FDA just approved mifepristone, also known as RU486, for the termination of early pregnancy.

Sorry for late notice

All press inquiries to go to central press office

Mifepristone

- approved to terminate preg up to day 49
- part of a combination regimen w misoprostol Day 1 & Day 3 followed by 14 day checkup
- all drugs to be administered in physician's office

- Regimen 92% effective in complete medical termination
  - 8% require further surg intervention mainly incomplete ab termination
  - 1% ongoing preg
  - 1.2% heavy bleeding

- Major side effects -
  - Bleeding - sometimes heavy rarely transfusion 1/8000
  - Incomplete procedure
  - Discomfort - nausea cramps HA etc.

~~Ele~~ Risk management for the product

- Product has black box warning of the possible need for surgical intervention

- Product approved under Subpart H regulations - establish controls on distribution
  - Distribution will be restricted to physicians who meet specific qualifications
    - Ability to date preg
    - Ability to dx ectopic preg
    - Ability to provide surg intervention for complications, or has made plans
    - Read & understand RX info
    - Agrees to give each pt a Medication Guide, fully explain the info, provide pt counseling, allow pt to sign, & sign as well
    - Notify sponsor in writing of on-going preg not terminated
    - Report serious event to sponsor

- Physical controls on distribution

- Physical packaging in unit of use during

Patient level
Medication Guide
Patient agreement

Phase 4 study commitments to ~~assess~~ assess additional question

Ongoing pregnancies
Some preg will not undergo rx termination
Outcome data on human preg. included in label

Contraindications
- ~~A Pos~~ tubal preg
- IUD in place
- adrenocortical insuff. or prolonged steroid use
- blood dyscrasias or anticoagulation

More complete info will be placed on FDA web site today, including the scientific review of the product

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date October 18, 2000

From Nashville Branch
New Orleans District
Compliance (HFR-SE340)

Subj. FOI Requests - RU 486

To CDER/OTCOM/DFOI
Attn: [redacted] (HFD-205)

The attached copies of 3 sheets of handwritten notes prepared by our Public Affairs Specialist [redacted] on 9/28/00 in anticipation of telephoned inquiries that never materialized are the only possibly responsive records on this subject I was able to locate in the Nashville Branch files. We have had no complaints or inquiries about the drug.

The attached record requires no redacti.

/S/

[redacted]
Compliance Officer

[redacted]

Attachment

Cc: [redacted] w/Copy Attachment

9/28/00

Mifepristone 1a doc

Up to day 49
First day of last period
Prostaglandin analog

92% Effective
8% — will require further surgical intervention — possibly D&C

Side Effects — Bleeding
Heavy Bleeding lead to bleeding
Major discomfort

Risk Mgmt —
Approved w/ Black Box Warning

Subpart H —
Restricted distribution —
MD must be a physician — NO pharmacy
> Ability to date pregnancy - must be USI
> " " diagnose topic
> " perform or manage surgical intervention —
> Have read understood - sign agreement to notify distributor of ongoing
> Agree to report serious events to ~~physician~~ sponsor —

Specific inventory controls are in place

Pkg'd Unit of Dose Only

Patient - Medicine Guide
Must sign

Scientific reviews of the product

We evaluated this product on _____
on a scientific basis on its
effectiveness on this yyy—

Sponsor has told us it will be available
w/i a month

Label will be on the web

Popular Control

Panko

Name of manufacturer or locations on responsibility

1% of pregnancies will not end
these carried to full term had no birth
defects (28)
10 had additional surgery (1 w/ defect?)

How to find physicians
FDA does not and will not maintain list
These persons

Phone # of Sponsor —
DANCO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date October 16, 2000

From [redacted] HFR-P140/FOI

Subject Request for Records on RU-486

To [redacted] /CDER/HFD-205

Per your request for records/information regarding RU-486, enclosed are dairy notes which were obtained by [redacted] CSO, SAN-DO on 9/25/89.

The following charges apply:

[redacted] GS-13, 1 hour @ $29.00

[redacted] GS-8, 1/2 hour @ $7.00

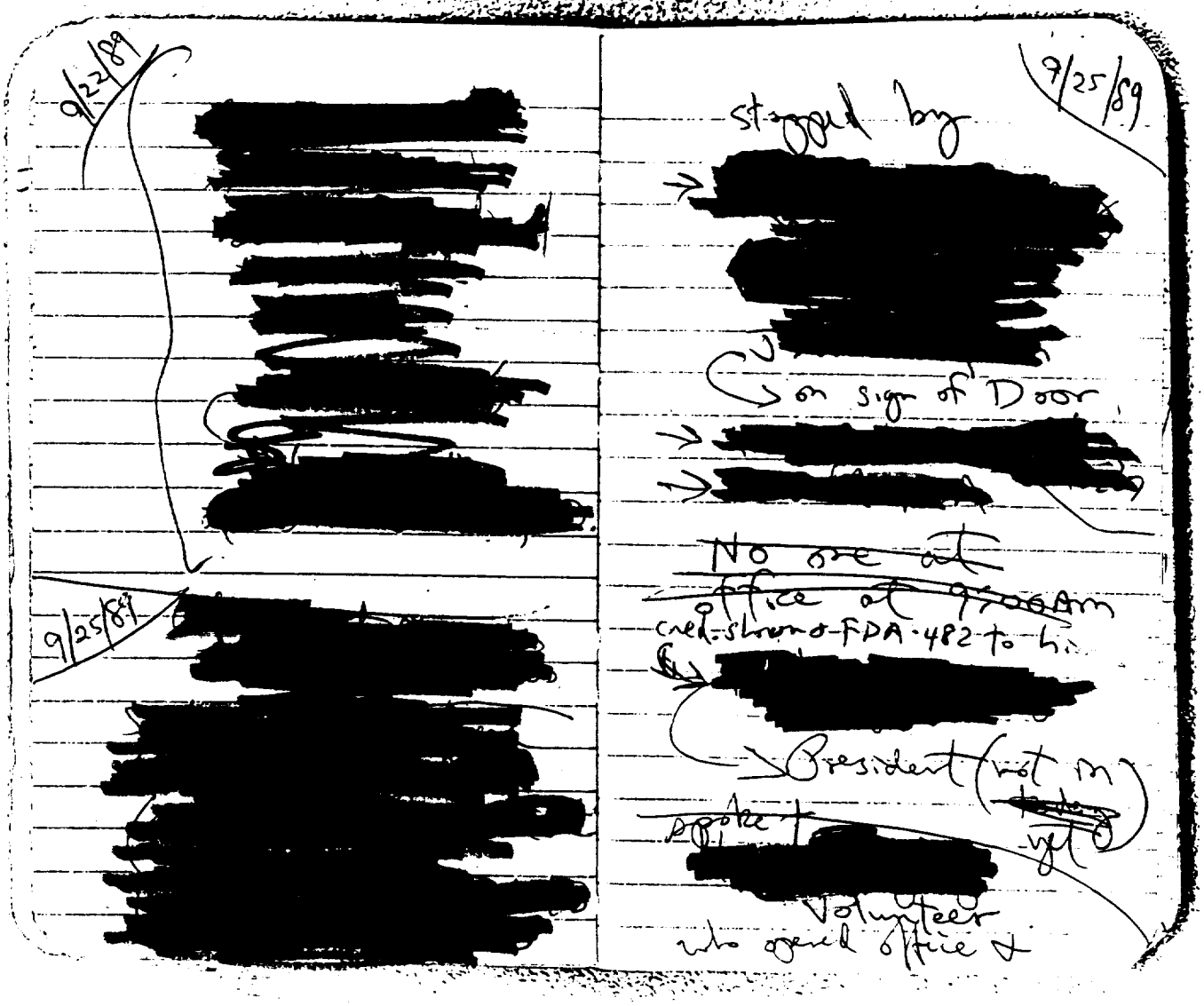
Total: $36.00

If you have any questions, please call me at [redacted]

Sincerely,

/S/

Freedome of Information Tech



APPEARS THIS WAY
ON ORIGINAL

9/25/89

Immediately placed
[redacted] at
his home, who
said he would
be right down
re distribution of
drugs taking
place on [redacted]
[redacted].

organization is
strictly educational,
lobbying, sponsor
of bills =>
often frequently
corresponds with
FDA on issue
of interest to their
members & consumers

9/25/89

the correspondence
on the French
abortifacient drug
RU486
was simply an
attempt [redacted] act
as a go between
[redacted] said they
will not defy the
FDA's decision, but
question the proced
importation of drug
policy.
He gave me copies
of correspondence
with FDA

APPEARS THIS WAY
ON ORIGINAL

10/5/00

Please copy all documents, notes, e-mails ~~etc.~~ in my personal file for INS — except journal articles (unless I have written notes on one journal article, in which case a copy needs to be made).

Thanks,

/S/

.....
(Original Signature of Member)

106TH CONGRESS
2D SESSION

H.R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. COBURN introduced the following bill; which was referred to the Committee on _____

A BILL

To require the Food and Drug Administration to establish restrictions regarding the qualifications of physicians to prescribe the abortion drug commonly known as RU-486.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

October 3, 2000

SECTION 1. SHORT TITLE.

This Act may be cited as the "RU-486 Patient Health and Safety Protection Act".

SEC. 2. ESTABLISHMENT OF RESTRICTIONS REGARDING PRESCRIBING OF CERTAIN ABORTION DRUG.

With respect to the application that was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the drug mifepristone (commonly referred to as RU-486, to be marketed as MIFEPREX), and that was approved on September 28, 2000, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promptly modify the conditions of the approval of such drug to establish the additional restriction that the drug may not be prescribed by any person other than a licensed physician who meets the following requirements:

(1) The physician is qualified to handle complications resulting from an incomplete abortion or ectopic pregnancy.

(2) The physician has been trained to perform surgical abortions and has met all applicable legal requirements to perform such abortions.

(3) The physician is certified for ultrasound dating of pregnancy and detecting ectopic pregnancy.

(4) The physician has completed a program regarding the prescribing of such drug that uses a curriculum approved by the Secretary.

(5) The physician has admitting privileges at a hospital to which the physician can travel in one hour or less, determined on the basis of starting at the principal medical office of the physician and traveling to the hospital, using the transportation means normally used by the physician to travel to the hospital, and under the average conditions of travel for the physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

DAVID A. KESSLER, M.D.

COMMISSIONER

OF

FOOD AND DRUGS

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES,

AND TECHNOLOGY

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

MAY 16, 1994

TO BE RELEASED ONLY UPON DELIVERY

Mr. Chairman, the Food and Drug Administration (FDA) has encouraged the submission of a new drug application (NDA) for mifepristone, commonly called RU-486, for interruption of early pregnancy so that we can determine whether it is safe and effective for that indication. If there is a safe and effective medical alternative to any surgical procedure, American women should have access to that drug regimen. We cannot form, however, any definitive conclusions about the drug's safety and effectiveness, or approve it for marketing in the United States, without first reviewing the studies and other data that would be submitted in a new drug application.

On January 22, 1993, President Clinton executed a memorandum to the Secretary of Health and Human Services directing her to assess initiatives to promote the testing and licensing in the United States of RU-486. In response, FDA's efforts have been focused on encouraging and facilitating the submission of an NDA.

Immediately after the President issued the memorandum, I wrote to Dr. Edouard Sakiz, President of Roussel Uclaf, and requested a meeting to discuss the possible therapeutic uses of anti-progestational drugs and, in particular, FDA's interest in receiving an NDA for RU-486 for interruption of early

pregnancy. Both the Secretary and I also let Hoechst AG, Roussel Uclaf's parent corporation, know of our interest.

On February 24, 1993, senior representatives of FDA and Roussel Uclaf met to discuss the clinical and manufacturing data on the drug that FDA would need to review as part of an NDA for an abortifacient indication. At that meeting, FDA received a strong commitment from Dr. Sakiz that he would find a way to bring RU-486 to the U.S. market. Dr. Sakiz stated that Roussel Uclaf would not be directly involved, but instead would work through a third party in the United States. Dr. Sakiz also committed to making the drug available for research on other potential uses. FDA and Roussel Uclaf agreed to continue to work on this matter until remaining issues could be resolved.

At an April 20, 1993 meeting at the FDA, Roussel Uclaf indicated its willingness to modify its 1982 contract with the Population Council, a non-profit scientific and technical organization. These modifications would permit the Population Council and its sublicensees to produce, test, and distribute RU-486 in the United States. The Population Council agreed to work to identify a manufacturer for RU-486 for the United States market and to begin a clinical trial to test the drug in the United States.

At that point, we thought that clinical trials on RU-486 would begin soon in the United States. This proved not to be the case. Before the Population Council would begin clinical trials, the Population Council and Roussel Uclaf undertook complex negotiations pertaining to the transfer of the RU-486 patents and the basis for distribution of the drug in the United States. After a year of these negotiations, on April 14, 1994, the Secretary and senior Department officials met with the heads of Roussel Uclaf and the Population Council.

At that meeting, the parties indicated their willingness to continue their negotiations, and the Secretary made it clear to the negotiating parties that agreement on all outstanding issues should be reached no later than by May 15, 1994.

We are pleased that Roussel Uclaf and the Population Council have concluded their negotiations, and that Roussel Uclaf has donated the patents on RU-486 without remuneration. We anticipate that the Population Council will now pursue the clinical testing of RU-486 in the United States. We will work with the Population Council to make certain that their clinical trials are well-designed and carefully conducted, in order to provide useful information on how the drug might be properly used in this country. We also understand that the Population Council will file a new drug application for RU-486. We will

review it carefully under the appropriate medical and scientific criteria.

It should be recognized that the termination of a pregnancy is not a simple procedure, whether it is done surgically or through a medical regimen. Women should not think that pregnancy termination using a medical regimen will be simple. It will not be. In Europe, where RU-486 has been used in over 150,000 women, the procedure requires several visits to a medical facility, a precise dosing scheme using two different drugs, and close monitoring to care for women who may experience excessive bleeding or other complications. We anticipate that any use of RU-486 in the United States would have to follow the same type of strict distribution and use conditions.

Date

AND TRANSMITTAL SLIP 7/16/92

...ice symbol, room number, ... Agency/Post)	Initials	Date
.. Kessler		

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Comment		Investigate		Signature	
Coordination		Justify			

.EMARKS

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MIF 000020

No. A-40

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1992

LEONA BENTEN, ET AL., APPLICANTS,

v.

DAVID KESSLER, COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION, ET AL.

ON APPLICATION TO VACATE THE STAY PENDING APPEAL ENTERED BY THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MEMORANDUM FOR THE RESPONDENTS IN OPPOSITION

Applicants request this Court immediately to countermand the respondents' detention of certain drugs applicants sought to bring into the United States from abroad. The drug at issue in this case, RU-486, has not been approved for use in the United States. Indeed, the manufacturer of the drug has not even sought FDA approval. The statute provides that all unapproved drugs shall be refused admission into the United States. 21 U.S.C. 381(a)(3). There is accordingly no basis for applicants' claim that the FDA must be required to permit them to bring this unapproved drug into the United States.

1. a. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 301 et seq., prohibits the importation of drugs that have not been approved through the comprehensive procedures mandated by the statute. 21 U.S.C. 355(a), 381(a)(3). The United States Food and Drug Administration (FDA) is charged with administering the FDCA. Under the FDCA, any unapproved drugs "shall be refused admission" into the United States. 21 U.S.C. 381(a)(3); see also 21 U.S.C. 334 (unapproved drugs "shall be liable to be proceeded against" through seizures).

For many years, the FDA has exercised its enforcement discretion by not challenging importation of certain unapproved drugs by individuals for personal use. Thus, for example, primarily as a matter of resource allocation, the FDA has not restrained importation of certain innocuous drugs acquired abroad for treatment of non-serious conditions.[1] In addition, primarily as a matter of humanitarian concern, the agency has allowed individuals to import certain drugs of unproven efficacy for serious conditions for which no effective treatment exists.[2]

b. On June 29, 1992, applicants Leona Benten and Lawrence Leder travelled to London to obtain a 600 mg. dose of RU-486, an abortifacient drug that has not been approved for importation into

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[1] The FDA advises us, for example, that it does not ordinarily exercise its enforcement power to block the importation for personal use of unapproved headache remedies purchased over the counter abroad. Other examples include anti-itch and anti-wrinkle creams.

[2] For example, the FDA has permitted importation of certain AIDS-related and cancer treatment drugs.

the United States pursuant to the requirements of the FDCA.[3] In advance of their reentry into the United States, Mr. Lader notified the FDA that applicants would be carrying the RU-486 with them. The FDA had previously determined, however, that it would not exercise its discretion to forego enforcement of the statutory bar to importation of RU-486, and had issued bulletins to that effect to agency personnel in September 1988 and again in June 1989. See Application to Vacate Stay, App. A. Accordingly, upon applicants'' arrival at Kennedy Airport on July 1, the illegally imported RU-486 was detained by the United States Customs Service.

2. On July 7, 1992, applicants brought suit in the United States District Court for the Eastern District of New York, alleging that the FDA's decision to enforce the FDCA's ban on importation of RU-486 violated the Administrative Procedure Act (APA), 5 U.S.C. §§ 706(2)(A) and 553, 21 C.F.R. 10.70, and the United States Constitution. See Application, attachment 4. On July 14, 1992, the district court issued a preliminary injunction requiring the FDA to allow Ms. Benten to import the RU-486 into the United States. See Application, attachment 3.

The district court held that Ms. Benten would be irreparably

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[3] Under the FDCA, drug manufacturers bear the responsibility for demonstrating the safety and efficacy of new drugs and for submitting new drug applications to the FDA for approval. See 21 U.S.C. 355(b)(1), (c)(1), (d). No approved new drug application is in effect for RU-486, and applicants do not allege that such an application has been made and denied. Nor do applicants assert that they sought or obtained approval to import RU-486 pursuant to 21 U.S.C. 355(i), which permits importation of unapproved drugs, including RU-486, for use in scientific studies. Thus, importation of RU-486 into the United States is forbidden by the express terms of the FDCA.

injured absent injunctive relief because she would have to have an abortion, "an invasive surgical procedure which she has experienced before and does not want to go through again." Application, attachment 3, at 14.[4] The court rejected respondents' arguments that Ms. Benten could not demonstrate irreparable injury because other alternative means for terminating the pregnancy were available to her. Id. at 15.

The district court also concluded that applicants had shown the requisite likelihood of success on the merits. The court held that the FDA's discretionary enforcement policy permitting importation of some unapproved drugs was a substantive rule that gave applicants a right to individualized consideration of their attempt to import RU-486, and that the FDA's import bulletins expressing the agency's decision to enforce the provisions of the FDCA with respect to RU-486 were invalid because the bulletins had not been promulgated pursuant to the APA's notice-and-comment procedures, 5 U.S.C. 553. Id. at 16-20. In the alternative, the court ruled that the FDA had failed to articulate a sufficiently reasoned basis for its decision to enforce the FDCA by forbidding importation of RU-486, and that the FDA's decision was therefore arbitrary and capricious in violation of the APA, 5 U.S.C. 706(2)(A). Id. at 20-21.

