Table 2 (Cont'd)

Patient No.	Clinic No.	Adverse Event	D&C/ Asp.	Meth./ oxy.	IV Fluids	Trans-fusion	Hosp.	DA	Race	IND No. and Date
116	24	Hemorrhagia Cramping Fever Endometritis	X		X			61		149 09/21/95
165	25	Hemorrhage Dizziness	X		X		X	60		154 11/02/95

Summary of Table 2

Total No. of Patients	Total No. of Clinics	Total No. of Adverse Events	Total Number of Treatments				Total No. Hospitalized
			D&C/ Asp.	Meth./ oxy.	IV Fluids	Transfusion	
52	13	Hemorrhage 41 Faint/Dizziness** 20 Cramping 14 Vomiting 06 Hypotension 05 Tachycardia 04	34	15	28	04	26

* Listed in chronological order as reported to the FDA.
+ Surgical procedure not reported on Med Watch form.
D&C/Asp = Dilatation and Curettage/Aspiration.
Meth/oxy = Methergine/Oxytocin.
Hosp = Hospitalizations.
DA = Number of days of amenorrhea.
** includes fainting, feeling faint or lightheaded, dizziness, vasovagal reaction, syncope and passing out.

Table 3

Correlation between Population Council Subject and Serious Adverse Event Coded by Roussel

Patient No.	Clinic No.	IDSN*	SAE** Coded by Roussel	Location in NDA Volume Page
C01 (005)	22	199500076RU	Metrorrhagia Anemia	Vol. 1.66
		199500439RU	Metrorrhagia Abdominal pain	Vol. 3.2
036	02	199500072RU	Metrohagia Vomiting Malaise	Vol. 1.66
033	02	199500442RU	Dehydration Nausea Vomiting Diarrhea	Vol. 3.2
027	02	199500074RU	Abdominal pain Anemia Metrorrhagia	Vol. 1.66
042	02	199500075RU	Abdominal pain Metrorrhagia Anemia	Vol. 1.66
WD(057)	01	199500071RU	Metrorrhagia Hypotension Anemia	Vol. 1.66
		199500440RU	Metrorrhagia Hypotension Headache	Vol. 3.2
015	25	199500066RU	Metrorrhagia	Vol. 1.66
012	25	199500067RU	Metrorrhagia	Vol. 1.66
061	01	199500068RU	Hypotension	Vol. 1.66
076	02	199500069RU	Urogenital Disorder	Vol. 1.66
033	03	199500070RU	Metrorrhagia Syncope	Vol. 1.66
		199500444RU	Metrorrhagia Dizziness Headache	Vol. 3.2
022	25	199500441RU	Abdominal Pain Hypotension	Vol. 3.2
		199500064RU	Metrorrhagia	Vol. 1.66

Table 3 (Cont'd)

Patient No.	Clinic No.	IDSN*	SA** Coded by Roussel	Location in NDA Volume Page
050	03	199500065RU	Metrorrhagia Postural hypotension	Vol. 1.66
009	26	199500077RU	Metrorrhagia	Vol. 1.66
062	01	199500102RU	Metrorrhagia	Vol. 1.66
107	01	199500443RU	Vomiting Nausea Dizziness	Vol. 3.2
114	01	199500104RU	Metrorrhagia	Vol. 1.66
123	01	NA***	NA	Vol. 1.66
037	04	199500106RU	Metrorrhagia	Vol. 1.66
109	01	199500100RU	Metrorrhagia Fever	Vol 1.66
116	01	199500101RU	Chest pain	Vol. 1 66
048	03	199500140RU	Metrorrhagia	Vol. 1.66
076	03	NA	NA	Vol. 1.66
060	24	199500139RU	Metrorrhagia Hypotension	Vol. 1.66
017	23	199500135RU	Metrorrhagia Postural Hypotension	Vol. 1.66
070	02	NA	NA	Vol. 1.66
030	23	199500175RU	Metrorrhagia Syncope	Vol. 1.6
032	23	199500446RU	Syncope	Vol. 3.2
035	23	199500447RU	Metrorrhagia	Vol. 3.2
037	23	199500176RU	Metrorrhagia	Vol. 1.66
081	26	199500172RU	Metrorrhagia Syncope	Vol. 1.66
158	02	199500179RU	Metrorrhagia	Vol. 1.66
159	01	NA	NA	Vol. 1.66
036	27	199500247RU	Pneumonia	Vol. 1.66

Table 3 (Cont'd)

