; var:2/27/91
CONG-3373 and No. 3922
————\DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

1990

Senator John McCain,

I am interested in obtaining the latest information you or your agencies have as to why aren't pharmaceutical companies exploring the use of RU-486 as a surgical alternative to abortion. In France I know this drug is used commonly and is accepted as a working alternative to an abortion. Would you please send me any information you have on this topic and or your opinion on the matter? I would like this information so as to present it to my government class. Thank you.

Sincerely yours,

/S/

[redacted]

MIF 005780

JOHN McCAIN
ARIZONA

United States Senate

WASHINGTON, D.C. 20510

February 5, 1991

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

Dear Hugh:

I have enclosed an inquiry which I have recently received from _____

I would greatly appreciate it if you would review this material and provide me with a prompt response addressing this issue.

PLEASE MARK THE ENVELOPE TO THE ATTENTION OF: John Desser in my Washington office, 111 Russell Senate Office Building, Washington, D.C. 20510. Thank you very much for your kind assistance and cooperation.

Sincerely,

John McCain
United States Senator

JM/jdm
Enclosure

APPEARS THIS WAY
ON ORIGINAL

H-3922

A.I. [redacted] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 12 1991

The Honorable Chalmers P. Wylie
Member, United States
House of Representatives
Federal Building
200 North High Street
Columbus, Ohio 43215

Dear Mr. Wylie:

This is in response to your recent letter of May 16, 1991, on behalf of [redacted], regarding the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, [illegible] provides

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	6/12/91						

/S/ 6/12/91

FILE COPY

MIF 005782

*U.S.GPO:1988-0-213-062

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be 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
New Drug Development in
the United States
FDA Testimony
cc: HFW-10(2)
F/D: [redacted] :5/26/91
F/T; var:6/10/91
CONG-4108 and No. 4786
[redacted] ,DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

15TH DISTRICT, OHIO

2310 RAYBURN HOUSE
OFFICE BUILDING
TELEPHONE: (202) 225-2015

DISTRICT OFFICE:
FEDERAL BUILDING
200 NORTH HIGH STREET
COLUMBUS, OH 43215
TELEPHONE: (614) 469-5614

WALLER C. BLOOM
DISTRICT REPRESENTATIVE

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

BANKING, FINANCE AND URBAN AFFAIRS

SUBCOMMITTEES:
CONSUMER AFFAIRS
HOUSING AND COMMUNITY DEVELOPMENT
FINANCIAL INSTITUTIONS SUPERVISION, REGULATION AND INSURANCE

VETERANS' AFFAIRS

SUBCOMMITTEES:
COMPENSATION, PENSION, AND INSURANCE
EDUCATION AND TRAINING

JOINT ECONOMIC

May 16, 1991

Hugh Cannon, Associate Commissioner
for Legislative Affairs
Food and Drug Administration
Room 1555
5600 Fishers Lane
Rockville, MD 20857

REPLY: Columbus, OH

Dear Mr. Cannon:

Transmitted herein please find a copy of correspondence I received from a constituent of mine, [redacted] regarding the release of RU 486.

I indicated to [redacted] I would write the FDA requesting some insight in this regard. A response I can share with my constituent would be appreciated.

Thank you for your consideration.

Very truly yours,

CHALMERS P. WYLIE
Representative to Congress

CPW:g

Enclosure

APPEARS THIS WAY
ON ORIGINAL

#4786

MIF 005785

R.F. [redacted] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 12 1991

The Honorable Bob Graham
United States Senator
Post Office Box 3050
Tallahassee, Florida 32315

Dear Senator Graham:

This is in response to your letter of April 29, 1991, on behalf of [redacted] concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug, and Cosmetic Act (FDC), 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 a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

/S/

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	4/10/91						

/S/ 4/24

FILE COPY

MIF 005786

*U.S.GPO:1988-0-213-062

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

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For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

We hope the information provided will be 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
New Drug Development in
the United States
FDA Testimony
cc: HFW-10(2)
F/D: [redacted] 5/26/91
F/T; var:6/7/91
CONG-4036 and No. 4696
[redacted] \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