The district court refused to grant a temporary stay pending appeal. Application, attachment 2. The government sought a

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[4] Ms. Benten, who is seven-and-a-half weeks pregnant, alleges that she must use the drug by July 18, 1992.

temporary stay pending appeal from the United States Court of Appeals for the Second Circuit. On July 14, 1992, the court of appeals granted a temporary stay pending its consideration of the government's motion for a stay pending appeal. Application, attachment 1. On July 15, the court of appeals granted the government's motion and issued a stay pending appeal. See App., infra, 1a.

3. It is well established that "a Circuit Justice should not disturb, 'except upon the weightiest considerations, interim determinations of the Court of Appeals in matters pending before it.'" New York v. Kleppe, 429 U.S. 1307, 1310 (1976) (Marshall, J., in chambers) (quoting O'Rourke v. Levine, 80 S. Ct. 623, 624 (1960) (Harlan, J., in chambers)). Because applicants' legal claim is without merit, and because the balance of equities weighs against entry of the requested relief, the application to vacate the stay entered by the Second Circuit should be denied.

a. Applicants contend (Application at 7-9) that the FDA's issuance of import bulletins informing agency personnel of its decision not to permit importation of RU-486 -- the so-called "import ban" -- was invalid because the import bulletins were not promulgated pursuant to the notice-and-comment rulemaking requirements of the APA. As a result, applicants contend, they must be permitted to import RU-486 into the United States despite the clear statutory bar against such conduct. Applicants cannot demonstrate any likelihood of success on their claim.

The most obvious flaw in applicants' argument is that they

would not be entitled to any relief even if the FDA's "import ban" bulletins were deemed wholly invalid for failure to satisfy APA notice-and-comment requirements.[5] Those bulletins merely restated the unambiguous command of the FDCA, which forbids importation of unapproved drugs such as RU-486; invalidation of the bulletins would not remove the statutory bar to the relief applicants seek. Rather, applicants could prevail only if they could establish a legal entitlement to escape enforcement of the express command of the FDCA.

In an attempt to establish such entitlement, applicants rely on the FDA's longstanding policy of permitting importation of certain drugs for personal use in some circumstances. See Application at 3-4.[6] As even a cursory reading of the FDA's

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[5] Moreover, applicants are incorrect in asserting that those bulletins were subject to the notice-and-comment requirement. The bulletins merely expressed the FDA's internal policy decision to enforce the express requirements of the FDCA with respect to RU-486, and did not impose burdens or requirements beyond those created by the plain language of the FDCA. The "import ban" of which applicants complain derives from the statute itself, not from any bulletin issued by the FDA. As general statements of enforcement policy, the bulletins were exempt from the notice and comment requirements of the APA and the FDA's regulations governing rulemaking. See 5 U.S.C. 553(b)(A); 21 C.F.R. 10.40(d).

[6] The district court ruled that the FDA's internal guidance was invalid for failure to comply with the procedural requirements of the APA. Application, attachment 3, at 18-19. If that ruling were correct, and the internal guidance were invalid, then applicants would be deprived even of their argument that the internal guidance somehow entitles them to import RU-486 despite the unambiguous statutory command to the contrary. While applicants do not expressly defend this aspect of the district court's ruling in their papers in this court, the district court's ruling on this issue is nonetheless of considerable significance, because it demonstrates quite clearly that acceptance of applicants' sweeping interpretation of the APA's procedural requirements leads inevitably to the conclusion that the very

internal policy manual indicates, however, that policy creates no entitlement on the part of any individual to import any particular unapproved drug in contravention of the statutory ban. The relevant internal policy guidance provides:

> Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the products before making a final decision. Although FDA may use its enforcement discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

FDA Regulatory Procedures Manual ("RPM") 9-71-30 (12/11/89) (emphasis added), reproduced at Application, App. B.

The internal guidance then notes two situations in which, "in deciding whether to exercise discretion[,] * * * FDA personnel should consider a more permissive policy * * *." RPM 9-71-30(C). The first circumstance is for non-serious conditions where "the product is not known to represent a significant health risk." Ibid. The second is for serious conditions for which no effective treatment is available, and where the product does not present "an unreasonable risk." Ibid.

The provisions of the internal guidance at issue here obviously provide no basis for applicants' assertion that they possess a judicially enforceable right to evade the clear mandate of the FDCA. The internal guidance is written entirely in terms of discretion, advising FDA personnel to "use their discretion" to

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policy of discretionary waivers on which they rely must be deemed invalid.

"consider" a "more permissive policy" under extremely general criteria that do not purport to be exclusive. Thus, the internal guidance reflects merely the general areas in which the FDA has decided that it may consider relaxed enforcement of the statutory mandate. Even if a particular drug qualified under each and every criterion set forth in the Manual, the agency would in no sense have surrendered its authority to preclude importation in accordance with the statute. The internal guidance itself makes that clear by its own terms. RPM 9-71-30 (exercise of discretion "should not be interpreted as a license to individuals to bring in such shipments").

Far from conferring vested rights on applicants, the internal guidance cited by applicants merely serves as a non-binding expression of agency enforcement policy in an area that this Court has already held is "committed to agency discretion by law," 5 U.S.C. 701(a)(2), and is therefore not subject to judicial review under the APA. As this Court made clear in Heckler v. Chaney, 470 U.S. 821 (1985), "the [FDCA's] enforcement provisions * * * commit complete discretion to the Secretary to decide how and when they should be exercised."[7] This Court held in Chaney that there can

[7] Chaney, like this case, involved a challenge to the FDA's enforcement of the FDCA. In Chaney, prison inmates alleged that drugs used for capital punishment violated the FDCA because they were unapproved for that purpose, and therefore misbranded under 21 U.S.C. 352, and that the drugs violated 21 U.S.C. 355 because they had not been shown to be "safe and effective." 470 U.S. at 824. The plaintiffs requested the FDA to take enforcement action against these drugs, and the FDA refused. The Supreme Court held that this decision by the FDA was committed to the FDA's discretion, despite the requirement of the FDCA that "any person who violates the Act's substantive prohibitions 'shall be imprisoned ... or fined.'" Id.

be no judicial review of such agency action because "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." The Court declared that "if no judicially manageable standards are available for judging how and when an agency should exercise its discretion, then it is impossible to evaluate agency action for 'abuse of discretion.'" Id. at 830. See also Webster v. Doe, 486 U.S. 592, 600 (1988); Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410 (1971).

Here, the clearly discretionary language of the internal guidance cannot alter the result reached in Chaney. This Court in fact refused to read an FDA policy statement at issue in Chaney "to circumscribe agency enforcement discretion." 470 U.S. at 836. As in Chaney, the internal policy guidance relied upon by applicants simply creates no binding legal requirement for the courts to enforce.[8]

This case is a particularly appropriate one for judicial deference to the exercise of agency discretion, because applicants essentially seek to reverse the FDA's decision to enforce the express requirements of the FDCA. When a plaintiff challenges an

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at 835 (citation omitted).

[8] Indeed, since the internal guidance is found in the FDA's internal policy manual rather than in any regulation, even a provision phrased in mandatory terms would almost certainly not create any judicially enforceable rights. See Schweiker v. Hansen, 450 U.S. 785, 789 (1981). At the very least, such an agency policy manual could never be used to enjoin an agency from enforcing the unambiguous commands of a statute; yet that is precisely the relief applicants seek in this case.

agency's implementation of its enforcement discretion, "the presumption is that judicial review is not available." Heckler v. Chaney, 470 U.S. at 831. Applicants offer no basis on which to overcome that presumption, which is reinforced by the non-binding language of the internal guidance on which applicants rely. In short, the FDA's "enforcement actions [a]re committed to the complete discretion of the FDA to decide when and how they should be pursued." Webster v. Doe, 486 U.S. at 600.

If anything, the FDA's enforcement decision in this case falls even more clearly within its unreviewable discretion than did the decision at issue in Chaney. In Chaney, the plaintiffs were at least able to allege that the agency was failing to enforce the requirements of the statute. Here, by contrast, the statute clearly prohibits the importation of RU-486, and the agency is merely attempting to enforce that prohibition. Applicants seek judicial review, not to force the FDA to comply with the provisions of the FDCA, but rather to evade the express terms of that statute in reliance on a strained interpretation of an internal agency policy manual. Applicants' attempt to make this end-run around the requirements of the FDCA cannot be permitted to succeed.

For all the foregoing reasons, the FDA's decision to enforce the indisputable terms of a concededly valid statute against an unmistakably clear statutory violation is not the proper subject of judicial review. This result is not affected by the fact that the FDA notified its personnel that the statute should be enforced when it issued its 1988 and 1989 import bulletins concerning RU-486.

discretion. The bulletins themselves are not an "import ban." Unapproved drugs are banned by statute; an import bulletin merely effectuates the statutory command.

Finally, even if the FDA's decision to enforce the statutory ban against importation of RU-486 were properly subject to judicial review, applicants' claim would still fail. Assuming, as applicants' allegations seem to recognize (see Application, attachment 4, at 4 ¶ 5), that pregnancy is properly characterized as a "serious" condition, FDA personnel would have discretion under the internal guidance to permit importation of the drug only if "effective treatment may not be available domestically." RPM 9-71-30(C). No such finding could possibly be made with respect to RU-486, given the alternative options available in the United States. If, on the other hand, pregnancy could be characterized as a non-serious condition, the internal guidance would nonetheless suggest that importation should not be approved, because the agency has not concluded that RU-486 poses no "significant health risk." Ibid. Moreover, the agency's interpretation of the application of its own policy to RU-486 would be entitled to substantial deference. See, e.g., Lyng v. Payne, 476 U.S. 926, 939 (1986) (court could not run "roughshod" over an agency's understanding of its own directive). Accordingly, the district court's holding that the FDA's action in this case was arbitrary and capricious cannot withstand scrutiny.

b. Applicants have also failed to demonstrate that the balance of equities support the entry of an order forbidding enforcement of the statute. See Holtzman v. Schlesinger, 414 U.S.

1304, 1308-1309 (1973). Ms. Benten states that she would prefer a drug-induced abortion to a surgical abortion, but does not allege that a surgical abortion would be ineffective or unusually unsafe in her case. She also states that she would prefer to take the drug in the comfort of her own home, but does not allege that she could not have taken the drug abroad.[9]

Against this asserted harm, the Court must weigh the impact of precluding the FDA from enforcing the health and safety statute enacted by Congress. The governing statute requires that drugs may not be imported unless they are approved by the FDA through established procedures. Persons seeking unapproved treatments for a variety of illnesses and conditions may question the wisdom of that legislative judgment. But that is the congressional determination, and the courts have repeatedly recognized the importance of the overriding goal of the statute. See, e.g., United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 784 (1969); United States v. Dotterweich, 320 U.S. 277 (1943). See generally Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950) (denying injunction against FDA seizure actions although enforcement actions could cause "irreparable damage to a business").

The government and the public interest are irreparably harmed when the judiciary mandates contravention of fundamental safety

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[9] Ms. Benten now claims (Application at 6 n.2), without substantiation, that British law would have precluded her from taking the drug in Britain. Even assuming she is correct, she has never claimed that she was unable to travel to any country where she could have both obtained and taken the drug.

laws. Indeed, even when health and safety concerns are not directly at issue, it is well-established that interference with governmental regulatory and enforcement schemes is a serious and irreparable injury. See New Motor Vehicle Bd. v. Orrin W. Fox Co., 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers) ("any time [the government] is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury"); Coleman v. Paccar Inc., 424 U.S. 1301, 1307-08 (1976) (Rehnquist, J., in chambers). In sum, the district court erred in setting aside the plain dictate of the FDCA and the agency's enforcement action and arrogating to itself the role of supervisor of the public's health and safety, and the court of appeals properly stayed enforcement of the district court's decision pending appeal.

It is therefore respectfully submitted that the application for a stay should be denied.

KENNETH W. STARR
Solicitor General

JULY 1992

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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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.

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.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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LEONA BENTEN, Plaintiff, v. DAVID KESSLER, et al., Defendants.	Civil No. 92-3161 **MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

INTRODUCTION

As outlined in defendants' brief in support of their motion to dismiss, plaintiff has requested this Court to enter a judgment that would prevent the United States Food and Drug Administration (FDA) from enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") and to order the FDA and the Customs Service to allow an unapproved drug to be illegally imported into the United States.

In examining plaintiff's attempt, it is important to note that there is no "import ban" on the importation of RU486 (mifepristone), as plaintiff has characterized the import alert.

RU486 is permitted into the country when imported as part of Investigational New Drug (IND) studies, and it is being imported at the present time for studies for abortifacient and non-abortifacient uses. FDA has in no way interfered with the importation of RU486 when used as part of a careful, controlled study pursuant to an IND, and has publicly indicated support for such studies. Such INDs are part of the comprehensive, thorough, and detailed statutory process that Congress has required to be utilized in order for a drug to be legally marketed in this country. The culmination of this process is the submission of a New Drug Application (NDA) by the party seeking to manufacture or distribute a drug, and the FDA's analysis of this application. A drug can only be approved under this process if FDA concludes that it is "safe and effective" for its intended use after review of the voluminous NDA.

It is undisputed that RU486 has not gone through this process, and is not approved for use in this country outside of IND trials. Although FDA has done nothing to hamper the drug approval process, plaintiff seeks to evade this process altogether by having this Court conclude that RU486 is safe and effective for use as an abortifacient, and should be permitted into the country without restriction for that use. In other words, plaintiff wants this Court to take over the functions of the FDA. As discussed below, the scientifically-based drugapproval process is intricate and thorough and requires a significant amount of scientific knowledge and expertise, which is one of the main reasons that Congress has entrusted the task to FDA.

Congress has also entrusted FDA with the authority and discretion to prevent the importation of drugs that are not approved in this country. It is undisputed that RU486 is not approved; thus, FDA has authority and discretion to preclude the importation of this drug. The agency does not need to engage in rule-making procedures to enforce the law. As defendants demonstrated in their motion to dismiss, this case should be dismissed as moot because it is unlikely that plaintiff will again attempt to bring this drug into the country. The case should also be dismissed because the challenged action is committed to agency discretion and because plaintiff has failed to exhaust her administrative remedies.

However, if the case is not dismissed for those reasons, judgment should be granted in favor of the defendants because the challenged import alert is not a rule for which notice and comment were necessary, because the import alert is reasonable and not arbitrary or capricious, and because it does not violate the Constitution. These issues are discussed in further detail below. Also, this case is now moot for a second reason notdiscussed in the defendants' motion to dismiss, and that reason is discussed below.

ARGUMENT

As defendants discussed in their initial memorandum, it is well-established that "federal courts are without power to decide questions that cannot affect the rights of litigants in the case before them." North Carolina v. Rice, 404 U.S. 244, 246 (1971). "To invoke the jurisdiction of a federal court, a litigant must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." Lewis v. Continental Bank Corp., 494 U.S. 472, 477 (1990).

The "case-or-controversy requirement subsists through all stages of federal judicial proceedings, trial and appellate." Id. at 477. See also New York City Employees' Retirement System v. Dole Food Co., 969 F.2d 1430 (2d Cir. 1992); Deeper Life Christian Fellowship, Inc. v. Sobol, 948 F.2d 79, 81 (2d Cir. 1991); Christopher P. v. Marcus, 915 F.2d 794, 802 (2d Cir. 1990), cert. denied 498 U.S. 1123 (1991).

Even though some cases are not moot because the issues are "capable of repetition, yet evading review," this doctrine is applicable only in "exceptional situations." See Lewis, supra, 494 U.S. at 481; Deeper Life, supra, 948 F.2d at 82. The SupremeCourt has stated that, in order to meet this limited exception, the challenged action must be too short in duration to be fully litigated prior to its cessation, and there must be a "reasonable expectation" or "demonstrated probability" that the same controversy will recur involving the same parties. Murphy v. Hunt, 455 U.S. 478, 482 (1982). A "mere physical or theoretical possibility" of repetition is insufficient. Id. See also Lewis, supra, 494 U.S. at 481; Weinstein v.Bradford, 423 U.S. 147, 149 (1975); Deeper life, supra, 948 F.2d at 82; Direct Marketing Association v. U.S. Postal Service, 721 F.2d 55, 58-59 (2d Cir. 1983) ("unusual circumstances" make case "not likely to recur."); Trane Co. v. O'Connor Securities, 718 F.2d 26, 27 (2d Cir. 1983) (while recurrence was "abstractly ... conceivable," it was not likely).

Although this Court has stated that the fact that plaintiff Benten has terminated her pregnancy does not moot this case, Memorandum and Order on Motion to Intervene at 3, Sept. 30, 1992, additional factors render plaintiff's complaint moot and not capable of repetition. As discussed in defendants' memorandum in support of their motion to dismiss, it is not likely that plaintiff will be able to attempt to bring RU486 into the country again to challenge FDA's import alert, and the case is moot for that reason.

An additional reason that this case is now moot is that RU486 is presently available in this country for investigational use as an abortifacient, and there is nothing to suggest thatplaintiff could not now obtain this drug legally in the United States for that purpose. As shown in Attachment A hereto, the Population Council has stated that it is presently clinical trials of RU486 at various clinics around the country. As that

News Release makes clear, the manufacturer of RU486, Roussel Uclaf, donated the U.S. rights to the drug to the Population Council, without renumeration. Attachment A at 2. The Population Council plans to submit a New Drug Application to the FDA and hopes to gain FDA approval by 1996. Id. at 2, 6. In an earlier News Release, the Population Council noted that these clinical trials required that it amend its current IND. Attachment B.

This drug would be available to plaintiff as a participant in the clinical trial under the IND. The record reflects that plaintiff has associations with people connected to the ongoing clinical trial. One of plaintiff's declarants for her 1992 complaint, Dr. Wayne C. Bardin, is Vice President of the Population Council and, apparently, submitted the IND that is currently underway on their behalf. See Declaration of Wayne C. Bardin at 1-3; Attachment A at 1. Another of plaintiff's declarants, Dr. David Grimes, is stated to have "[c]onducted clinical trials with mifepristone," and has the "most experience with [the] drug in U.S."). See Attachment A listing of "Mifepristone Expert Resources Group." Moreover, plaintiff'sphysician, Dr. Louise Tyrer, stated in her Declaration that plaintiff Benten is an appropriate candidate for RU486, and that Dr. Tyrer has met with Dr. Grimes and with the person who developed RU486. See Tyrer Declaration, exhibit B to plaintiffs' memorandum in support of their motion for preliminary relief.