Patient No.	Clinic No.	IDSN*	SAE** Coded by Roussel	Location in NDA Volume Page
012	29	199500248RU	Metrorrhagia	Vol. 1.66
028	04	199500249RU	Metrorrhagia	Vol. 1.66
075	04	199500448RU	Dehydration	Vol. 3.2
004	28	199500251RU	Metrorrhagia	Vol. 1.66
027	28	199500455RU	Metrorrhagia	Vol. 3.2
071	23	199500329RU 199500449	Vomiting Metrorrhagia Dizziness	Vol. 1.66 Vol. 1.66
030	28	199500330RU	Metrorrhagia	Vol. 1.66
033	28	199500454RU	Metrorrhagia	Vol. 1.66
063	28	199500340RU	Depression	Vol. 1.66
147	77	199500342RU	Meningitis	Vol. 3.2
074	28	199500450RU 199500355RU	Metrorrhagia Hypotension Metrorrhagia Hypotension Anemia	Vol. 3.2 Vol. 3.2
088	28	199500356RU 199500451RU	Metrorrhagia Metrorrhagia	Vol. 3.2 Vol. 3.2
018	07	199500365RU	Abdominal pain	Vol. 3.2
019	07	199500366RU	Metrorrhagia	Vol. 3.2
104	28	199500452RU	Metrorrhagia Uterine spasm	Vol. 3.2
108	28	199500375RU	Abdominal pain Fever	Vol. 3.2
116	24	199500453RU	Metrorrhagia Endometrial disorder	Vol. 3.2
165	25	199500427RU	Metrorrhagia Malaise	Vol. 3.2

*IDSN= International Drug Surveillance Number.
**SAE = Serious Adverse Event.
***NA = Not available, not yet assigned by Roussel

FINANCIAL INTEREST AND PROFESSIONAL RELATIONSHIP CERTIFICATION FOR GUEST AND GUEST SPEAKERS

A. To be Completed by FDA Committee Executive Secretary

Guest/Guest Speaker Name R. Azziz, M.D. Date of Meeting July 19, 1996

Name of Committee/Panel/Section Reproductive Health Drugs Advisory Committee

Center/Office Name Center for Drug Evaluation & Research

Issue at Hand at Specific Meeting mifepristone (RU486)

Product prostaglandin misoprostol Firm The Population Council,

Closely Competing Products/Firms GD Searle, Monsanto Co., Roussel UCLAF, Hoechst AG, Gideon-Richter

B. To Be Completed by FDA Center/Office Designated Official (Check Appropriate Box and Sign)

☐ The issue to be addressed at the advisory committee meeting specified in Section A above would not constitute a conflict of interest for the above named guest/guest speaker.

☒ The issue to be addressed at the meeting specified in Section A could possibly present an opportunity for a conflict of interest or the appearance thereof, and therefore this form must be forwarded to the guest/guest speaker to obtain additional information.

/S/ 7-12-96

Signature of Designated FDA Official Date

C. To Be Completed by Guest/Guest Speaker (Check appropriate boxes and sign: This must be completed and signed before participation in advisory committee meeting) (See Reverse Side for OPTIONAL INFORMATION).

☐ I do not have a financial interest in or professional relationship with any of the products or firms or close competitors as specified in Section A.

☐ I do have a financial interest in and/or professional relationship with one or more of the firms specified in Section A and authorize FDA to include the following information regarding that interest(s) or relationship(s) in the public record:

Products Firms

Closely Competing Product(s)/Firm(s)

☐ I have provided additional OPTIONAL INFORMATION about these interests on the reverse side which will be included as part of the public record to address any possible concerns about conflict of interest.

☐ I do not believe it is necessary to provide any additional OPTIONAL INFORMATION about these interests.

Signature of Guest/Guest Speaker Date

D. To be Completed by FDA Center/Office Designated Official (Check appropriate box and sign)

☐ I have reviewed the information provided in Sections A and C above and have determined that no potential conflict of financial or professional interest exists by allowing this guest/guest speaker to attend/speak at this specific advisory committee meeting.

☐ I have reviewed the information provided in Sections A and C above and have determined that the possibility of a potential conflict of financial or professional interest does exist with this guest/guest speaker attending/speaking at this particular committee meeting; however, because his/her service is considered essential, the information provided on this form will be made a matter of public record to allow meeting participants to objectively evaluate any presentation made by the guest/guest speaker.

Signature of Designated FDA Official Date

OPTIONAL INFORMATION

Check appropriate items and indicate name of firm/product beside applicable entry.