A.F. 42-212

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 2 1991

The Honorable Tom Campbell
Member, United States
House of Representatives
599 North Mathilda Avenue, Suite 105
Sunnyvale, California 94086

Dear Mr. Campbell:

This is in response to your letter of February 4, 1991, concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FC12	/S/	4/2/91						

/S/ 4/2/91
(S)

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*U.S.GPO:1990-0-213-062

MIF 005789

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APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be 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
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ——— :3/11/91
F/T; var:3/12/91
CONG-3477 and No. 4040
——— \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

TOM CAMPBELL
12TH DISTRICT, CALIFORNIA

516 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5411

DISTRICT OFFICES:
599 NORTH MATHILDA AVENUE, SUITE 105
SUNNYVALE, CA 94086
(408) 245-4835
(415) 321-9154

1 CIVIC CENTER DRIVE
SCOTTS VALLEY, CA 95066
(408) 438-7985

7415 EIGLEBERRY STREET, SUITE D
GILROY, CA 95020
(408) 848-5101

Congress of the United States
House of Representatives

COMMITTEE ON THE JUDICIARY

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

CO-CHAIRMAN, TASK FORCE ON TECHNOLOGY AND POLICY

CO-CHAIRMAN, TASK FORCE ON TOXICS

HOUSE COMPETITIVENESS CAUCUS

ENVIRONMENTAL AND ENERGY STUDY CONFERENCE

CONGRESSIONAL HUMAN RIGHTS CAUCUS

ARMS CONTROL AND FOREIGN POLICY CAUCUS

CONGRESSIONAL CAUCUS FOR WOMENS' ISSUES

February 4, 1991

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

Dear Commissioner Benson:

I understand the Food and Drug Administration has banned research of RU486 which may have an affect on breast cancer. I know the FDA is most sensitive to this disease, but according to a breast cancer organization in my district RU486 is a potential cure based on the information they have.

Could you kindly provide me with the reason why the Agency has prohibited research of this drug in the United States and also forward me any background information? I would be grateful if you would direct your reply to my Sunnyvale District Office, attention Ramona Zacharkevics.

Thank you for your willingness to address my question.

Best regards,

Tom Campbell
Congressman Tom Campbell

TC:rz

APPEARS THIS WAY
ON ORIGINAL

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 2 1991

The Honorable Bob Dole
United States Senate
Washington, D.C. 20510

Dear Senator Dole:

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

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushings syndrome, and other types of cancer.

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

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

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

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-26	/S/	4/2/91						

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*U.S.GPO:1988-0-213-062

MIF 005793

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, the publicity in this country regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted]:3/25/91
F/T; var:4/1/91
CONG-3586 and No. 4168
[redacted]\DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

001038

February 18, 1991

The Honorable Robert Dole

Room SH-141
Hart Senate Office Building
Washington DC 20510

Dear Mr. Dole:

I am a victim of breast cane, our daughters will be doubly vulnerable because of paternal grandmother.

Can you tell me what actions need to be taken to reverse the order of the Reagon administration to ban RU-486? I am more interested in the drug for treatment, but since abortion is legal, why do we continue to ban?

Thanks for your response.

151

United States Senate

Respectfully referred to:

Hugh C. Cannon
Associate Commissioner for Leg. Affairs
Food And Drug Administration
U.S. Department of Health and Human Services
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

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

BOB DOLE

RESPOND TO: **U.S.S.**
David Wilson
Senator Bob Dole
141 Hart Senate Building
Washington, D.C. 20510

Form #2

GPO : 1981 O - 76-237

APPEARS THIS WAY
ON ORIGINAL

F 4116

MIF 005797

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 2 1991

A.F. _____ FILE

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

Dear Senator Adams:

This is in response to your letter of February 11, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug, and Cosmetic Act (FDC), 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 a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

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*U.S.GPO:1988-0-213-062

MIF 005798

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

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For your information, we are also enclosing a copy of testimony presented at a hearing before the Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted] 3/11/91
F/T; var:3/12/91
CONG-3409 and No. 3963
[redacted] \DRUGS\RU486.MDG)

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