There is no evidence to indicate that FDA has ever restricted in any way the importation of RU486 for legitimate research pursuant to INDs. See RU486 Hearings, Testimony of Ronald Chesemore at 35, 36, 43, 46, statement of Dr. Sobel at 40, 50-51; statement of Ms. Barnes at 42, 48. Also, the Secretary of HHS and the Commissioner of the FDA have encouraged the submission of an NDA for RU486. FDA has written to the manufacturer of RU486, Roussel Uclaf, and both HHS and FDA have met with Roussel Uclaf and Population Council representatives. See Statement By David A. Kessler, M.D., Commissioner of FDA Before the Subcommittee on Regulation, Business Opportunities, and Technology, Committee on Small Business, U.S. House of Representatives, May 16, 1994, Attachment C hereto. FDA has stated its willingness to work with the Population Council "to make certain that their clinical trials are well-designed and carefully conducted." Id. at 3.

Thus, contrary to plaintiff's argument, Memorandum in Support of Plaintiffs' Motion for Summary Judgment (Pl. Mem.) at 2, this drug is now available to plaintiff through clinical trials and her complaint is, therefore, moot. For this reason, plaintiff's complaint should be dismissed.

II. IMPORT ALERT 66-47 IS NOT A RULE REQUIRING PUBLICATION

Plaintiff's characterization of the FDA's internal guidance

concerning its enforcement policy as an Administrative Procedure Act (APA) "rule" subject to notice and comment must be rejected. In fact, the Supreme Court stated that plaintiff had "failed to demonstrate a substantial likelihood of success" on this very issue. Benten v. Kessler, 112 S.Ct. 2929 (1992) (per curiam). Import alert 66-47 is simply not a rule, but agency guidance regarding its enforcement policy, and it is intended solely as guidance to FDA employees. Further, plaintiff's attempt to strike down this alleged "rule" so that she can take advantage of the personal use policy is unavailing. Neither of these policies creates rights or obligations nor do they give plaintiff any "right" to import RU486.

The APA notice and comment requirements do not apply to "interpretative rules, general statements of policy or rules of agency organization, practice or procedure." 5 U.S.C. § 553(b). The exceptions "accommodate situations where the policies promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition and reduction in expense." Guardian Federal Savings and Loan Ass'n v. Federal Savings and Loan Insurance Corp., 589 F.2d 658, 662 (D.C. Cir. 1978).

Until 1991, FDA, by its own regulation, required publication of "interpretive rules and rules of agency practice and procedure." 21 C.F.R. §10.40(d) (1991), repealed May 6, 1991, 56 Fed. Reg. 65 (April 4, 1991).

Neither import alert 66-47 nor the personal import policy is a substantive rule, interpretive rule, or rule of agency practice or procedure that was required to be published. Both were issued to FDA employees as guidance to assist them in the discretionary enforcement of the law. Both the personal import policy andimport alerts are part of the agency's Regulatory Procedures Manual (RPM). The Manual itself provides that statements in the Manual "are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended merely for internal guidance." (emphasis added).

A. The FDCA's Provisions for the Regulation and Approval of Drugs

Import alert 66-47 cannot be viewed in isolation from the Congressionally-created system of drug regulation in the United States. To protect the public from drugs that are not safe or effective, Congress enacted a regulatory scheme that requires that any new drug, such as RU486, be approved by FDA before it is distributed or marketed. 21 U.S.C. § 355. To gain such approval, the drug must be the subject of an NDA, which must be reviewed and approved by FDA before it may be introduced into interstate commerce, which includes importation. 21 U.S.C. §§ 355, 331(d). Congress has determined that unapproved drugs shall not be imported into the United States, except pursuant to an IND, even if they have been approved in a foreign country.

To obtain FDA approval of an NDA, the drug sponsor must demonstrate, to FDA's satisfaction, that the drug is both safe and effective for each of it claimed uses. 21 U.S.C. § 355(b). To obtain FDA approval, a sponsor of a new drug must submit: 1) full reports of investigations to establish that the drug is safeand effective; 2) a full list of the drug's components; 3) a full statement of the drug's composition; 4) a full description of the methods, facilities, and controls used for the drug's manufacturing, processing, and packing; 5) samples of the drug and its components; and 6) samples of the proposed labeling for the drug. The drug's sponsor has the burden of proving that the drug is both safe and effective. The bulk of the information submitted to FDA in an NDA usually consists of the reports of clinical (human) and non-clinical (animal) data, describing and analyzing a variety of tests (in vitro, in animals, and in humans), performed by or for the drug's sponsor in an effort to establish the drug's safety and effectiveness.

The clinical data submitted in an NDA is based on testing and research conducted pursuant to an IND. FDA has jurisdiction to assess independently both the validity of the methodology used in such studies and the ultimate questions of safety and effectiveness. Warner-Lambert Co. v. Heckler, 787 F.2d 147, 152-53 (3d Cir. 1986).

B. FDA's Authority Over Drugs Offered For Import and the Personal Import Policy

FDA's authority under 21 U.S.C. § 381(a) to refuse admission of drugs offered for import is extremely broad, reflecting Congress' complete power over imports in general. Sugarman v. Forbragd, 267 F. Supp. 817, 824-25 (N.D. Cal. 1967), aff'd, 405 F.2d 1189 (9th Cir. 1968), cert. denied, 395 U.S. 960 (1969); Board of Trustees of Univ. of Illinois v. United States, 289 U.S. 48, 56-57 (1933); Buttfield v. Stranahan, 192 U.S. 470, 493(1904). There is no unqualified right to import drugs into this country. Sugarman, 267 F. Supp. at 824-25. Indeed, FDA does not need to establish that a drug offered for import actually violates the FDCA in order to refuse admission; any article that "appears" to violate the FDCA may be refused. 21 U.S.C. § 381(a); see Sugarman v. Forbragd, supra; Continental Seafoods v. Schweiker, 674 F.2d 38, 42-43 (D.C. Cir. 1982).

The importation of unapproved new drugs, whether for personal use or otherwise, violates the Act unless the importation is pursuant to an IND. Under certain conditions, however, FDA has, for many years, exercised its discretion to permit the importation of small quantities of unapproved drugs that are not available domestically and are intended for personal use. In 1988, FDA's Office of Regulatory Affairs issued the "Pilot Guidance for Release of Mail Importations" as part of its Regulatory Procedures Manual. Exh. A to Plaintiff's Complaint. The Pilot Guidance provided guidance for allowing the importation of unapproved "articles for treatment of serious and

life-threatening conditions like AIDS and cancer," which are subject to refusal of admission because they are not approved. Id. The Pilot Guidance was issued to help assure uniformity among FDA districts when field personnel use their discretion. Id. at 2.

In December 1989, the agency issued RPM Chapter 9-71, which consolidated the information in the Pilot Guidance and related documents concerning the personal import policy. The personal import policy is by its very terms discretionary. See U.S. Mem.at 9-10. The policy does not provide anyone with a right to import any drug, nor does it require that field personnel use their discretion to examine the background, risk, and purpose of unapproved drugs imported for personal use before making a final decision as to admissibility. See RPM Chap. 9-71-30. The personal import policy provides guidance for use in those instances in which field personnel determine that the exercise of discretion may be appropriate. The policy provides that release of an unapproved drug for personal use may be appropriate if, among other considerations, it is intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and is not considered to represent an unreasonable risk. Id.

As discussed below, import alert 66-47, which informs FDA personnel that RU486 and other abortifacients are not appropriate for release under this guidance and, therefore, should be initially detained when brought into the country, is simply intended to provide guidance to FDA personnel.

C. Import Alerts and FDA's Import Operations

In general, import alerts are the means the agency uses to identify and disseminate information relevant to imports in order to help ensure a uniform and effective import coverage program. All import alerts are part of the Regulatory Procedures Manual, and are "filed at the end of [] chapter [9-79]." The agency uses import alerts and import bulletins "[t]o identify and disseminate import information (problems, violative trends, etc.) thusproviding a more uniform and effective import coverage program." 9-79-00. Import bulletins are advisory only and provide information, but do "not provide policy or coverage guidance." 9-79-20, 9-79-40. Import alerts "identify problem commodities . . . and provide[] guidance for import coverage," including the identification of products that meet the criteria for automatic detention. 9-79-20. Regulatory Procedures Manual chapter 9-25, issued April 11, 1988, provides guidance regarding automatic detention. It provides:

> Automatic detention is the administrative act of detaining an entry of a specified article without physical examination solely on the basis of information regarding its past violative history and/or other information indicating that the product may be violative. Automatic detention actions are

implemented through the issuance of Import Alerts.

9-25-10. The agency has by regulation stated that if a product appears to be subject to refusal of admission, FDA may detain it and, if the product is detained, FDA will advise the importer of the opportunity to have a hearing. 21 C.F.R. § 1.94. The importer may introduce testimony either orally or in writing. Id. See 21 U.S.C. § 381(a); Sugarman v. Forbragd, 267 F. Supp. at 824. This hearing can take many forms, including telephone conversations and letters. The hearing is the importer's opportunity to present her defense of the importation. RPM Chapter 9-35-40, "Response (Hearing) to Notice of Detention and Hearing." A decision as to the admissibility of detained goods is made only after the importer has an opportunity to present testimony and that testimony is considered. Further, an importermay appeal the decision of the field office to the FDA Commissioner.

D. Import Alert 66-47 Is Not a Rule Requiring Notice and Comment

Consistent with the discussion in the preceding section, import alert 66-47 imposes no new obligations or requirements on either individuals seeking to import RU486 or on FDA personnel, but only informs field personnel that RU486 is an unapproved new drug that can, therefore, be detained and further informs them that it does not meet the criteria of the personal import policy. The FDA need not engage in rule-making procedures to be able to enforce the law in this respect.

Import alert 66-47 does not require field personnel to detain RU486, but instead informs them that statutory authority exists for them to detain shipments or entries identified as RU486 without physically examining them or seeking further information. Even if import alert 66-47 required detention of RU486, refusal of admission is not automatic. If RU486, or any article, is detained -- whether pursuant to an import alert or based on other information -- the importer can request a hearing to challenge the detention, as discussed above. During that proceeding, which can be appealed to the FDA Commissioner, the FDA can reach any decision. That is, the drug can be released based upon the information presented, or a decision may be made to refuse admission. The import alert is not the final agencydecision; the final decision may be that the product should not be refused admission.

Most significantly, the statute, not import alert 66-47, provides the law for the regulation of unapproved drugs. Import alert 66-47 is not "finally determinative" of whether a particular importation of RU486 violates the Act. See Pacific Gas & Electric v. FPC, 506 F.2d 33, 38 (D.C. Cir. 1974). The ultimate decision on the admissibility of RU486 would not be based upon the import alert, it would be based upon the statute. That is, FDA would examine whether RU486 appears to be

unapproved or otherwise in violation of the Act, not whether RU486 was subject to an import alert. Import alerts are themselves not binding on the agency or the public, and FDA cannot rely on an import alert, by itself, in a final decision excluding a drug. In other words, they are not the law.

Thus, as guidance advising FDA personnel and the public of the manner in which the agency intends preliminarily to exercise its discretion, import alerts are exempt from the notice-and-comment rulemaking procedures of the APA. Many courts have recognized that guidance documents similar to the import alert are not subject to notice and comment. In Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533 (D.C. Cir. 1986), the courtheld that "Enforcement Policy and Guidelines for Independent Contractors," which were used a "guidance in making individual enforcement decisions," were not required to be published. Id. at 535-38. In American Mining Congress v. Marshall, 671 F.2d 1251 (10th Cir. 1982), the court held that a "strategy" outlining how the Secretary planned to enforce a standard was not required to be published. Id. at 1262-63. The Fifth Circuit, in Southeastern Minerals, Inc. v. Harris, 622 F.2d 758 (5th Cir. 1980), recognized that FDA Compliance Policy Guides (CPGs) do not require rulemaking procedures. Id. at 766. See also Cowdin v. Young, 681 F. Supp. 366, 370 (W.D. La. 1987) (CPGs are not binding legal requirements); see also Panhandle Producers v. EPA, 847 F.2d 1168, 1174-75 (5th Cir. 1988) (Economic Regulatory Administration guidelines relating to approval of natural gas imports were statements of policy, not binding rule; rulemaking not required); Mercury Motor Express, Inc. v. United States, 648 F.2d 315, 319 (5th Cir. 1981) (ICC order announcing new criteria for approving for-hire operating authority applications was policy statement).

Plaintiff relies heavily on Bellarno International Ltd. v. FDA, 678 F. Supp. 410 (E.D.N.Y. 1988). This reliance is misplaced. As an initial matter, Bellarno's conclusion that an import alert required publication is simply incorrect, for the reasons stated above -- an import alert is simply a preliminary step in the administrative process, and not a binding legal decision. Even if this were not the case, however, the facts inBellarno are distinguishable from the facts in this case in a critical respect. Most significantly, the import alert in Bellarno contained a requirement that went beyond satisfaction of the statutory standard applicable to all drugs imported into the United States. The import alert there also required proof of five additional elements. The Bellarno court found that the agency had created a new obligation (i.e., acquiring and maintaining a paper chain of custody) with which importers had to comply to satisfy the statutory requirements. 678 F. Supp. at 414 & n.4. In the instant case, no such obligation has been created: enforcement of the statutory requirement to have an approved NDA or IND to import a drug product does not impose any

new standards or requirements on RU486. It is undeniable that, under the plain meaning of the statute, importation of RU486 is illegal absent an IND. Neither the personal use policy nor the import alert change that fact; hence, the import alert does not create any "rights and obligations" beyond the statute. The RU486 import alert only provides guidance regarding initial steps in the enforcement of the statute with respect to RU486. Therefore, the specific facts in Bellarno prevent any useful comparison between the two cases.

Import alert 66-47 does not fit into any of the categories of rules requiring publication. A recent case from in this Circuit shows that the import alert is not a substantive rule. In New York City Employees' Retirement System v. SEC, 45 F.3d 7 (2d Cir. 1995), the court followed a test (laid out originally bythe D.C. Circuit) to determine whether a rule has "legal effect" and is therefore "legislative." Id. at 13. If any of these four criteria are met, it is an indication that the rule is legislative:

> (1) in the absence of the rule, no legislative basis would exist for an enforcement action; (2) the agency has published the rule in the Code of Federal Regulations; (3) the agency explicitly invoked its general legislative authority to pass the rule; (4) the rule effectively amends a prior legislative rule.

Id. at 13. See American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993).

Under this test, the import alert is clearly not a legislative rule: In its absence, there would be an adequate legislative basis to exclude unapproved drugs from import (the Food, Drug, and Cosmetic Act); it was not published in the CFR; the FDA did not invoke its legislative authority; and the rule did not amend a prior legislative rule.

Nor is import alert 66-47 an interpretative rule; it does not explain or define any provision of the Act. See New York City Employees' Retirement System v. SEC, 45 F.3d at 12 (interpretive rules "'clarify an existing statute orregulation.'" (quoting White v. Shalala, 7 F.3d 296, 303 (2d Cir. 1993)). Nor does it outline a rule of agency practice or procedure; it is simply guidance for the exercise of discretion.

For these reasons, no law required that the import alert for RU486 be published for notice and comment, and plaintiff's arguments to the contrary must be rejected.

III. THE IMPORT ALERT IS CONSISTENT WITH THE FDCA AND IS REASONABLE.

Even if the Court were to determine that jurisdiction existed for it to examine the merits of import alert 66-47, it is reasonable and must be upheld.

In reviewing this action, the Court must first determine

whether Congress has spoken directly to the question at issue. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). If the intent of Congress is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent ofCongress." Id. at 842-43 (footnote omitted). Significantly, this case involves an issue on which Congress has spoken directly and without ambiguity. Congress has made it illegal to import unapproved new drugs into this country except under an IND, and the RU486 import alert is based on this fact. For this reason, the RU486 import alert must be upheld and no further inquiry into this matter is necessary or required. This agency action is consistent with the statute and, as noted in the defendants' motion to dismiss, committed to the discretion of the agency.

If, however, this Court were to examine the matter further, the RU486 import alert is reasonable and not arbitrary or capricious. Under the "arbitrary and capricious" standard, judicial review of agency action is narrowly circumscribed:

> [T]he Court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. ... Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The Court is not empowered to substitute its judgment for that of the agency.

Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971) (citations omitted). See also Bowman Transportation Co. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 285-86 (1974).

Great deference is given to the agency. Chevron U.S.A., 467 U.S. at 844. Further, if the agency's choice "represents a reasonable accommodation of conflicting policies," it is not to be disturbed unless "it appears from the statute or its legislative history that the accommodation is not one thatCongress would have sanctioned." Id. at 845 (emphasis added). See also Udall v. Tallman, 380 U.S. 1, 16-17 (1965); Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 413-14 (1945).

This is less than a substantial evidence test, or even a preponderance of the evidence test. See, e.g., Ethyl Corp. v. EPA, 541 F.2d 1, 37-38 (D.C. Cir.), cert. denied, 426 U.S. 941 (1976); Action For Children's Television v. FCC, 564 F.2d 458, 478 (D.C. Cir. 1977); Henley v. FDA, 873 F. Supp. 776, 782 (E.D.N.Y. 1995). The FDA's decisions must be presumed to be valid. It is plaintiff's burden to demonstrate that there is no rational basis for the decisions. Even if this Court were to determine that there were other actions that the FDA could have

taken that would have been, in the Court's view, preferable, the Court may not substitute its judgment for that of the FDA nor interject itself into the area of discretion reserved for the agency. Chevron U.S.A., 467 U.S. at 843 n.11. See also Mourning v. Family Publications Service, Inc., 411 U.S. 356, 371-72 (1973); New York Dep't of Social Services v. Shalala, 21 F.3d 485, 492 (2d Cir. 1994). "As this standard indicates, the scope of our review is relatively narrow. There will be occasions when 'we must affirm decisions with which we disagree' as long as they are rational and reflect a full consideration of relevant factors." National Industrial Sand Ass'n v. Marshall, 601 F.2d 689, 699 (3d Cir. 1979) (footnote omitted). Deference is especially important here: "[T]he Court is mindful that when it reviews agency action that is based upon scientific inquiry andtechnical expertise, a high degree of deference is appropriate." Henley v. FDA, 873 F. Supp. at 782.

Under this narrow and deferential scope of review, plaintiff's challenge must be rejected. The RU486 import alert is reasonable, fully consistent with the FDCA, and not arbitrary or capricious.

A. The Issuance of Import Alert 66-47 was Reasonable and Consistent with the FDCA

FDA's Director of Field Investigations issued an "Import Bulletin" for RU486 on September 26, 1988. Exh. C to Plaintiff's Complaint. This Bulletin informed FDA field personnel that because RU486 was not consistent with the criteria of the "Pilot Guidance for Release of Mail Importations," which was issued on July 20, 1988, it should not be allowed admission into the United States pursuant to that Pilot Guidance. Id. As discussed in section II, FDA's Office of Regulatory Affairs had issued that Pilot Guidance on a trial basis to provide guidance for allowing the importation of unapproved "articles for treatment of serious and life-threatening conditions like AIDS and cancer." Exh. A toPlaintiff's Complaint. The Pilot Guidance noted that individuals had been purchasing unapproved products from foreign sources for these life-threatening conditions, and that such products are subject to refusal of admission because they are not approved. Id. The Pilot Guidance was, by its very terms, discretionary. Id. at 2. The original purpose of this guidance was to allow treatment for diseases that would lead to severe debilitation or death if untreated and for which adequate treatment was not currently available. The personal use of RU486 as an abortifacient does not fall within this purpose.