(Provide any relevant information that you feel would address possible concerns about conflict of interest or appearances thereof with respect to your interests and the issues at hand. This could include a closely competing product/firm to the issue cited in Section A above. You may also provide a general statement about the size of these investments whether it is large or insignificant, or include the actual amount if you feel it would be helpful. This information will be made part of the public record.)

Stocks_____

Bonds_____

Contracts_____

Grants_____

Principal Investigator_____

Researcher_____

Consulting Fees_____

APPEARS THIS WAY
ON ORIGINAL

Full-Time Employment_____

Part-Time Employment_____

Speaker Fees_____

Employment of Relative_____

Scientific Advisor_____

Other Fiduciary Relationship_____

Other (Specify)_____

_____

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.:
- e. PRESENT DUTY STATION: Rockville, MD
- f. RESIDENCE (City and State):

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)

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	$217.00	AA	Contract	Los Angeles, CA	Washington, D.C. and return Approval granted for excessive ta Fares. /S/

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 ▶ /S/ 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 /S/ ;SGE Programs Officer DATE 9-10-96

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
7560600 6-6992862 D-51758 o.c.2135 22320Q20

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

MIF 002807

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 _____
AirfareS _____ TrainfareS _____ (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

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

1. TRAVEL ORDER NO.: D-51758

2. APPROPRIATION NO.: 7560600 22320Q20

3. ESTIMATED COST*

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

4. NAME AND POSITION OR RANK (Member-F&M): Ezra C. Davidson,Jr., M.D.

5. SSAN:

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

7. PRESENT OFFICIAL STATION: Rockville, 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)

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

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

11. SPECIAL AUTH/JTR

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

12. 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 COLLECTION DOC.	101-108 PPBS 101-106 CATEGORY	101-108 PPBS 107-108 ACTIVITIES	109 CASE #
2					130					6	6992862 D-51758	2135	600.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF OC[illegible] TRAVEL

[illegible], 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 BY /S/ 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 002809

GAITHERSBURG Marriott.
WASHINGTONIAN CENTER
9731 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 number, please stop by the Front Desk. Thank you.

GUEST FOLIO

ROOM	NAME	RATE	DEPART	TIME	ACCT#
531	DAVIDSON/E	64.00	07/20/96	10:12	
NSKG			07/18/96	18:40	
			ARRIVE	TIME	

HG#: 066384546

ROOM CLERK	ADDRESS	PAYMENT			
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		
07/19	CITY TAX	531, 1	4.48		
07/20	CCARD-AX			265.32	

PAYMENT RECEIVED BY

.00

GAITHERSBURG Marriott.
WASHINGTONIAN CENTER
9731 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 _____

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 TRA
- [x] TEMPORARY
- [ ] PERMANENT CHANGE OF STATION

3 VOUCHER NO

4 SCHEDULE NO

TRAVELER (PAYEE)

5. a NAME (Last, first, middle initial): Daling, Janet R.

b SOCIAL SECURITY NO

6. PERIOD OF TRAVEL: a FROM 7/18/96 b TO 7/19/96

c MAILING ADDRESS (Include ZIP Code):
Fred Hutchinson Cancer Research Center
1124 Columbia Street
Seattle, WA 98104

d. OFFICE TELEPHONE NO

7. TRAVEL AUTHORIZATION: a. NUMBER(S) D-51763; 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-4,699172	$636.00	UA	Contract	Seattle, WA	Washington, D.C. and return Approval grante for excessive taxi fares. 151

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 ▶ 151 DATE 7/24/96 AMOUNT CLAIMED ▶ $ 26850

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. 680b).)*

APPROVING OFFICIAL SIGN HERE ▶ 151 SGE Programs Officer DATE 9-10-96

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
7560600 6-6992862 D-51763 o.c.2135 22320Q20

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

MIF 002811

TRAVEL EXPENSES - TALLY SHEET

Day of Departure: Date 7/18/96 Time Dep 8:30 am/pm Arr 4:00 am/pm

Name of Air Carrier United Airlines Private Auto _____ Train _____
Airfare $ 636 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)..... $ 53.00

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
(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)..... $ _____

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

418 DALING/JANET — 110.71 — 07/19/96 — ACCT#
ROOM NAME — RATE — DEPART — TIME

NSKG FRED HUTCHINSON CANC — 07/18/96 — 19:11
TYPE — ARRIVE — TIME — GROUP

50 1124 COLUMBIA ST — 5082

SEATTLE WA 98104 — HG#:

ROOM CLERK — ADDRESS — PAYMENT

DATE	REFERENCE	CHARGES	CREDITS	BALANCE DUE
07/18	JW STEAK 1273 418	32.51		
07/18	ROOM. 418, 1	110.71		
07/18	STATE TX 418, 1	5.54		
07/18	CITY TAX 418, 1	7.75		
07/19	BK CARD		$165.91	

CURRENT BALANCE .00

MIF 002813

DEPARTMENT OF HEALTH AND H N SERVICES

TRAVEL ORDER

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

1. TRAVEL ORDER N: D-51763

2. APPROPRIATION NO.: 7560600 22320Q20

3. ESTIMATED COST*

	TO DHHS	TO OTHERS
TRAVEL	$ 700.00	$
PER DIEM	200.00	
OTHER	150.00	
TOTAL	$ 1050.00	$

4. NAME AND POSITION OR RANK (Member-F&M): Janet R. Daling, Ph.D.

5. SSAN:

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

7. PRESENT OFFICIAL STATION: Rockville, MD

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

8. 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)

To proceed Seattle, WA to Rockville, MD and return.

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

Prysock 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 356: ☐ 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 COLLECTION DOC.	101-106 PPBS 101-106 CATEGORY	101-106 PPBS 107-106 ACTIVITIES	109 CASE #
2					130					6	6992862 D-51763	2135	1050.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF 151 ABOVE TRAVEL: SGE Programs Officer 6/21/96 151 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 151 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 002814

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: ☒ TEMPORARY DUTY ☐ PERMANENT CHANGE OF STATION

3 VOUCHER NO

4 SCHEDULE NO

TRAVELER (PAYEE)

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)

5e PRESENT DUTY STATION: Rockville, MD

5f 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-4,699,179	$371.00	US	Contract	Lexington, KY	Washington, D.C. and return

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 ▶ /S/ DATE 7/26/96 AMOUNT CLAIMED ▶ $ 328.58

NOTE: Falsification of an item in an expense account rights 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; Id. 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 ▶ /S/ SGE Programs Officer DATE 9-10-96

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

7560600 6-6992862 D-51754 o.c.2135 22320Q20

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

MIF 002815

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).....$_____

DEPARTMENT OF HEALTH AND H N SERVICES

TRAVEL ORDER

1. TRAVEL ORDER NO: D-51754

2. APPROPRIATION NO: 7560600 22320Q20

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

3. ESTIMATED COST*

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

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

5. SSAN:

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

7. PRESENT OFFICIAL STATION: Rockville, MD

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

8. 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)

To proceed Nashville, TN to Rockville, MD and return.

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

11. SPECIAL AUTH/TN

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 16-28 DOCUMENT NO.	OTHER DOCUMENTS 25-27 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 COLLEC. TION DOC.	101-108 PPBS 101-106 CATE-GORY	101-108 PPBS 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 TRAVEL: /S/ SGE Programs Officer 6/21/96

/S/ 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: /S/ 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 002817

DEPARTMENT OF HEALTH AND HUMAN SERVICES

TRAVEL ORDER

TRAVEL ORDER NO. D-51754

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

2. APPROPRIATION No. 7560600 22320Q 20

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

5. SSAN: _____

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

7. PRESENT OFFICIAL STATION: Rockville, MD

3. ESTIMATED COST

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

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

8. 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.

11. SPECIAL AUTH'N

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

12. 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 COLLECTION DOC.	101-106 PPBS CATEGORY	107-108 PPBS ACTIVITIES	109 CASE #
2					130					6	6992862 D-51754	2135	775.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF OFFICER R[illegible] TRAVEL

(S1) SGE Programs Officer 7-3-96 FUNDS ARE AVAILABLE (S1)

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

AUTHORIZED BY /S1/ 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 002818

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#

ROOM — NAME — RATE — DEPART — TIME

NSKG — 07/18/96 — 19:40

TYPE — ARRIVE — TIME

HG#:

ROOM
CLERK

ADDRESS

PAYMENT

DATE	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

please apply the 37 daily allowance to this.

total reimbursable = 269.82 .00

277.51

APPEARS THIS WAY
ON ORIGINAL

MIF 002819

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
☒ 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

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

e. PRESENT DUTY STATION
rockville,MD

f. RESIDENCE (City and State)

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

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

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-4,699,170 $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 voucher

TRAVELER SIGN HERE ▶ /S/ 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 ▶ /S/ SGE Programs Officer DATE 9-10-96

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. 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
7560600 6-6992862 D-51761 o.c.2135 22320Q20

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

MIF 002820

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~~ 51

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).....$_____

DEPARTMENT OF HEALTH AND H[illegible]N SERVICES

TRAVEL ORDER

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

1. TRAVEL ORDER NO.: D-51761

2. APPROPRIATION NO.: 7560600 22320Q20

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): Vivian Lewis, M.D.