The agency replaced this import bulletin with an import alert on June 6, 1989. Exh. D to Plaintiff's Complaint. The import alert reiterated that importation of abortifacients such as RU486 was inappropriate under the Pilot Guidance. Id. at 2. It also stated that "[t]he intended use of such drugs could pose a risk to the safety of the user." Id.

The import alert was prompted by publicity concerning the

use of RU486 as an abortifacient that led FDA to believe that the drug might be imported for commercial purposes or for unsupervised or clandestine use. See Letter from James Benson to Ron Wyden, Exh. E to Plaintiff's Complaint ("Exh. E") at 2; RU486: The Import Ban and Its Effect on Medical Research: Hearing Before the House Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business, 101st Cong., 2d Sess. 36, 41, 175-78 (1990) (hereinafter "RU486 Hearings") (partially reprinted at Exh. H to Plaintiff'sComplaint. This reasoning was based on inquiries from the public and FDA field offices about this drug, the history of misuse of abortifacients, and uncertainty about whether supervision by physicians would occur. See Exh. E at 2; RU486 Hearings at 42-43; 175-78. See also Letter from Frank Young to Robert Dornan, Exh. G to Plaintiff's Complaint ("Exh. G").

The agency revised the import alert on April 17, 1990, to encompass the known chemical names for RU486, and to refer to RPM Chapter 9-71, issued December 11, 1989, which consolidated the information in the Pilot Guidance and related documents concerning the personal import policy. The revised Import Alert repeated the statements in the original import alert concerning the inappropriateness of releasing abortifacients under the personal importation policy.

The primary rationale for the Import Alert was that RU486, as well as other abortifacients, pose an unacceptable safety risk because, by their very nature, the drug would likely be used without supervision, and such unsupervised use could be hazardous to health. See Exh. E; RU486 Hearings at 175-78. Additionally, RU486 is generally used in conjunction with another drug, a prostaglandin, which is also not approved for this use in the United States. See Exh. E; RU486 Hearings at 175-78.

Use of RU486 as an abortifacient can result in "uterine bleeding, severe nausea, vomiting, and weakness, which might require prompt medical intervention." See Exh. G; Patient Informed Request, Exhibit B-3 to plaintiffs' motion for preliminary relief. In France, where the distribution and use of RU486 is highly regulated, RU486 is used in accordance with a strict regime under close medical supervision. In this medically-supervised environment, use of RU486 is frequently accompanied by a variety of side effects. These side effects, which occur primarily after administration of the prostaglandin, include cramps and abdominal pain similar to those associated with a very heavy period, nausea, vomiting, and/or diarrhea that sometimes require medical attention, and uterine bleeding that can last as long as three weeks. Attachment A hereto at 3 and clinical information attached thereto at 2. One of plaintiff's exhibits states that about one percent of women in a French report required treatment to control bleeding. Exhibit B-4 to plaintiffs' motion for preliminary relief, at 275. This source

also noted three cases of major cardiovascular complications, and that postabortion bleeding is more prolonged after medical abortion than surgical abortion. Id. at 275-76. See also Exh. B-5 at 48 (4 to 5 percent of women had heavy bleeding). When used in accordance with a strict regime, RU486 has a failure rate of about 4 in 100 (ongoing pregnancy in 1 of 100 attempts, incomplete terminations in 3 of 100 attempts). In such instances, a vacuum aspiration or curettage is necessary toterminate the pregnancy. Attachment A hereto at 3 and clinical information attached thereto at 3; see also Patient Informed Request, Exhibit B-3 to Plaintiffs' motion for preliminary relief.

Further, serious cardiovascular complications have occurred in women, including one fatality, when RU486 is used with certain prostaglandins that are no longer used in controlled settings, Attachment A hereto at clinical information attached thereto at 2, but might be used inadvertently in a less well-supervised environment.

These potential complications can be monitored and treated in a controlled clinical trial, but not in the context of personal use. In issuing the import alert, the agency was concerned not only with the risks of RU486, but also with the fact that RU486 does not meet the criteria of the personal import policy. The relevant portion of the personal import policy contains two parts which describe the situations in which it may be appropriate for field personnel to consider releasing an unapproved drug for personal use. RPM Ch. 9-71-30(C).

The first part of the policy applies to unapproved drugs that are not intended for the treatment of a serious condition and are not known to represent a significant health risk. See RPM 9-71-30(C). This provision is intended for such drugs as cold medications that a person might buy abroad to treat a minor illness while traveling and bring back into the United States. Exh. H to Plaintiff's Complaint at 36. RU486 does not qualifyunder this provision because it is used for a serious condition and because its use, as discussed above, represents a significant health risk.

The second part of the policy applies to unapproved drugs that are, among other considerations, intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and are "considered not to represent an unreasonable risk." RPM Ch. 9-71-30(C). RU486 does not fall within this provision because it is proposed for use in treating a condition for which an alternative treatment does exist and because it poses a safety risk. Id.; RU486 Hearings at 36. Other means of abortion are available in the United States, and RU486 is not necessary to make abortion available. See RU486 Hearings at 36. Moreover,RU486 is available in controlled clinical trials at the present time.

B. The Relief Plaintiff Seeks Is Inconsistent With the FDCA and Long-Standing Principles of Deference to FDA's Expertise

Evidently acknowledging that inadequately supervised use of RU486 as an abortifacient poses serious risks to health, plaintiff requests that this Court require the agency to permit the importation of RU486 for personal use as an abortifacient under medical supervision. It is not clear whether plaintiff is asking the Court to reject the agency's conclusion that personal importation is inappropriate even if an individual identifies a physician responsible for her treatment, or whether plaintiff is proposing that FDA become actively involved in controlling how RU486 is used and administered for personal use as an abortifacient.

The former scenario is inconsistent with long-standing principles of deference to FDA's expertise and judgment in matters involving the public health and safety. The latter would require FDA to create and administer a system of medicalcontrols for the use and administration of an unapproved new drug independent of its statutorily mandated system for regulating the investigational use of unapproved new drugs. 21 U.S.C. § 355(i); 21 C.F.R. Part 312. Although, by statute and regulation, FDA can regulate the conditions for use for investigational drugs covered by an IND, no controls exist to minimize the risks associated with the use of unapproved drugs imported by individuals for personal use. In order to minimize the risks associated with the use of RU486 as an abortifacient, a physician must know many things about the use and effects of RU486 and prostaglandins. As a result, to release RU486 for personal use as an abortifacient under medical supervision in a manner consistent with FDA's concerns would require significantly more than a physician's name and address. Active supervision by FDA in the personal use of an unapproved drug would require FDA to devote significant resources to such supervision rather than to the process by which the agency evaluates and approves drugs.

As discussed in Section II, the FDCA's drug approval scheme is the mechanism by which new drugs can be approved and legally marketed and distributed. Plaintiff is using this litigation in an attempt to circumvent the Congressionally established procedure for drug approvals, and to have this Court examine the safety and effectiveness of RU486. In so doing, plaintiff blatantly ignores the fact that only the FDA has the authority to determine whether a drug is safe and effective. Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 803-04 (2d Cir. 1980). Thus, despite plaintiff's numerous assertions that RU486 is "safe" and "effective" for use as an abortifacient, this court lacks authority to make such a finding. For all of these reasons, even if reviewable, import alert 66-47 is reasonable and must be upheld.

IV. THE IMPORT ALERT IS CONSTITUTIONAL

BECAUSE IT HAS NEITHER THE PURPOSE NOR THE EFFECT OF BEING AN UNDUE BURDEN ON PLAINTIFF'S ABILITY TO CHOOSE TO TERMINATE A PREGNANCY

The plaintiff's claim that an import alert on RU486 violates her constitutional right to privacy lacks merit. The Constitution does not preclude the government from regulating medical care, including abortion. Further, the Supreme Court has repeatedly held that the government has a legitimate interest in protecting the health of women seeking abortions.

The ability to choose abortion before viability of the fetus is a constitutional right. See Planned Parenthood of Southeastern Pennsylvania v. Casey, 112 S.Ct. 2791 (1992); Webster v. Reproductive Health Services, 492 U.S. 490 (1989); Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747 (1986); Akron v. Akron Center For Reproductive Health, Inc., 462 U.S. 416 (1983); Roe v. Wade, 410 U.S. 113 (1973). In Casey, the Supreme Court reaffirmed "Roe's essential holding" that the Due Process Clause of the Fourteenth Amendment protects a substantive liberty interest that encompasses a right to choose to terminate a pregnancy. Casey, 112 S.Ct. at 2803-05. Casey further reaffirmed the principle that the government may regulate abortion in certain circumstances.

The issue is whether import alert 66-47 imposes an undue burden on a woman's ability to choose to terminate her pregnancy. An undue burden is a governmental action "that has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." Id. at 2821 (emphasis added). As explained below, the import alert has no such purpose or effect and, therefore, passes constitutional scrutiny.

A. The Import Alert Is Reasonably Related to the Preservation and Protection of Health

In Casey, the Supreme Court distinguished between those government actions that have legitimate purposes and those that substantially restrict a woman's right to choose to terminate her pregnancy with the sole purpose of impeding abortion. The Court reiterated that the government has a legitimate interest in protecting the health of a woman seeking an abortion. 112 S.Ct. at 2804; see Roe v. Wade, 410 U.S. at 150 (government "has a legitimate interest in seeing to it that abortion . . . is performed under circumstances that insure maximum safety"). The import alert serves legitimate and important purposes "reasonably directed to the preservation and protection of maternal health." Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52, 80 (1976), citing Roe v. Wade, 410 U.S. at 163.

Unapproved drugs violate the FDCA. Drugs that appear to be unapproved may be refused entry pursuant to 21 U.S.C. § 381(a).

Products known to be unapproved new drugs may, therefore, be the subject of an import alert. The issuance of import alerts is a routine FDA action. The fact that FDA has issued over forty import alerts based on the absence of an approved NDA shows that FDA did not subject RU486 to any special treatment or standards. Import alerts serve a compelling government interest that is entirely unrelated to abortion: they provide field personnel with information concerning illegal products so that the public will not be exposed to them. The import alert in question here does not interfere with the right to choose abortion. Its principal purpose is to prevent unapproved drugs such as RU486 from being used in uncontrolled and potentially hazardous circumstances.

The import alert exists because the safety and effectiveness of RU486 has not been demonstrated to the FDA, and FDA is concerned about the potential for harm associated with the inadequately controlled or unsupervised use of RU486 as an abortifacient. Existing information about RU486 indicates that use of RU486 as an abortifacient must follow a precise regimen, and frequently results in a number of side effects, including cramps, abdominal pain, nausea, vomiting, and uterine bleeding that can last as long as three weeks. In some cases, the bleeding is severe enough to require a blood transfusion. Forall of these reasons, the import alert is reasonably related to the preservation and protection of health.

By contrast, the prohibition on saline amniocentesis that the Supreme Court invalidated in Danforth did not have legitimate public health purposes, but instead had as its motive the restriction of abortion. Danforth, 428 U.S. at 79. At the time, saline amniocentesis was the method of abortion "most commonly used nationally by physicians after the first trimester." Id. at 78. The Court found the remaining abortion methods available to women in Missouri, such as hysterotomy and hysterectomy, were actually more dangerous to health than the method prohibited on safety grounds, and further found that the prohibition had the effect of inhibiting the vast majority of abortions after the first twelve weeks. Id. at 76-79.

However, RU486 is not a method of abortion commonly used in the United States, although it is being used in limited number of well-controlled clinical studies within United States. Further, although the plaintiff asserts "the proven safety of RU486 as an abortifacient," Pl. Mem. at 16, this assertion is conclusory. As discussed above, it cannot be said that RU486 is safe and effective, let alone safer or more effective than surgical abortions.

Unlike the governmental action at issue in Danforth, the import alert does not have the purpose or the effect of substantially interfering with the right to abortion. Commonly used methods of abortion remain available. An import alert onRU486 is entirely different from the ban on saline amniocentesis in Danforth, and upholding this alert would not

allow the government to "ban commonly used methods of early surgical abortion." Pl. Mem. at 15. Despite the plaintiff's assertions to the contrary, the import alert was instituted to prevent RU486, an unapproved drug, from being used in uncontrolled and potentially hazardous circumstances.

B. The Import Alert On RU486 Does Not Impose An Undue Burden On A Woman's Right To Choose Abortion

The Supreme Court has recognized that many health regulations "might have the incidental effect of increasing the cost or decreasing the availability" of abortions. Casey, 112 S.Ct. at 2819. However, a governmental action that "serves a valid purpose" will not be invalidated simply because it has "the incidental effect of making it more difficult or more expensive to procure an abortion." Id. Consequently, "[r]egulations designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden." Id. at 2820-21. The import alert creates no burden at all; it prohibits no one from having an abortion, and is designed to foster women's health.

The plaintiff argues that it is insufficient that traditionally accepted methods of abortion remain available, and that any ban on any method of abortion is unconstitutional. Pl. Mem. at 13, 15. The plaintiff further contends that the import alert constitutes a substantial obstacle to a woman seeking an abortion because it curtails a woman's right to determine thecourse of her own medical treatment in that it prevents women from employing a non-surgical method of abortion. Pl. Mem. at 14.

Under plaintiff's theory, the government could not prohibit any unsafe abortion techniques, and the FDA would be powerless to prevent untested and potentially dangerous or ineffective drugs and medical devices from being sold and used simply because they relate to abortion. Plaintiff's position is not the law.

Although an individual's decision whether or not to have medical treatment is generally a protected right, her ability to select a particular type of treatment, especially when it involves the use of a particular medication, is within the area of governmental interest in protecting the public health. Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980). An individual does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider if the government has reasonably prohibited that type of treatment or provider. Mitchell v. Clayton, 995 F.2d 772, 775 (7th Cir. 1993). That the governmental action at issue affects a woman's decision to choose abortion does not alter this principle. See Connecticut v. Menillo, 423 U.S. 9, 11 (1975) (no constitutional right to an abortion by a non-physician); Roe v. Wade, 410 U.S. at 150, 165 (same); see also Casey, 112 S.Ct. at 2819-20 (a woman does not have an absolute right to an abortion).

The import alert does not create a prohibition on RU486. Rather, the FDCA makes it illegal to import unapproved new drugs such as RU486 into this country, and the import alert simply recognizes this fact. Courts have consistently held that the new drug approval system established by Congress and enforced by FDA is constitutional, and that an individual does not have a right to obtain an unapproved drug. Rutherford, 616 F.2d at 457; Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980); Duncan v. United States, 590 F. Supp. 39, 42-44 (W.D. Okla. 1984); Kulsar v. Ambach, 598 F. Supp 1124, 1126 (W.D.N.Y. 1984); United States v. Vital Health Products, Ltd., 786 F. Supp. 761, 777-78 (E.D. Wis. 1992), aff'd sub nom. United States v. LeBeau, 985 F.2d 563 (7th Cir. 1993). The reasonableness of the statutory and regulatory scheme is bolstered by the fact that the investigational new drug provisions permit access to unapproved drugs, such as RU486, in controlled clinical settings.

Constitutional protection for RU486 would inevitably mean constitutional protection for other unproven, potentially dangerous methods of abortion. The potential for harm to health is great, and the government's interest in preventing this outcome and preserving the public protection now afforded by the FDCA, is significant. The import alert, which permits women to use other abortion methods, does not unduly burden a woman's right to choose abortion and is, therefore, constitutional.

CONCLUSION

For the foregoing reasons, plaintiff's complaint should be dismissed, or judgment should be granted in favor of the defendants.

Respectfully submitted,

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Date: June 30, 1995

Summary of July 19, 1996 Reproductive Health Drugs Advisory Committee (AC) Meeting On Mifepristone: Outstanding Issues for FDA to Address

1) Further Efficacy Studies Recommendations by Two AC Members

In reference to the 6 to 2 vote for demonstration of efficacy, one advisory committee member did not feel efficacy was proven and requested "less-selective" patients who are not highly motivated and who had terminations paid for by the clinical trials. (p.278-Henderson) Address this in reviews.

Another advisory committee member wanted to see final U.S. data prior to an approval vote. (p.279-O'Sullivan) Address this in reviews.

2) U.S. Data to Go to the Committee for Review

Dr. O'Sullivan voted no for approval citing need to see U.S. data. (p.279) The committee expressed desire to see all U.S. safety data (p.288) once available. [redacted] stated that if the U.S. data was worse, FDA may hold another AC meeting; if the U.S. data was the same or better, the FDA may mail the results out for comment by the AC (p.290). Was this done?

3) Reconciliation of Differences between Clinical Trials Eligibility, Labeling, and Patient Package Insert (PPI)

The advisory committee (AC) recommends that all conditions of exclusion (cardiovascular diseases and other medical conditions like insulin-dependent diabetes, etc.), information given to patients/physicians, and restrictions in the clinical trials should also be in the physician label and PPI. If there are no data or risks are unknown, state this. (p. 300 Daling, p. 301-2 O'Sullivan, p. 306 Davidson, 308 Zones)

- Exclusion Criteria

Clinical trials prohibited smoking 10 or more cigarettes a day or drinking alcohol during the 48 hours following mifepristone administration and on the day of misoprostol; the AC asks if is this in current physician labeling and PPI? (p.254-Davidson)

Women over the age of 35 were excluded; how is this handled in the label? Why? (p.256-Robbins)

Adolescents were excluded from the trials, is this in the label and PPI? (p.301 Henderson)

-Timing of 2nd Drug

The AC recommends changing the labeling from 36-48 hours for administration of the second drug to "two days" in the medical and patient label. (p.276-Davidson)

4) **Labeling Recommendations**

-"Safety" Not be Misinterpreted

The term "safety" should not be misinterpreted as "free of adverse effects and free of actually serious adverse effects" and this idea should be in the physician and patient package information. (p.285-Petitti)

-"Acceptability of Adverse Events"

The AC suggests to the extent possible for the Agency, that this method of termination be compared with alternatives in terms of adverse effects and events and this be in the labeling. (p.287-88, Lewis and Davidson)

-Clarify Drug-Drug Interaction Term

Define what are the drugs that cause enzyme induction in the label. (p.302 O'Sullivan)

-Define Risk of Malformation if Pregnancy Continues

Provide information on the risk of malformation for embryo if pregnancy is not terminated with use of drugs; if not known, state. (p.303 O'Sullivan)

-Consideration for Termination if Pregnancy Continues due to Unknown Teratogenic Risk

AC recommends to FDA that all cautions, conditions of exclusion and information given in the clinical trials to patients/physicians be in the label and PPI. Because of the drugs unknown teratogenic risk, the label should read termination of pregnancy should be considered. (p.304-306 discussion, Davidson)

-Decrease in Misoprostol Effectiveness if Administration is Delayed

For information to physicians and patients, state in label and PPI that the effectiveness of misoprostol decreases with delay in its administration and it should be administered as directed. (p.307-Azziz)

-Explain in Label Why Two Days for Misoprostol is Optimal

The label and PPI should explain medically why two days is the optimal time for administering misoprostol. (p. 307 Davidson)

-Patients Should be Asked if they are Taking Other Drugs

Both the physician label and PPI should have statements stating patients should inform their physicians if they are on any other medications. (p.308 Zones)

-Nursing Mothers

Both the misoprostol label and mifepristone label need to be consistent and say to nursing mothers to either not use these drugs or to stop breast-feeding while using them. (p.309-310 Petitti)

-Define Pediatric Patients

Make sure the label and PPI are clear what are the age groups defined when FDA says safety and effectiveness in pediatric patients have not been established. (p.310-O'Sullivan)

-Label Should Mention Efficacy Decreases after Gestational Age of 49 days

The data say there is significant decrease in efficacy occurs for women who carry a fetus of greater than 49 days gestation age. This should be emphasized in label/PPI. (p.310-11 Davidson)

-Label Should State Informed Consent be Written

Physician and PPI should mention written informed consents should be obtained. (p.313-Petitti)

Some suggested wording for the written informed consent: "My physician has discussed with me alternatives to medical abortion, including surgical abortion, continuation of pregnancy...My doctor has confirmed that I am pregnant and that the pregnancy has not lasted more than 49 days..." (p.313 Petitti)

-Label Should Mention Use of Drugs Under Supervision of a Qualified Physician

Nurses can administer this drug, but under the direction of a qualified physician-one who is experienced in handling pregnancies, terminations, and complications of both. (p.314-315 Azziz)

5) Distribution System Issues

The AC proposed the model of the IUD system for tracking distribution of mifepristone. Concern was expressed about not making the tracking system too onerous for physicians. (p.315 Winikoff, O'Sullivan)

Mifepristone would not be distributed to the pharmacy but to physicians directly as proposed by the sponsor. (p.314 Davidson)

-Training of Qualified Physicians through Distributors

The distributors would be responsible for ensuring drug got into hands of physicians who were trained ~~in~~ dating pregnancies, handling complications, identifying ectopic pregnancies, and performing surgical evacuations and emergency procedures. Training seminars for use of mifepristone would be conducted, without financial incentive to physicians, and only those physicians who completed training would be distributed the drug. A tracking system of these physicians would be needed. The AC did not want the distributor to train non-ob-gyns or non-surgeons the use of this drug and manual vacuum aspiration. Identification of adequate back-up with skills for emergency procedures is needed. FDA must respond by describing qualifications of skills of physicians to whom the drug can be distributed to ensure appropriate use of drug and management of potential complications. There is clearly concern that this drug not be expanded to hands of

physicians who are not already skilled in managing pregnancies, terminations, and complications of both. Family practitioners with adequate back up were mentioned as acceptable (p. 316, 318-325Azziz [Davidson 324], 327-328Azziz).

Post Market Issues

-Concerns about Compliance with Returning: Study Suggested

The AC expresses concern that compliance with three visits maybe more problematic for minorities, patients with barriers to health care, transportation, child care, etc. and these types of women were not in the clinical trial; can these factors be studied in patients who do and do not return post-marketing to understand appropriate selection of patient population for this drug? (p.269 Henderson, p.270 O'Sullivan, p.280 Henderson, p.291 Henderson, p. 329 Daling) [In response, see p.293 Dr. Zones, on how medical practitioners have historically assessed compliance in their patients as part of what therapeutic options are appropriate. Also see Dr. Daling p.293, who states Planned Parenthood has experience in this population.]

What can be done for patients who complete the medications but cannot afford the surgical terminations, if needed? (p.271 O'Sullivan)

What if the patient does not return to confirm the abortion? (p.296 Dr. Henderson)

-Concerns about Distribution System: Who are the Physicians who Get Drug and Are They Qualified

Concern was raised from p.318-25 that physicians not skilled in handling pregnancies, terminations, or complications from both not be trained to give drug. This should be monitored post-market. (p.326 Henderson)

-Failed Pregnancy Terminations and Resulting Surgical Complications Be Tracked for Everyone being Distributed the Drug

Monitoring the number of failed pregnancy terminations and any resulting surgical complications is advised. (p.326 Henderson) This monitoring is recommended for every physician being distributed the drug for a limited time period (6 months, one year, and two years). (p.328 Azziz) Concern that backup physicians handling complications may appear to have more problems must be adjusted for. (p. 328 O'Sullivan)

-Study Long-term Effects of Both Single and Multiple Use in Patients

Collect data on the long-term effects of both single use and multiple use in patients from a subgroup. (p. 329 Davidson)

-Study Effects of Women over 35, under 20, who Smoke/Don't Smoke

These patients may accept risk to take drug, it would be useful to quantify cardiovascular risk. (p.329 Davidson, Henderson, Daling)

-Study Effects in Pregnancies that Continue after Drugs Administered and No Terminations Result and Further Terminations Not Pursued

What are effects of drug on the fetus, pregnancy, newborn, etc. (p.330 Azziz)?

TRAVEL VOUCHER

(Read the Privacy Act Statement on the back)

1 DEPARTMENT OR ESTABLISHMENT BUREAU DIVISION OR OFFICE: DHHS/FDA/CDER/HFD-21

2 TYPE OF TRAVEL: [X] TEMPORARY DUTY [ ] PERMANENT CHANGE OF STATION

3 VOUCHER NO.

4 SCHEDULE NO.

5. TRAVELER (PAYEE)

a. NAME (Last, first, middle initial): Lewis, Vivian

b. SOCIAL SECURITY NO.

6. PERIOD OF TRAVEL: a. FROM 07/18/96 b. TO 07/19/96

c. MAILING ADDRESS (Include ZIP Code):
Dir.Div. of Repro. Endocrinology
Univ. of Rochester Med. Ctr.
601 Elmwood Ave., Box 668
Rochester, NY 14642

d. OFFICE TELEPHONE NO.

7. TRAVEL AUTHORIZATION: a. NUMBER(S) D-51761 b. DATE(S)

e. PRESENT DUTY STATION: rockville,MD

f. RESIDENCE (City and State)

10. CHECK NO.

8. TRAVEL ADVANCE
a. Outstanding
b. Amount to be applied
c. Amount due Government (Attached: [ ] Check [ ] Cash)
d. Balance outstanding

9. CASH PAYMENT RECEIPT
a. DATE RECEIVED
b. AMOUNT RECEIVED $
c. PAYEE'S SIGNATURE

11. PAID BY

FILE COPY

12. GOVERNMENT TRANSPORTATION REQUESTS, OR TRANSPORTATION TICKETS, IF PURCHASED WITH CASH (List by number below and attach passenger coupon; if cash is used show claim on reverse side.)

I hereby assign to the United States any right I may have against any parties in connection with reimbursable transportation charges described below, purchased under cash payment procedures (FPMR 101-7) ▶ Traveler's Initial

AGENT'S VALUATION OF TICKET (a)	ISSUING CARRIER (Initials) (b)	MODE, CLASS OF SERVICE AND ACCOMMODATIONS (c)	DATE ISSUED (d)	POINTS OF TRAVEL FROM (e)	POINTS OF TRAVEL TO (f)
B-4,699,170 $511.00	US	Contract		Rochester,NY	Washington,D.C. and return

Prysock 3-5455

13. I certify that this voucher is true and correct to the best of my knowledge and belief, and that payment or credit has not been received by me. When applicable, per diem claimed is based on the average cost of lodging incurred during the period covered by this vo.

TRAVELER SIGN HERE [signature] DATE 7-21-96 AMOUNT CLAIMED ▶ $ 268 00

NOTE: Falsification of an item in an expense account works a forfeiture of claim (28 U.S.C. 2514) and may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 287; i.d. 1001).

14. This voucher is approved. Long distance telephone calls, if any, are certified as necessary in the interest of the Government. (NOTE: If long distance telephone calls are included, the approving official must have been authorized in writing by the head of the department or agency to so certify (31 U.S.C. 680a).)

APPROVING OFFICIAL SIGN HERE ▶ [signature] DATE 9-10-96

SGE Programs Officer

17. FOR FINANCE OFFICE USE ONLY COMPUTATION

a. DIFFERENCES, IF ANY (Explain and show amount) $

15. LAST PRECEDING VOUCHER PAID UNDER SAME TRAVEL AUTHORIZATION
a. VOUCHER NO. b. D.O. SYMBOL c. MONTH & YEAR

b. TOTAL VERIFIED CORRECT FOR CHARGE TO APPROPRIATION $
Certifier's Initials:

16. THIS VOUCHER IS CERTIFIED CORRECT AND PROPER FOR PAYMENT

AUTHORIZED CERTIFYING OFFICIAL SIGN HERE ▶ DATE

c. APPLIED TO TRAVEL ADVANCE (Appropriation symbol): $

d. NET TO TRAVELER ▶ $

18. ACCOUNTING CLASSIFICATION

1012-116 NSN 7540-00-634-4180 STANDARD FORM 1012 (REV. 10-77) Prescribed by GSA, FPMR (41 CFR) 101-7

MIF 000071

DEPARTMENT OF HEALTH AND HUMAN SERVICES

TRAVEL ORDER

D-51761

2. APPROPRIATION NO.

☒ Original ☐ Amendment No. _____ ☐ Cancellation
(See HHS Travel Manual, Part 3, for Detailed Instructions)

3. ESTIMATED COST

	TO DHHS	TO OTHERS
TRAVEL	$ 405.00	$
PER DIEM	200.00	
OTHER	150.00	
TOTAL	$ 755.00	$

4. NAME AND POSITION OR RANK (Member-F&M)

vian Lewis, M.D.

5. SSAN

6. CONSTITUENT/BUREAU/DIVISION/REGION

A/CDER (HFD-21)

7. PRESENT OFFICIAL STATION

ckville, MD

8. APPROX. DATE OF DEPARTURE

07/18/96

9. APPROX. DATE OF RETURN

07/19/96

10. ITINERARY AND PURPOSE OF TRAVEL (Show city, state or country, dates and reasons—use continuation sheet if necessary)

proceed Rochester, NY to Rockville, MD and return.

rpose: To attend and participate in the July 19,1996 meeting of the Reproductive Health Drugs Advisory Committee.

ysock 3-5455

11. SPECIAL AUTHORIZATIONS

TRAVEL BY PRIVATELY OWNED AUTO IS AUTHORIZED ON MILEAGE BASIS RATE SPECIFIED BELOW FOR: ☐ EMPLOYEE AND/OR ☐ DEPENDENTS

0.00¢ PER MILE AS MORE ADVANTAGEOUS TO GOVT | 0.00¢ PER MILE NOT TO EXCEED COMMON CARRIER COSTS | 0.00¢ PER MILE NOT TO EXCEED COSTS BY GOVT-OWNED AUTO

☐ GSA AUTO ☒ AUTO RENTAL UNDER GSA CONTR ☐ OTHER (Specify below)

☐ EXCESS BAGGAGE ☐ REGISTRATION FEE taxi,limos,etc

11A. CHANGE OF STATION

TRANSPORTATION OF ☐ DEPENDENTS ☐ H/H GOODS & PERS. EFFECTS

☐ TEMPORARY QTRS ☐ RESIDENCE TRANSACTIONS ☐ TEMPORARY STORAGE

☐ HOUSE HUNTING TRIP ☐ MISC. EXP. ALLOWANCE ☐ OTHER (Specify)

HHS 355: ☐ SIGNED ☐ NOT REQUIRED

13. FOREIGN TRAVEL

TRAVEL & PER DIEM IS AUTHORIZED IN ACCORDANCE WITH DHHS POLICY AND:

☐ FTRs ☐ JTR'S ☐ OTHER (Specify)

PER DIEM: ☐ NONE ☒ IN U.S. ☐ OUTSIDE U.S. ☐ VARYING RATES PER ABOVE REGS.

RATE $ 162.00 ☒ LODGINGS PLUS ☐ ACTUAL EXPENSE ☐ FIXED

L=$124.00 M&IE=$38

TO BE PERFORMED FOR (DHHS, UN, etc.)

EXPENSES TO BE PAID BY

SECURITY APPROVAL GRANTED FOR TRAVEL OF

☐ 90 DAYS OR LESS ☐ OVER 90 DAYS DATE _____

RESPONSIBLE FOR SECURITY CLEARANCE OF TRAVELER ASSUMED BY:

12. ACCOUNTING DATA (See HHS Acct'g Manual & Acct'g Code Book)

2-7 EFF DATE	8-10 TRANSACTION CODE	11 REVERSE CODE	12 MODIFIER	ORIGINAL OBLIGATION 13-15 DOC. REF. CODE	ORIGINAL OBLIGATION 16-25 DOCUMENT NO.	OTHER DOCUMENTS 26-27 DOC. REF. CODE	OTHER DOCUMENTS 28-38 DOCUMENT NO.	39 GEO. CODE	40 FISCAL YEAR	41-47 COMMON ACCOUNTING NO.	48-51 OBJ. CLASS CODE	52-63 AMOUNT DOLLARS & CENTS	64 FED/NON FED	65-79 VENDOR/ CUSTOMER CODE (PRIMARY RECIPIENT)	95-100 PAYMENT COLLECTION DOC.	101-106 PPBS CATEGORY	107-108 PPBS ACTIVITIES	109 CASE #
				130					6	6992862 D-51761	2135	755.00	1					2

14. NAME AND TITLE OF OFFICIAL RECOMMENDING ABOVE TRAVEL

SGE Programs Officer 6/26/96 FUNDS ARE AVIALABLE

AUTHORITY IS HEREBY GRANTED TO PERFORM TRAVEL AND TO INCUR SUCH EXPENSES AS MAY BE NECESSARY UNDER THE CONDITIONS SET FORTH ABOVE.

AUTHORIZED BY _____ TITLE: Senior Management Officer

DATE: 6/28/96

To be completed by Office Initiating Travel Order; Other Accounting Data to be Completed by Fiscal/Accounting Office.

HHS-1 (REV. 6/86)

TRAVELER FISCAL-ACCOUNTING TELETICKETING FISCAL-AUDIT ADVANCE OF FUNDS TRAVEL UNIT ORIGINATING OFFICE SECURITY REPRESENTATIVE

MIF 000072

TRAVEL ORDER

2. APPROPRIATION NO. D-51761

☐ Original ☒ Amendment No. _____ ☐ Cancellation
(See HHS Travel Manual, Part 3, for Detailed Instructions)

3. ESTIMATED COST*

	TO DHHS	TO OTHERS
TRAVEL	$ 106.00	$
PER DIEM		
OTHER		
TOTAL	$ 106.00	$

4. NAME AND POSITION OR RANK (Member-F&M)
ivian Lewis, M.D.

5. SSAN

6. CONSTITUENT/BUREAU/DIVISION/REGION

7. APPROX. DATE OF DEPARTURE
07/18/96

8. PRESENT OFFICIAL STATION
ockville,Maryland

9. APPROX. DATE OF RETURN
07/19/96

10. ITINERARY AND PURPOSE OF TRAVEL (Show city, state or country, dates and reasons—use continuation sheet if necessary)

mend to increase travel from $405.00 to $511.00 for increase of $106.00.
otal increase of $106.00.

rysock 3-5455

11. SPECIAL AUTHZTN

TRAVEL BY PRIVATELY OWNED AUTO IS AUTHORIZED ON MILEAGE BASIS RATE SPECIFIED BELOW FOR: ☐ EMPLOYEE AND/OR ☐ DEPENDENTS

___¢ PER MILE AS MORE ADVANTAGEOUS TO GOVT ___¢ PER MILE NOT TO EXCEED COMMON CARRIER COSTS ___¢ PER MILE NOT TO EXCEED COSTS BY GOVT-OWNED AUTO

☐ GSA AUTO ☐ AUTO RENTAL UNDER GSA CONTR ☐ OTHER (Specify below)

☐ EXCESS BAGGAGE ☐ REGISTRATION FEE

11A. CHANGE OF STATION

TRANSPORTATION OF ☐ DEPENDENTS ☐ H/H GOODS & PERS. EFFECTS

☐ TEMPORARY QTRS ☐ RESIDENCE TRANSACTIONS ☐ TEMPORARY STORAGE

☐ HOUSE HUNTING TRIP ☐ MISC. EXP. ALLOWANCE ☐ OTHER (Specify)

HHS 355: ☐ SIGNED ☐ NOT REQUIRED

12. TRAVEL & PER DIEM IS AUTHORIZED IN ACCORDANCE WITH DHHS POLICY AND:

☐ FTRs ☐ JTR'S ☐ OTHER (Specify)

PER DIEM: ☐ NONE ☐ IN U.S. ☐ OUTSIDE U.S. ☐ VARYING RATES PER ABOVE REGS.

RATE $_____ ☐ LODGINGS PLUS ☐ ACTUAL EXPENSE ☐ FIXED

13. FOREIGN TRAVEL

TO BE PERFORMED FOR (DHHS, UN, etc.)

EXPENSES TO BE PAID BY

SECURITY APPROVAL GRANTED FOR TRAVEL OF

☐ 90 DAYS OR LESS ☐ OVER 90 DAYS DATE _____

RESPONSIBLE FOR SECURITY CLEARANCE OF TRAVELER ASSUMED BY:

14. ACCOUNTING DATA (See HHS Acct'g Manual & Acct'g Code Book)

1 RECORD TYPE	2-7 EFF DATE	8-10 TRANSACTION CODE	11 REVERSE CODE	12 MODIFIER	ORIGINAL OBLIGATION 13-15 DOC. REF. CODE	ORIGINAL OBLIGATION 16-25 DOCUMENT NO.	OTHER DOCUMENTS 26-28 DOC. REF. CODE	OTHER DOCUMENTS 29-38 DOCUMENT NO.	39 GEO. CODE	40 FISCAL YEAR	41-47 COMMON ACCOUNTING NO.	48-51 OBJ. CLASS CODE	52-63 AMOUNT DOLLARS & CENTS	64 FED/NON FED	65-79 VENDOR/ CUSTOMER CODE (PRIMARY RECIPIENT)	95-100 PAYMENT COLLEC-TION DOC.	101-106 PPBS CATE-GORY	107-108 PPBS ACTIV-ITIES	109 CASE #
2					130					6	6992862 D-51761	2135	106.00	1					2
2																			
2																			
2																			

15. FUNDS ARE AVAILABLE

AUTHORITY IS HEREBY GRANTED TO PERFORM TRAVEL AND SUCH EXPENSES AS MAY BE NECESSARY UNDER THE CONDITIONS SET FORTH ABOVE.

AUTHORIZED BY _____ TITLE: Senior Management Officer

DATE: 8/19/96

* To be completed by Office Initiating Travel Order; Other Accounting Data to be Completed by Fiscal/Accounting Office.

HHS-1 (REV. 8/86)

TRAVELER FISCAL-ACCOUNTING TELETICKETING FISCAL-AUDIT ADVANCE OF FUNDS TRAVEL UNIT ORIGINATING OFFICE SECURITY REPRESENTATIVE

GAITHERSBURG Marriott.
WASHINGTONIAN CENTER
9751 Washingtonian Boulevard, Gaithersburg, Maryland 20878 (301) 590-0044 Fax: (301) 212-6155

For your protection we have NOT used a credit card receipt on this express check out. Please accept this statement as a receipt. Any additional charges will be added to the total amount charged to your credit card. If you need an updated receipt or credit card voucher, please stop by the Front Desk. Thank you.

GUEST FOLIO

606 LEWIS/VIVIAN/DR 110.71 07/19/96 09:35 ACCT# 7739
ROOM NAME RATE DEPART TIME
NSKG 07/18/96 20:08
TYPE ARRIVE TIME GROUP 5082 /0599

HG#:

ROOM CLERK ADDRESS PAYMENT

DATE	REFERENCE	CHARGES	CREDITS	BALANCE DUE
07/18	JW STEAK 1278 606	27.00		
07/18	ROOM. 606, 1	110.71		
07/18	STATE TX 606, 1	5.54		
07/18	CITY TAX 606, 1	7.75		
07/19	ROOMSERV 2770 606	9.23		
07/19	CCARD-BK ROOM C/O		160.23	
	PAYMENT RECEIVED BY MASTERCARD			.00

GAITHERSBURG Marriott.
WASHINGTONIAN CENTER

9751 Washingtonian Boulevard
Gaithersburg, Maryland 20878
(301) 590-0044 Fax: (301) 212-6155

This statement is your only receipt. You have agreed to pay in cash or by approved personal check or to authorize us to charge your credit card for all amounts charged to you. The amount shown in the credits column opposite any credit card entry in the reference column above will be charged to the credit card number set forth above. (The credit card company will bill in the usual manner.) If for any reason the credit card company does not make payment on this account, you will owe us such amount. If you are direct billed, in the event payment is not made within 25 days after check-out, you will owe us interest from the check-out date on any unpaid amount at the rate of 1.5% per month (ANNUAL RATE 18%), or the maximum allowed by law, plus the reasonable cost of collection, including attorney fees.

Signature X _____

2955 For Reservations At Any Marriott Hotel Call 1-800-228-9290

TRAVEL VOUCHER

(Read the Privacy Act Statement on the back)

1. DEPARTMENT OR ESTABLISHMENT, BUREAU, DIVISION OR OFFICE: DHHS/FDA/CDER/HFD-21

2. TYPE OF TRAVEL: [X] TEMPORARY DUTY [ ] PERMANENT CHANGE OF STATION

3. VOUCHER NO.

4. SCHEDULE NO.

5a. NAME (Last, first, middle initial): DEBORAH NARRIGAN

5b. SOCIAL SECURITY NO.

5c. MAILING ADDRESS

5d. OFFICE TELEPHONE NO.

6. PERIOD OF TRAVEL: a. FROM 07/18/96 b. TO 07/20/96

7. TRAVEL AUTHORIZATION: a. NUMBER(S) D-51754 b. DATE(S)

8a. PRESENT DUTY STATION: Rockville, MD

8b. RESIDENCE (City and State)

10. CHECK NO.

TRAVEL ADVANCE
- Outstanding
- Amount to be applied
- Amount due Government (Attached: [ ] Check [ ] Cash)
- Balance outstanding

9. CASH PAYMENT RECEIPT
- a. DATE RECEIVED
- b. AMOUNT RECEIVED $
- c. PAYEE'S SIGNATURE

11. PAID BY

FILE COPY

12. GOVERNMENT TRANSPORTATION REQUESTS, OR TRANSPORTATION TICKETS, IF PURCHASED WITH CASH (List by number below and attach passenger coupon; if cash is used show claim on reverse side.)

I hereby assign to the United States any right I may have against any parties in connection with reimbursable transportation charges described below, purchased under cash payment procedures (FPMR 101-7) ▶ Traveler's Initials

AGENT'S VALUATION OF TICKET (a)	ISSUING CARRIER (Initials) (b)	MODE, CLASS OF SERVICE AND ACCOMMODATIONS (c)	DATE ISSUED (d)	POINTS OF TRAVEL FROM (e)	POINTS OF TRAVEL TO (f)
B-4,699,179	$371.00	US	Contract	Lexington, KY	Washington, D.C. and return

Prysock 3-5455

13. I certify that this voucher is true and correct to the best of my knowledge and belief, and that payment or credit has not been received for me. When applicable, per diem claimed is based on the average cost of lodging incurred during the period covered by this voucher.

TRAVELER SIGN HERE ▶ [signature] DATE 7/26/96 AMOUNT CLAIMED ▶ $ 328.58

NOTE: Falsification of an item in an expense account works a forfeiture of claim (28 U.S.C. 2514) and may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 287; i.d. 1001).

14. This voucher is approved. Long distance telephone calls, if any, are certified as necessary in the interest of the Government. (NOTE: If long distance telephone calls are included, the approving official must have been authorized in writing by the head of the department or agency to so certify (31 U.S.C. 680a).)

APPROVING OFFICIAL SIGN HERE ▶ [signature] DATE 9-10-96

Programs Officer

15. LAST PRECEDING VOUCHER PAID UNDER SAME TRAVEL AUTHORIZATION
- a. VOUCHER NO.
- b. D.O. SYMBOL
- c. MONTH & YEAR

16. THIS VOUCHER IS CERTIFIED CORRECT AND PROPER FOR PAYMENT

AUTHORIZED CERTIFYING OFFICIAL SIGN HERE ▶ DATE

17. FOR FINANCE OFFICE USE ONLY COMPUTATION
- a. DIFFERENCES, IF ANY (Explain and show amount) $
- b. TOTAL VERIFIED CORRECT FOR CHARGE TO APPROPRIATION (Certifier's initials) $
- c. APPLIED TO TRAVEL ADVANCE (Appropriation symbol): $
- d. NET TO TRAVELER ▶ $

18. ACCOUNTING CLASSIFICATION

1012-116 NSN 7540-00-634-4180 STANDARD FORM 1012 (REV. 10-77) Prescribed by GSA, FPMR (41 CFR) 101-7

MIF 000075

EDULE

ENSES
)
OUNTS
IMED

Col. (c) If the voucher includes per diem allowances for members of employee's immediate family, show members' names, ages, and relationship to employee and marital status of children (unless information is shown on the travel authorization.)

Complete only for actual expense travel

Col. (d) thru (g) Show amount incurred for each meal, including tax and tips, and daily ... meal cost

(h) Show expenses, such as laundry, cleaning and pressing of clothes, tips to bellboys, porters, etc (other than for meals).

(i) Complete for per diem and actual expense travel.

(j) Show total subsistence expense incurred for actual expense travel.

(m) Show per diem amount, limited to maximum rate, or if travel on actual expense, show the lesser of the amount from col. (j) or maximum rate.

(n) Show expenses, such as taxi/limousine fares, air fare (if purchased with cash), local or long distance telephone calls for Government business, car rental, relocation other than subsistence, etc.

If this is a continuation of ... sheet. PAGES

TRAVEL AUTHORIZATION NO.

TRAVELER'S LAST NAME

TE	TIME (Hour and am/pm) (b)	DESCRIPTION (Departure/arrival city, per diem computation, or other explanations of expense) (c)	ITEMIZED SUBSISTENCE EXPENSES: MEALS: BREAKFAST (d)	LUNCH (e)	DINNER (f)	TOTAL (g)	MISCELLANEOUS SUBSISTENCE (h)	LODGING (i)	TOTAL SUBSISTENCE EXPENSE (j)	MILEAGE RATE: ¢ NO. OF MILES (k)	AMOUNT CLAIMED: MILEAGE (l)	SUBSISTENCE (m)	OTHER (n)
18	2:00p	LvLexington,KY											
	5:00p	Ar:Washington,D.C.											
20	8:50p	Lv:Washington,D.C.											
	1:30p	Ar:Lexington,KY											
8		Meals				19 00							
		Lodging						124 00	143 00			143 00	
19		Meals				38 00							
		Lodging						71 68	109 68			109 68	
20		Meals				28 50			28 50			28 50	
18		Taxi:Airpt-Motel											20 00
		Airport Parking											15 00
18		POA Resid-Airpt (21 miles)								21	6 51		
20		POA Airpt-Resid (19 miles)								19	5 89		
									SUBTOTALS ▶				
									TOTALS ▶		12 40	281 18	35 00

Additional space is required, continue on another SF 1012-A BACK, leaving the front blank.

Enter grand total of columns (l), (m) and (n), below and in item 13 on the front of this form.

TOTAL AMOUNT CLAIMED ▶ $328.58

Compliance with the Privacy Act of 1974, the following information is provided: Solicitation of the information on this form is authorized by 5 U.S.C. 57 as implemented by the Federal Travel Regulations (FPMR 101-7), 11609 of July 22, 1971, E.O. 11012 of March 27, 1962, E.O. 9397 of ...ember 22, 1943, and 26 U.S.C. 6011(b) and 6109. The primary purpose the requested information is to determine payment or reimbursement to ...ate individuals for allowable travel and/or relocation expenses incurred ...er appropriate administrative authorization and to record and maintain ...s of such reimbursements to the Government. The information will be ...d by officers and employees who have a need for the information in the ...rmance of their official duties. The information may be disclosed to ...opriate Federal, State, local or foreign agencies, when relevant to civil, criminal, or regulatory investigations or prosecutions, or when pursuant to a requirement by this agency in connection with the hiring or firing of an employee, the issuance of a security clearance, or investigations of the performance of official duty while in Government service. Your Social Security Account Number (SSN) is solicited under the authority of the Internal Revenue Code (26 U.S.C. 6011(b) and 6109) and E.O. 9397, November 22, 1943, for use as a tax payer and/or employee identification number. Disclosure is MANDATORY on vouchers claiming travel and/or relocation allowance expense reimbursement which is, or may be, taxable income. Disclosure of your SSN and other requested information is voluntary in all other instances, however, failure to provide the information (other than SSN) required to support the claim may result in delay or loss of reimbursement.

...(Rev. 10-77)

STANDARD FORM 1012 BACK (10-77)

Deborah Narrigan 7/12/96 mtg.

TRAVEL EXPENSES - TALLY SHEET

Day of Departure: Date: 7/12/96 Time: Dep 2p am/(pm) Arr 5p am/(pm)

Name of Air Carrier US Air Private Auto _____ Train _____
Airfare $371.00 Trainfare $_____ (SUBMIT AIRFARE/TRAIN RECEIPT and BUFF COPY OF GTR)

Privately Owned Auto (POA) Odometer Readings:
(Computed at 30¢ per mile) *(please see reverse) _____ Starting Mileage _____ Final Destination

Taxis/Limos: Office/Residence to Airport (SUBMIT RECEIPT).....$_____

Taxis/Limos: Airport to Motel/Meeting Place (SUBMIT RECEIPT).....$ 20.00

Lodgings: (SUBMIT RECEIPT).....$ 269.82

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$ —

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$ —

POA Odometer Readings: From Motel to Meeting Place
(Computed at 30¢ per mile) _____ Starting Mileage _____ Ending Mileage

---

For Additional Day OTHER THAN Day of Return: Date:_____

Lodgings: (SUBMIT RECEIPT).....$_____

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$_____

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$_____

For Additional Day OTHER THAN Day of Return: Date:_____

Lodgings: (SUBMIT RECEIPT).....$_____

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$_____

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$_____

Day of Return: Date 7/26/96 Time Dep 8:55 (am)/pm Ar

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPA

Taxis/Limos: Motel to Meeting Place (SUBMIT RECEIPT).....

Taxis/Limos: Meeting Place to Airport (SUBMIT RECEIPT).....

Taxis/Limos: Airport to Residence (SUBMIT RECEIPT).....

POA: Airport Parking: (SUBMIT RECEIPT).....

POA: Odometer Readings: From Airport to Residence _____
(Computed at 30¢ per mile) Starting Mileage

Tolls:
(Name individually and submit receipts)

To Meeting Place	Amount	From

Note:
This Tally Sheet is to be returned to the Office of Advisors and Consultan
your travel voucher with current address and signature, buff copy of trans
ticket receipt and any other receipts (i.e., airport parking, taxis, tolls, shut
can not be honored unless hotel receipt is submitted with travel expenses. To obtain reimbursement for official telephone calls please complete the following:

Telephone Calls Made for FDA Official Business: (only if FTS services are not available)

Date	Calling No.	No. Called	Person	Topic	Amount

* Special circumstances for travel -
I was, at the time of the mtg, working in Hyden, Ky. I drove a rental car 130 mi (one way) to and from Lexington Ky Airport ("Blue Grass Fld. I would like to be reimbursed for gas (or mileage) and parking at that airport from 7/18-7/26, for $15.00 Receipts for both costs are attach.
Thank you DN.

Submitted By: _____ 7/19/96
Signature and Date Please Meeting Date

HEDULE

PENSES
ID
IOUNTS
AIMED

Col. (c) If the voucher includes per diem allowances for members of employee's immediate family, show members' names, ages, and relationship to employee and marital status of children (unless information is shown on the travel authorization.)

Complete only for actual expense travel

Col. (d) thru (g) Show amount incurred for each meal, including tax and tips, and daily total meal cost

(h) Show expenses, such as laundry, cleaning and pressing of clothes, tips to bellboys, porters, etc. (other than for meals).

(i) Complete for per diem and actual expense travel.

(j) Show total subsistence expense incurred for actual expense travel.

(m) Show per diem amount, limited to maximum rate, or if travel on actual expense, show the lesser of the amount from col. (j) or maximum rate.

(n) Show expenses, such as taxi/limousine fares, air fare (if purchased with cash), local or long distance telephone calls for Government business, car rental, relocation other than subsistence, etc.

If this is a continuation sheet. ____ OF ____ PAGES

TRAVEL AUTHORIZATION NO.

TRAVELER'S LAST NAME

ATE	TIME	DESCRIPTION	ITEMIZED SUBSISTENCE EXPENSES							MILEAGE RATE: ¢	AMOUNT CLAIMED		
			MEALS				MISCELLANEOUS SUBSISTENCE	LODGING	TOTAL SUBSISTENCE EXPENSE	NO. OF MILES	MILEAGE	SUBSISTENCE	OTHER
a)	(b)	(c)	BREAKFAST (d)	LUNCH (e)	DINNER (f)	TOTAL (g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)
/18	5:20p	Lv:Rochester,NY											
	6:30p	Ar:Washington,D.C.											
/19	9:00p	Lv:Washington,D.C.											
	10:30p	Ar:Rochester,NY											
/18		Meals				19 00							
		Lodging						124 00	143 00			143 00	
/19		Measl				38 00			38 00			38 00	
/18		Taxi:Airpt-Motel (receipt attached)											52 00
/19		Taxi:Mtg-Airpt (receipt attached)											20 00
		Airport Parking											15 00

additional space is required, continue on another SF 1012-A BACK, leaving the front blank.

SUBTOTALS ▶

TOTALS ▶ 181 00 | 87 00

Enter grand total of columns (l), (m) and (n), below and in item 13 on the front of this form.

TOTAL AMOUNT CLAIMED ▶ $268.00

...compliance with the Privacy Act of 1974, the following information is provided. Solicitation of the information on this form is authorized by 5 U.S.C. ... 57 as implemented by the Federal Travel Regulations (FPMR 101-7), ... 11609 of July 22, 1971, E.O. 11012 of March 27, 1962, E.O. 9397 of ...ovember 22, 1943, and 26 U.S.C. 6011(b) and 6109. The primary purpose ...f the requested information is to determine payment or reimbursement to ...igible individuals for allowable travel and/or relocation expenses incurred ...under appropriate administrative authorization and to record and maintain ...osts of such reimbursements to the Government. The information will be ...used by officers and employees who have a need for the information in the ...performance of their official duties. The information may be disclosed to ...appropriate Federal, State, local or foreign agencies, when relevant to civil, criminal, or regulatory investigations or prosecutions, or when pursuant to a requirement by this agency in connection with the hiring or firing of an employee, the issuance of a security clearance, or investigations of the performance of official duty while in Government service. Your Social Security Account Number (SSN) is solicited under the authority of the Internal Revenue Code (26 U.S.C. 6011(b) and 6109) and E.O. 9397, November 22, 1943, for use as a tax payer and/or employee identification number, disclosure is MANDATORY on vouchers claiming travel and/or relocation allowance expense reimbursement which is, or may be, taxable income. Disclosure of your SSN and other requested information is voluntary in all other instances, however, failure to provide the information (other than SSN) required to support the claim may result in delay or loss of reimbursement.

TRAVEL EXPENSES - TALLY SHEET

Day of Departure: Date: July 18 Time: Dep 5:20 am/pm Arr 6:30 am/pm

Name of Air Carrier US Air Private Auto _____ Train _____
Airfare$ 511 Trainfare$ _____ (SUBMIT AIRFARE/TRAIN RECEIPT and BUFF COPY OF GTR)

Privately Owned Auto (POA) Odometer Readings:
(Computed at 30¢ per mile) Starting Mileage _____ Final Destination _____

Taxis/Limos: Office/Residence to Airport (SUBMIT RECEIPT).....$_____

Taxis/Limos: Airport to Motel/Meeting Place (SUBMIT RECEIPT).....$ 52

Lodgings: (SUBMIT RECEIPT).....$ 124

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.) ~~27~~ 22

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$ ✓

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$ ✓

POA Odometer Readings: From Motel to Meeting Place
(Computed at 30¢ per mile) Starting Mileage _____ Ending Mileage _____

For Additional Day OTHER THAN Day of Return: Date:_____

Lodgings: (SUBMIT RECEIPT).....$_____

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$_____

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$_____

For Additional Day OTHER THAN Day of Return: Date:_____

Lodgings: (SUBMIT RECEIPT).....$_____

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$_____

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$_____

Day of Return: Date: 7-19-96 Time: Dep 900 am/pm Arr 1030 am/pm

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxis/Limos: Motel to Meeting Place (SUBMIT RECEIPT)..... $_____

Taxis/Limos: Meeting Place to Airport (SUBMIT RECEIPT)..... $ 20

Taxis/Limos: Airport to Residence (SUBMIT RECEIPT)..... $_____

POA: Airport Parking: (SUBMIT RECEIPT)..... $ 15

POA: Odometer Readings: From Airport to Residence
(Computed at 30¢ per mile) _____ Starting Mileage _____ Final Destination

Tolls: (Name individually and submit receipts)	To Meeting Place	Amount	From Meeting Place	Amount

Note:
This Tally Sheet is to be returned to the Office of Advisors and Consultants at completion of travel along with your travel voucher with current address and signature, buff copy of transportation request (GTR) and airline ticket receipt and any other receipts (i.e., airport parking, taxis, tolls, shuttle, hotel receipt, & etc.). Your travel can not be honored unless hotel receipt is submitted with travel expenses. To obtain reimbursement for official telephone calls please complete the following:

Telephone Calls Made for FDA Official Business: (only if FTS services are not available)

Date	Calling No.	No. Called	Person	Topic	Amount

Submitted By: _____ 7-19-96
Signature and Date Please Meeting Date

TRAVEL ORDER

D-51754

☒ Original ☐ Amendment No. _____ ☐ Cancellation
(See HHS Travel Manual, Part 3, for Detailed Instructions)

2. APPROPRIATION NO.

3. ESTIMATED COST

	TO DHHS	TO OTHERS
TRAVEL	$ 425.00	$
PER DIEM	200.00	
OTHER	150.00	
TOTAL	$ 775.00	$

NAME AND POSITION OR RANK (Member-F&M)

eborah L. Narrigan, M.S.N., C.N.M.

5. SSAN

CONSTITUENT/BUREAU/DIVISION/REGION

DA/CDER (HFD-21)

8. APPROX. DATE OF DEPARTURE
07/18/96

PRESENT OFFICIAL STATION

ockville, MD

9. APPROX. DATE OF RETURN
07/19/96

8. ITINERARY AND PURPOSE OF TRAVEL (Show city, state or country, dates and reasons—use continuation sheet if necessary)

'o proceed Nashville, TN to Rockville, MD and return.

urpose: To attend and participate in the July 19,1996 meeting of the Reproductive Health Drugs Advisory Committee.

'rysock 3-5455

11. SPECIAL AUTHZTN

TRAVEL BY PRIVATELY OWNED AUTO IS AUTHORIZED ON MILEAGE BASIS RATE SPECIFIED BELOW FOR: ☐ EMPLOYEE AND/OR ☐ DEPENDENTS

0.00¢ PER MILE AS MORE ADVANTAGEOUS TO GOVT | 0.00¢ PER MILE NOT TO EXCEED COMMON CARRIER COSTS | 0.00¢ PER MILE NOT TO EXCEED COSTS BY GOVT-OWNED AUTO

☐ GSA AUTO ☒ AUTO RENTAL UNDER GSA CONTR ☐ OTHER (Specify below)

☐ EXCESS BAGGAGE ☐ REGISTRATION FEE taxi,limos,etc

11A. CHANGE OF STATION

TRANSPORTATION OF ☐ DEPENDENTS ☐ H/H GOODS & PERS. EFFECTS

☐ TEMPORARY QTRS ☐ RESIDENCE TRANSACTIONS ☐ TEMPORARY STORAGE

☐ HOUSE HUNTING TRIP ☐ MISC. EXP. ALLOWANCE ☐ OTHER (Specify)

HHS 355: ☐ SIGNED ☐ NOT REQUIRED

12. TRAVEL & PER DIEM IS AUTHORIZED IN ACCORDANCE WITH DHHS POLICY AND:

☐ FTRs ☐ JTR'S ☐ OTHER (Specify)

PER DIEM: ☐ NONE ☒ IN U.S. ☐ OUTSIDE U.S. ☐ VARYING RATES PER ABOVE REGS.

RATE $ 162.00 ☒ LODGINGS PLUS ☐ ACTUAL EXPENSE ☐ FIXED

L=$124.00 M&IE=$38

13. FOREIGN TRAVEL

TO BE PERFORMED FOR (DHHS, UN, etc.)

EXPENSES TO BE PAID BY

SECURITY APPROVAL GRANTED FOR TRAVEL OF

☐ 90 DAYS OR LESS ☐ OVER 90 DAYS DATE _____

RESPONSIBLE FOR SECURITY CLEARANCE OF TRAVELER ASSUMED BY:

14. ACCOUNTING DATA (See HHS Acct'g Manual & Acct'g Code Book)

1 RECORD TYPE	2-7 EFF DATE	8-10 TRANSACTION CODE	11 REVERSE CODE	12 MODIFIER	ORIGINAL OBLIGATION 13-15 DOC. REF. CODE	ORIGINAL OBLIGATION 16-25 DOCUMENT NO.	OTHER DOCUMENTS 26-28 DOC. REF. CODE	OTHER DOCUMENTS 29-38 DOCUMENT NO.	39 GEO. CODE	40 FISCAL YEAR	41-47 COMMON ACCOUNTING NO.	48-51 OBJ. CLASS CODE	52-63 AMOUNT DOLLARS & CENTS	64 FED/NON FED	65-79 VENDOR/ CUSTOMER CODE (PRIMARY RECIPIENT)	95-100 PAYMENT COLLEC-TION DOC.	101-106 PPBS CATE-GORY	107-108 PPBS ACTIV-ITIES	109 CABLE #
2					130					6	6992862 D-51754	2135	775.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF OFFICER ... TRAVEL

SGE Programs Officer 6/21/96 FUNDS ARE AVIALABLE

AUTHORITY IS HEREBY GRANTED TO PERFORM TRAVEL AND TO INCUR SUCH EXPENSES AS MAY BE NECESSARY UNDER THE CONDITIONS SET FORTH ABOVE.

AUTHORIZED _____ TITLE: Senior Management Officer

DATE: 6/28/96

To be completed by Office initiating Travel Order; Other Accounting Data to be Completed by Fiscal/Accounting Office.

HHS-1 (REV. 8/86)

TRAVELER FISCAL-ACCOUNTING TELETICKETING FISCAL-AUDIT ADVANCE OF FUNDS TRAVEL UNIT ORIGINATING OFFICE SECURITY REPRESENTATIVE

MIF 000082

DEPARTMENT OF HEALTH AND HUMAN SERVICES

TRAVEL ORDER

D-51754

☐ Original ☒ Amendment No. _____ ☐ Cancellation
(See HHS Travel Manual, Part 3, for Detailed Instructions)

2. APPROPRIATION NO.

4. NAME AND POSITION OR RANK (Member-F&M)
Deborah L. Narrigan, M.S.N., C.N.M.

5. SSAN

3. ESTIMATED COST*

	TO DHHS	TO OTHERS
TRAVEL	$ 425.00	$
PER DIEM	200.00	
OTHER	150.00	
TOTAL	$ 775.00	$

6. CONSTITUENT/BUREAU/DIVISION/REGION
FDA/CDER (HFD-21)

8. APPROX. DATE OF DEPARTURE
07/18/96

7. PRESENT OFFICIAL STATION
Rockville, MD

9. APPROX. DATE OF RETURN
07/19/96

10. ITINERARY AND PURPOSE OF TRAVEL (Show city, state or country, dates and reasons—use continuation sheet if necessary)

Amend travel to Lexington, KY to Rockville, MD and return.

Prysock 3-5455

11. SPECIAL AUTHZTN

TRAVEL BY PRIVATELY OWNED AUTO IS AUTHORIZED ON MILEAGE BASIS RATE SPECIFIED BELOW FOR: ☐ EMPLOYEE AND/OR ☐ DEPENDENTS

___¢ PER MILE AS MORE ADVANTAGEOUS TO GOVT ___¢ PER MILE NOT TO EXCEED COMMON CARRIER COSTS ___¢ PER MILE NOT TO EXCEED COSTS BY GOVT-OWNED AUTO

☐ GSA AUTO ☐ AUTO RENTAL UNDER GSA CONTR ☐ OTHER (Specify below)

☐ EXCESS BAGGAGE ☐ REGISTRATION FEE

11A. CHANGE OF STATION

TRANSPORTATION OF ☐ DEPENDENTS ☐ H/H GOODS & PERS. EFFECTS

☐ TEMPORARY QTRS ☐ RESIDENCE TRANSACTIONS ☐ TEMPORARY STORAGE

☐ HOUSE HUNTING TRIP ☐ MISC. EXP. ALLOWANCE ☐ OTHER (Specify)

HHS 355: ☐ SIGNED ☐ NOT REQUIRED

12. TRAVEL & PER DIEM IS AUTHORIZED IN ACCORDANCE WITH DHHS POLICY AND:

☐ FTRs ☐ JTR'S ☐ OTHER (Specify)

PER DIEM: ☐ NONE ☒ IN U.S. ☐ OUTSIDE U.S. ☐ VARYING RATES PER ABOVE REGS.

RATE $ 152.00 ☒ LODGINGS PLUS ☐ ACTUAL EXPENSE ☐ FIXED

L=$114 M&IE=$38

13. FOREIGN TRAVEL

TO BE PERFORMED FOR (DHHS, UN, etc.)

EXPENSES TO BE PAID BY

SECURITY APPROVAL GRANTED FOR TRAVEL OF ☐ 90 DAYS OR LESS ☐ OVER 90 DAYS DATE _____

RESPONSIBLE FOR SECURITY CLEARANCE OF TRAVELER ASSUMED BY:

14. ACCOUNTING DATA (See HHS Acct'g Manual & Acct'g Code Book)

1 RECORD TYPE	2-7 EFF DATE	8-10 TRANSACTION CODE	11 REVERSE CODE	12 MODIFIER	ORIGINAL OBLIGATION 13-15 DOC. REF. CODE	ORIGINAL OBLIGATION 16-25 DOCUMENT NO.	OTHER DOCUMENTS 26-28 DOC. REF. CODE	OTHER DOCUMENTS 29-38 DOCUMENT NO.	39 GEO. CODE	40 FISCAL YEAR	41-47 COMMON ACCOUNTING NO.	48-51 OBJ. CLASS CODE	52-63 AMOUNT DOLLARS & CENTS	64 FED/NON FED	65-79 VENDOR/ CUSTOMER CODE (PRIMARY RECIPIENT)	95-100 PAYMENT COLLEC-TION DOC.	101-106 PPBS 101-106 CATE-GORY	107-108 ACTIV-ITIES	109 CASE #
2					130					6	6992862 D-51754	2135	775.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF OFFICER [illegible] TRAVEL

SGE Programs Officer 7-3-96 FUNDS ARE AVAILABLE

AUTHORITY IS HEREBY GRANTED TO PERFORM TRAVEL AND TO INCUR SUCH EXPENSES AS MAY BE NECESSARY UNDER THE CONDITIONS SET FORTH ABOVE.

AUTHORIZED BY _____ TITLE: Senior Management Officer

DATE: 7/10/96

* To be completed by Office Initiating Travel Order; Other Accounting Data to be Completed by Fiscal/Accounting Office.

HHS-1 (REV. 8/86)

TRAVELER FISCAL-ACCOUNTING TELETICKETING FISCAL-AUDIT ADVANCE OF FUNDS TRAVEL UNIT ORIGINATING OFFICE SECURITY REPRESENTATIVE

MIF 000083

GAITHERSBURG Marriott.
WASHINGTONIAN CENTER
9751 Washingtonian Boulevard, Gaithersburg, Maryland 20878 (301) 590-0044 Fax: (301) 212-6155

For your protection we have NOT included a credit card receipt in this express check out. Please accept this statement as a receipt. Any additional charges will be added to the total amount charged to your credit card. If you need an updated receipt or credit card voucher, please stop by the Front Desk. Thank you.

GUEST FOLIO

827 NARRIGAN/DEBORAH — 64.00 — 07/20/96 — 07:44 — ACCT# 7745
ROOM — NAME — RATE — DEPART — TIME

NSKG — 07/18/96 — 19:40
TYPE — ARRIVE — TIME

/0798

HG#:

ROOM
CLERK

DATE	ADDRESS / REFERENCE	CHARGES	CREDITS	BALANCE DUE
07/18	JW STEAK 1277 827	35.14		
07/18	ROOM. 827, 1	110.71		
07/18	STATE TX 827, 1	5.54		
07/18	CITY TAX 827, 1	7.75		
07/19	JW STEAK 1440 827	46.69		
07/19	ROOM. 827, 1	64.00		
07/19	STATE TX 827, 1	3.20		
07/19	CITY TAX 827, 1	4.48		
07/20	CCARD-BK		277.51	
	PAYMENT RECEIVED BY VISA			.00

please apply the $38 daily allowance to this, please reimburse 1/2 of this total, ~~of $232.35~~

total reimbursable = 269.82

~~277.51~~

TRAVEL VOUCHER

(Read the Privacy Act Statement on the back)

1 DEPARTMENT, ESTABLISHMENT, BUREAU, DIVISION OR OFFICE: DHHS/FDA/CDER/HFD-21

2 TYPE OF TRAVEL: [X] TEMPORARY DUTY [ ] PERMANENT CHANGE OF STATION

3 VOUCHER NO.

4 SCHEDULE NO

5. TRAVELER (PAYEE)

a NAME (Last, first, middle initial): Davidson, Ezra

b SOCIAL SECURITY NO

c MAILING ADDRESS (Include ZIP Code):
Dept. of Obstetrics & Gynecology
Charles R. Drew Univ. of Med. + Science
1621 E. 120th Street
Los Angeles, CA 90059

d. OFFICE TELEPHONE NO

6. PERIOD OF TRAVEL
a FROM: 07/18/96
b TO: 07/20/96

7. TRAVEL AUTHORIZATION
a. NUMBER(S): D-51758
b. DATE(S)

e PRESENT DUTY STATION: Rockville, MD

f. RESIDENCE (City and State)

10. CHECK NO.

8. TRAVEL ADVANCE
a Outstanding
b Amount to be applied
c Amount due Government (Attached: [ ] Check [ ] Cash)
D. Balance outstanding

9. CASH PAYMENT RECEIPT
a. DATE RECEIVED
b. AMOUNT RECEIVED $
c. PAYEE'S SIGNATURE

11. PAID BY

FILE COPY

12. GOVERNMENT TRANSPORTATION REQUESTS, OR TRANSPORTATION TICKETS, IF PURCHASED WITH CASH (List by number below and attach passenger coupon; if cash is used show claim on reverse side.)

I hereby assign to the United States any right I may have against any parties in connection with reimbursable transportation charges described below, purchased under cash payment procedures (FPMR 101-7) ▶ Traveler's Initials

AGENT'S VALUATION OF TICKET (a)	ISSUING CARRIER (Initials) (b)	MODE, CLASS OF SERVICE AND ACCOMMODATIONS (c)	DATE ISSUED (d)	POINTS OF TRAVEL FROM (e)	POINTS OF TRAVEL TO (f)
B-4,699,167	AA	Contract		Los Angeles, CA	Washington, D.C. and return
$217.00					Approval granted for excessive ta: Fares.

Prysock 3-5455

13. I certify that this voucher is true and correct to the best of my knowledge and belief, and that payment or credit has not been received by me. When applicable, per diem claimed is based on the average cost of lodging incurred during the period covered by this voucher.

TRAVELER SIGN HERE ▶ _____ DATE _____ AMOUNT CLAIMED ▶ $ 440 08

NOTE: Falsification of an item in an expense account works a forfeiture of claim (28 U.S.C. 2514) and may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 287; i.d. 1001).

14. This voucher is approved. Long distance telephone calls, if any, are certified as necessary in the interest of the Government. (NOTE: If long distance telephone calls are included, the approving official must have been authorized in writing by the head of the department or agency to so certify (31 U.S.C. 680a).)

APPROVING OFFICIAL SIGN HERE ▶ _____ DATE 4-10-96

SGE Programs Officer

17. FOR FINANCE OFFICE USE ONLY COMPUTATION

a. DIFFERENCES, IF ANY (Explain and show amount) $

b. TOTAL VERIFIED CORRECT FOR CHARGE TO APPROPRIATION $
Certifier's initials:

c. APPLIED TO TRAVEL ADVANCE (Appropriation symbol): $

d. NET TO TRAVELER ▶ $

15. LAST PRECEDING VOUCHER PAID UNDER SAME TRAVEL AUTHORIZATION

a. VOUCHER NO. | b. D.O. SYMBOL | c. MONTH & YEAR

16. THIS VOUCHER IS CERTIFIED CORRECT AND PROPER FOR PAYMENT

AUTHORIZED CERTIFYING OFFICIAL SIGN HERE ▶ _____ DATE _____

18. ACCOUNTING CLASSIFICATION

1012-116 NSN 7540-00-634-4180 STANDARD FORM 1012 (REV. 10-77)
Prescribed by GSA, FPMR (41 CFR) 101-7

MIF 000085

TRAVEL EXPENSES - TALLY SHEET

Day of Departure: Date: 7-18-96 Time Dep 6 (am)/pm Arr 6 am/(pm)

Name of Air Carrier American Private Auto _____ Train _____
Airfare$_____ Trainfare$_____ (SUBMIT AIRFARE/TRAIN RECEIPT and BUFF COPY OF GTR)

Privately Owned Auto (POA) Odometer Readings: 5120 (Starting Mileage) 5140 (Final Destination)
(Computed at 30¢ per mile)

Taxis/Limos: Office/Residence to Airport (SUBMIT RECEIPT).....$ —

Taxis/Limos: Airport to Motel/Meeting Place (SUBMIT RECEIPT).....$ 52.00

Lodgings: (SUBMIT RECEIPT).....$ 124.00

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$ —

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$ —

POA Odometer Readings: From Motel to Meeting Place _____ (Starting Mileage) _____ (Ending Mileage)
(Computed at 30¢ per mile)

For Additional Day OTHER THAN Day of Return: Date: 7-19-96

Lodgings: (SUBMIT RECEIPT).....$ 71.68

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$ _____

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$ _____

For Additional Day OTHER THAN Day of Return: Date: _____

Lodgings: (SUBMIT RECEIPT).....$ _____

Meals: Flat rate of $38.00 (PRORATED BASED ON TIME OF DEPARTURE.)

Taxi: Motel to Meeting Place (SUBMIT RECEIPT).....$ _____

Taxi: Meeting Place to Motel (SUBMIT RECEIPT).....$ _____

DEPARTMENT OF HEALTH AND HU[illegible] SERVICES

TRAVEL ORDER

D-51758

2. APPROPRIATION NO.

☒ Original ☐ Amendment No. _____ ☐ Cancellation
(See HHS Travel Manual, Part 3, for Detailed Instructions)

3. ESTIMATED COST*

	TO DHHS	TO OTHERS
TRAVEL	$ 250.00	$
PER DIEM	200.00	
OTHER	150.00	
TOTAL	$ 600.00	$

NAME AND POSITION OR RANK (Member-F&M)

zra C. Davidson,Jr., M.D.

5. SSAN

CONSTITUENT/BUREAU/DIVISION/REGION

DA/CDER (HFD-21)

8. APPROX. DATE OF DEPARTURE
07/18/96

PRESENT OFFICIAL STATION

ockville, MD

9. APPROX. DATE OF RETURN
07/19/96

1. ITINERARY AND PURPOSE OF TRAVEL (Show city, state or country, dates and reasons—use continuation sheet if necessary)

o proceed Los Angeles, CA to Rockville, MD and return.

urpose: To attend and participate in the July 19,1996 meeting of the Reproductive Health Drugs Advisory Committee.

rysock 3-5455

11. SPECIAL AUTHZTN

TRAVEL BY PRIVATELY OWNED AUTO IS AUTHORIZED ON MILEAGE BASIS RATE SPECIFIED BELOW FOR: ☐ EMPLOYEE AND/OR ☐ DEPENDENTS

0.00¢ PER MILE AS MORE ADVANTAGEOUS TO GOVT

0.00¢ PER MILE NOT TO EXCEED COMMON CARRIER COSTS

0.00¢ PER MILE NOT TO EXCEED COSTS BY GOVT-OWNED AUTO

☐ GSA AUTO ☒ AUTO RENTAL UNDER GSA CONTR ☐ OTHER (Specify below)

☐ EXCESS BAGGAGE ☐ REGISTRATION FEE taxi,limos,etc

11A. CHANGE OF STATION

TRANSPORTATION OF ☐ DEPENDENTS ☐ H/H GOODS & PERS. EFFECTS

☐ TEMPORARY QTRS ☐ RESIDENCE TRANSACTIONS ☐ TEMPORARY STORAGE

☐ HOUSE HUNTING TRIP ☐ MISC. EXP. ALLOWANCE ☐ OTHER (Specify)

HHS 355: ☐ SIGNED ☐ NOT REQUIRED

12. FOREIGN TRAVEL

2. TRAVEL & PER DIEM IS AUTHORIZED IN ACCORDANCE WITH DHHS POLICY AND:

☐ FTRs ☐ JTR'S ☐ OTHER (Specify)

PER DIEM: ☐ NONE ☒ IN U.S. ☐ OUTSIDE U.S. ☐ VARYING RATES PER ABOVE REGS.

RATE $ 162.00 ☒ LODGINGS PLUS ☐ ACTUAL EXPENSE ☐ FIXED

L=$124.00 M&IE=$38

TO BE PERFORMED FOR (DHHS, UN, etc.)

EXPENSES TO BE PAID BY

SECURITY APPROVAL GRANTED FOR TRAVEL OF

☐ 90 DAYS OR LESS ☐ OVER 90 DAYS DATE _____

RESPONSIBLE FOR SECURITY CLEARANCE OF TRAVELER ASSUMED BY:

4. ACCOUNTING DATA (See HHS Acct'g Manual & Acct'g Code Book)

1 RECORD TYPE	2-7 EFF DATE	8-10 TRANSACTION CODE	11 REVERSE CODE	12 MODIFIER	ORIGINAL OBLIGATION 13-15 DOC. REF. CODE	ORIGINAL OBLIGATION 16-25 DOCUMENT NO.	OTHER DOCUMENTS 26-28 DOC. REF. CODE	OTHER DOCUMENTS 29-38 DOCUMENT NO.	39 GEO. CODE	40 FISCAL YEAR	41-47 COMMON ACCOUNTING NO.	48-51 OBJ. CLASS CODE	52-63 AMOUNT DOLLARS & CENTS	64 FED/NON FED	65-79 VENDOR/ CUSTOMER CODE (PRIMARY RECIPIENT)	95-100 PAYMENT COLLEC-TION DOC.	101-106 PPBS CATE-GORY	107-108 PPBS ACTIV-ITIES	109 CASE #
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15. NAME AND TITLE OF OFFICIAL PROGRAMMING [illegible] E TRAVEL

SGE Programs Officer 6/21/96 FUNDS ARE AVIALABLE

AUTHORITY IS HEREBY GRANTED TO PERFORM TRAVEL AND TO INCUR [illegible] MAY BE NECESSARY UNDER THE CONDITIONS SET FORTH ABOVE.

AUTH[illegible] TITLE: Senior Management Officer

DATE: 6/28/96

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HHS-1 (REV. 8/86)

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NSKG			07/18/96	18:40	
TYPE			ARRIVE	TIME	

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HG#: 066384546

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DATE	REFERENCE	CHARGES	CREDITS	BALANCE DUE
07/18	JW STEAK 1275 531	38.97		
07/18	ROOM. 531, 1	110.71		
07/18	STATE TX 531, 1	5.54		
07/18	CITY TAX 531, 1	7.75		
07/19	JW STEAK 1467 531	30.67		
07/19	ROOM. 531, 1	64.00		
07/19	STATE TX 531, 1	3.20		
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MIF 000088

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017

Sandra P. Arnold
Vice President, Corporate Affairs

July 26, 1996

US Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane, HGD021
Rockville, Maryland 20857

Dear [redacted]

Enclosed as you have requested are copies of the slides used by Dr. Ann Robbins, Dr. Irving Spitz, Dr. C. Wayne Bardin, and Dr. Beverly Winikoff at the meeting of the Advisory Committee on July 19. Let me draw your attention to the annotation in the lower right hand corner of each slide, indicating that the information is unpublished, and, in the case of Beverly Winikoff's slides, both preliminary and unpublished.

Since we wish to preserve the right to publish the data, we would prefer that the copies be used only to complete the FDA record of the event, as you and I have discussed, and not released to the press or others. In addition, the preliminary nature of the results reported by Dr. Winikoff make an even more compelling case for limiting the distribution of the information.

Thank you once again for the great care with which you and others managed the proceedings on the 19th. We are of course delighted with the results, and were very pleased with how smoothly everything functioned. We know that this doesn't happen by accident!

Please don't hesitate to contact me if there is anything further I can help you with.

Very truly yours,

Sandra Arnold

Enclosures

cc: C. W. Bardin
M. Catley-Carlson
E. Johansson
A. Robbins
I. Spitz
B. Winikoff

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

Reproductive Health Drugs Advisory Committee

FDA Technical Center
Gaithersburg, Maryland
19 July 1996

MINUTES

Members Present	Members Absent
Ezra C. Davidson, Jr, MD (Chair)	Kenneth Ryan, MD
Janet R. Daling, PhD	Edward Wallach, MD
Cassandra E. Henderson, MD	
Thomas S. Kosasa, MD	
Vivian Lewis, MD	
Deborah L. Narrigan, MSN, CMN	
Mary Jo O'Sullivan, MD	
Diana B. Petitti, MD, MPH	
Jane S. Zones, PhD	

Invited Guests

Ricardo Azziz, MD

Executive Secretary

Philip A. Corfman, MD

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"We certify that we attended the 19 July 1996 meeting of the Reproductive Health Drugs Advisory Committee and that these Summary Minutes accurately reflect what transpired."

Philip A. Corfman, MD
Executive Secretary
23 July 1996
Date

Ezra C. Davidson, MD
Chair
July 23, 1996
Date

The afternoon session began with the Open Public Session, with presentations by the following individuals, speaking either as private citizens or on behalf of the organizations they represented:

Office of Congressman Tom Coburn
Member, United States House of Representatives
Michael Schwartz

Alan Guttmacher Institute
Lisa Kaeser, JD

American College of Obstetricians and Gynecologists
Carolyn L. Westoff, MD

American Life League, Inc.
Rebecca Lindstedt

American Medical Student Association
Paul Jung, MD

American Medical Women's Association
Diana Dell, MD

American Public Health Association
Allan Rosenfield, MD

American Victims of Abortion
Olivia L. Gans

Baruch College
Joel Brind, PhD

Private citizen
Randy O'Bannon, speaking for Charles Cargille, MD

Center for Reproductive Law and Policy
Janet Benshoof, JD

Private citizen
Helen M. Donovan, JD

Family Research Council
Gracie S. Hsu, MHS

Feminist Majority Foundation
Eleanor Smeal

The Reproductive Health Drugs Advisory Committee of the Food and Drug Administration met on 19 July 1996 at the Food and Drug Adminstration's Technical Center in Gaithersburg, Maryland. A complete transcript of the meeting is available from the Dockets Management Branch. The following documents are annexed to these Summary Minutes:

1. The Agenda.
2. Questions put to the Committee.
3. A list of Committee members and the Guest invited by the FDA.

The meeting was opened by the Chair with comments concerning the exemplary service of the members whose terms on the Committee have ended, Drs. Janet Daling, Cassandra Henderson, and Jane Zones, and greetings to the Invited Guest, Dr. Ricardo Azziz, who becomes a member of the Committee this year. The Chair also introduced Agency staff at the Committee table: Commissioner David Kessler, Deputy Commissioner Mary Pendergast, and Acting Director of the Reproductive and Urologic Drugs Advisory Committee, Dr. Lisa Rarick.

Subsequent committee meeting dates were confirmed as follows:

20-22 November 1996
13-14 February 1997
5-6 June 1997

Ms. Marina Hooten, the Chief of the Ethics Branch in the Agency's Division of Ethics and Program Integrity, read the Conflict of Interest statement, noting that, due to the possibly apparent conflict of interest, Dr. Zones, though permitted to participate fully in the proceedings, has been asked not to vote, if votes are to be taken.

The Chair then opened the meeting to the principal topic.

NEW DRUG APPLICATION FOR THE USE OF MIFEPRISTONE FOR INTERRUPTION OF EARLY PREGNANCY

After an introduction to the topic by Commissioner David Kessler, the sponsor, the Population Council, presented its findings and recommendations. Presentations were given by Ms. Sandra Arnold, Drs. Ann Robbins, Irvin Spitz, Wayne Bardin, Beverly Winikoff, and Elizabeth Newhall. During these presentations there was discussion of the issues with Committee members. Dr. Robbins concluded the sponsor's presentations.

The next major agenda item was presentations of the Agency's review of the Application by staff of the Reproductive and Urologic Drugs Products Division, including the Acting Director, Dr. Lisa Rarick, and Drs. Alexander Jordan and Ridgely Bennett. There was discussion of the issues with Committee members during and after these presentations.

Feminist Women's Health Center
Marie Head

Life Issues Institute
Richard D. Glasow, PhD

National Abortion and Reproductive Rights League
Marcy J. Wilder, JD

National Abortion Federation
Paul Blumenthal, MD

National Association of Nurse Practitioners
in Reproductive Health
Susan Wysocki, RNC, NP

National Council of Jewish Women
Donna Gary

National Organization for Women, Inc.
Janice E. Erickson

National Women's Health Network
Cynthia A. Pearson

National Women's Health Organization
Susan Hill

National Women's Law Center
Ann Kolker

Northeast Waterloo Family Practice
M. Louviere, MD

Pharmacists for Life, International
Mary Jasinski Caldwell

Planned Parenthood Federation of America
Gloria M. Feldt

Planned Parenthood of Westchester and Rockland, Inc.
Lynn Borgatta, MD, MPH

Reproductive Health Technologies Project
Marie Bass

Private citizen
Wendy Simonds, PhD

Society of Physicians for
Reproductive Choice and Health
Seymour L. Romney, MD

Southwestern Medical Clinic, PC
Donna J. Harrison, MD

Women's Legal Defense Fund
Joanne L. Hustead

After completion of the Open Public Hearing, the Chair directed the attention of the Committee to the questions.

ANSWERS TO THE QUESTIONS

AGENCY STATEMENT INTRODUCING THE QUESTIONS
"The regimen proposed for the use of mifepristone for the termination of early pregnancy consists of the oral administration of 600 milligrams of mifepristone within 49 days after the beginning of the last menstrual period, followed by oral administration of 400 micrograms of misoprostol 48 hours later."
CHANGE IN STATEMENT
The Committee began its deliberations on the questions by changing the phrase "48 hours" to "2 days" in this statement.

QUESTION 1.

a. Do the results of the open-label, historically controlled studies conducted in France establish the efficacy of this regimen for use in the United States?
ANSWER
The Committee voted 6 in favor and 2 opposed in response to this question.

b. If not, what additional efficacy information should the applicant provide?
ANSWER
In response to this question, the Committee voted unanimously (8 to 0) in favor of the following motion:
"The Committee has some reservations about finally determining efficacy without access to the US data and recommends to the Agency that the Committee would like the opportunity to review the data when they are available."

QUESTION 2.
The safety database for this regimen consists of trials conducted in France, preliminary data from U.S. trials, and foreign post-marketing experience.

a. Do these data adequately demonstrate that the regimen is safe for use in the United States when used for the proposed indication?
In your discussion, please include comments on the following issues:
- o Whether the adverse events associated with the regimen can be adequately managed when the regimen is administered as labeled.
- o The acceptability of the frequency of adverse events.

ANSWER
The Committee voted 7 in favor and 1 in abstention in response to this question. (The Committee provided no specific responses to the two issues on this questions presented by the Agency.)

b. If not, what additional safety information should the applicant provide?
ANSWER
The Committee discussed the issue of safety at length and stated that it would like be to be informed of the final analysis of the safety data from the US studies.

QUESTION 3.
Taking into consideration the overall evidence for safety and effectiveness of the regimen, do you believe the benefits outweigh the risks for use of the regimen for the proposed indication in the United States?
ANSWER
The Committee voted 6 in favor and 2 in abstention in response to this question.

QUESTIONS 4 and 5.
4. If the regimen were to be approved, do you consider the labeling proposed by the applicant on how to administer the regimen and how to monitor patients who receive it to be appropriate?
5. If the regimen were to be approved, what further information, if any, do you recommend be included in the written information to be provided to the patient?
ANSWER
In response to Questions 4 and 5, the Committee made the following statement:
"With regards to labeling for both physicians and the patients, the Committee is concerned that the precautions and conditions employed in the clinical trials - such as under age 18, over age 35, smoking, and certain chronic medical conditions - be described in the labeling and noting that there are as yet no data concerning the safety of the use of the regimen by women with such conditions. The Committee also recommended that patient labeling include what is known about possible teratogenicity in humans, that the risk to fetuses of pregnancies that are not terminated by the regimen is not certain, but women should be offered surgical terminations when failures occur."

QUESTION 6.
If the regimen were to be approved, do you have recommendations concerning the drug distribution system proposed by the applicant?
ANSWER
The Committee voted unanimously (8 to 0) in favor of the following statement:
"We agree in concept with the proposal but have serious reservations on how it is currently described in terms of assuring safe and adequate credentialing of providers."

QUESTION 7.
If the regimen were to be approved, what recommendations, if any, do you have for post-marketing studies?
ANSWER
The Committee recommended that several issues be studied after the regimen is marketed including the following:

- *monitor the adequacy of the distribution and credentialing system by determining, among other end points, the frequency of post-surgical complications;*
- *follow-up on the outcome of all women who have surgical abortion because of method failure;*
- *studies of the long-term effects of multiple use of the regimen;*
- *ascertainment of the number of women who follow the complete regimen of treatment, and follow-up of women who do not;*
- *studies of the efficacy and safety of the regimen in women under age 18, over age 35, and in smokers; and*
- *ascertainment of the effect of the regimen on children born after treatment failure.*

The Committee having completed the agenda, the Chair closed the meeting.

P R O C E E D I N G S (9.00 a.m.)

DR. DAVIDSON: May I have your attention, please.

I would like to open this meeting of the Reproductive Health Drugs Advisory Committee, considering the topic that is well-published of this agenda.

To begin with, in terms of just some internal Committee issues, I would like to note and appreciate that this is the last meeting for three of the members who are with us today: Dr. Daling, Dr. Henderson and Dr. Zones. We certainly had the professional pleasure and benefit of their participation in this committee.

This is also the first meeting of Dr. Richard Azziz, and as has been customary, Richard, knowing that you are from the University of Alabama, I am sure you will take this opportunity to distinguish which campus that is.

Welcome to the Committee.

DR. AZZIZ: I am a professor in the Department of Obstetrics and Gynecology and the Department of Medicine at the University of Alabama at Birmingham. As we always have to say, there are three campuses, of which Birmingham is the important one.

DR. DAVIDSON: We have confirmed at the last meeting, but I would please have you note the dates of the future meetings that are at the top of the agenda today.

The conflict of interest statement will be read

today by Marina Hooten(?), who is chief of the Ethics Branch Division of Ethics and Program Integrity of the FDA.

DR. HOOTEN: Good morning.

The following announcement addresses the issue of conflict of interest with regard to the meeting, and it is made a part of the record to preclude even the appearance of such at this meeting.

Based on the submitted agenda for the meeting and all financial interests reported by the Committee participants, it has been determined that all interests in firms regulated by the Center for Drug Evaluation and Research, which have been reported by the participants, present no potential for conflict of interest at this meeting, with the following exception:

Dr. Jane Zones would like to report to reflect that she was, within the past year, a member of the Board of Directors for the National Women's Health Network, a membership-based, non-profit, public interest health advocacy organization. The National Women's Health Network is making a presentation today. However, she is not aware of what they are going to present.

Dr. Zones will be participating as a consumer representative member today, but she will not be voting with respect to this product.

In the event that the discussion involves any

other product or firm not already on the agenda for which the FDA participants have a financial interest, the participants are aware of the need to exclude themselves from such involvement and their exclusion will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that they disclose any current or previous financial interest or professional involvement with any firm whose products they may wish to comment upon.

DR. DAVIDSON: Thank you very much.

I should indicate before we begin that in addition to the Committee members seated around the table, there are four Agency persons: Dr. Phil Corfman, who is the secretariat of the Committee, who is immediately to my right; and to the end of the table to my right, Mary Pendergast, who is the Deputy Commissioner for the FDA; Dr. Kessler, who is the Commissioner and who will speak momentarily; and Dr. Lisa Rarick, who is the Acting Director of the Division of Reproductive and Urologic Drugs, a new position and a new title, for which she is to be congratulated for.

We will begin with opening comments by Dr. David Kessler, the Commissioner of the FDA.

TIMEKEEPERS PAYROLL RECORD - ADVISORS AND CONSULTANTS STAFF

Note to Executive Secretary/Division Director: List members of committee and any consultants, speakers or guests attending meeting and indicate dates for which salaries should be paid. PLEASE SIGN AND RETURN PROMPTLY TO THE ADVISORS & CONSULTANTS STAFF, Room 8B-45.

Name of committee member	Date(s)	Name of speaker	Date(s)
1. Davidson, Ezra	19 July 96	1.	
2. Petitti, Diana		2.	
3. O'Sullivan, MaryJo		3.	
4. Narrigan, Deborah		4.	
5. Lewis, Vivian		5.	
6. Kosasas, Thomas			
7.		Name of guest	Dates(s)
8.		1. Azziz, (new member) Ricardo	
9.		2.	
10.		3.	
11.		4.	
12.		5.	

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Name of consultant/expert	List names of all who did not attend
1. Daling, Janet	1. Ryan, Kenneth (current member)
2. Henderson, Cassandra	2. Wallach, Edward (old member)
3. Zones, Jane	3. Wingo, Phyllis (new member)
4.	4. Scott, Julia (new member)
5.	5. Brown, Haywood (new member)

A.C. for Reproductive Health
(Name of Committee)

24 July 96
(Please sign and date)