5. SSAN:

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

7. PRESENT OFFICIAL STATION: Rockville, 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)

To proceed Rochester, NY to Rockville, MD and return.

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

Prysock 3-5455

11. SPECIAL AUTHGTN

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 29-39 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 101-106 CATEGORY	101-106 PPBS 107-106 ACTIVITIES	100 CASE #
2					130					6	6992862 D-51761	2135	755.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF CERTIFYING OFFICER FOR TRAVEL: /S/ SGE Programs Officer 6/26/96

/S/ 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: /S/ 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 002822

DEPARTMENT OF HEALTH AND HUMAN SERVICES

TRAVEL ORDER

D-51761

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

2. APPROPRIATION NO.
7560600 22320Q 20

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)
Vivian Lewis, M.D.

5. SSAN

6. CONSTITUENT/BUREAU/DIVISION/REGION

7. PRESENT OFFICIAL STATION
Rockville, Maryland

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

8. 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 to increase travel from $405.00 to $511.00 for increase of $106.00.
Total increase of $106.00.

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 $_____ ☐ 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 COLLECTION DOC.	101-106 PPBS 101-106 CATEGORY	107-108 ACTIVITIES	109 CASE #
2					130					6	6992862 D-51761	2135	106.00	1					2
2																			
2																			
2																			

15. NAME AND TITLE OF OFFICER [illegible]
_____ SGE Programs Officer /S/ FUNDS ARE AVAILABLE /S/

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

AUTHORIZED BY _____ /S/ 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

MIF 002823

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

For your protection we have NOT ... and 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

606 LEWIS/VIVIAN/DR 110.71 07/19/96 09:35 ACCT#

ROOM NAME RATE DEPART TIME

NSKG 07/18/96 20:08

TYPE ARRIVE TIME GROUP 5082

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

.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 _____

6-2955 For Reservations At Any Marriott Hotel Call 1-800-228-9290

THIS ITEM PRINTED ON RECYCLED PAPER.

MIF 002824

Thereafter, on December 6, 1993 (58 FR 64121), the expiration date of the musculoskeletal system listings in both parts A and B was extended, as were the expiration dates for several other body system listings. That rule provided that the musculoskeletal system listings would no longer be effective on June 6, 1996.

Also, we published a notice of proposed rulemaking (NPRM) on December 21, 1993 (58 FR 67574) that included proposed revisions to these listings. We will publish any changes to the listings based on that NPRM in a subsequent final rule.

In this final regulation, we are extending for one year, to June 6, 1997, the date on which the musculoskeletal system listings will no longer be effective. We believe that the requirements in these listings are still valid for our program purposes. Specifically, if we find that an individual has an impairment that meets the statutory duration requirement and also meets or is equivalent in severity to an impairment in the listings, we will find that the individual is disabled without completing the remaining steps of the sequential evaluation process. We do not use the listings to find that an individual is not disabled. Individuals whose impairments do not meet or equal the criteria of the listings receive individualized assessments at the subsequent steps of the sequential evaluation process.

Regulatory Procedures

Pursuant to section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5), as amended by section 102 of Public Law 103–296, SSA follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for dispensing with the notice and public comment procedures in this case. Good cause exists because this regulation only extends the date on which the musculoskeletal system listings will no longer be effective. It makes no substantive changes to the listings. The current regulations expressly provide that the listings may be extended, as well as revised and promulgated again. Therefore, opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule, provided for by 5 U.S.C. 553(d). As explained above, we are not making any substantive changes in the listings. However, without an extension of the expiration date for the musculoskeletal system listings, we will lack regulatory guidelines for assessing musculoskeletal system impairments at the third step of the sequential evaluation processes after the current expiration date of the listings. In order to ensure that we continue to have regulatory criteria for assessing these impairments under the listings, we find that it is in the public interest to make this rule effective upon publication.

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that this rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, it was not subject to OMB review.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

This regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: May 20, 1996.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)).

2. Appendix 1 to subpart P of part 404 is amended by revising item 2 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

2. Musculoskeletal System (1.00 and 101.00): June 6, 1997.

* * * * *

[FR Doc. 96–13882 Filed 6–3–96; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee; Change of Name and Function

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and the function of the Fertility and Maternal Health Drugs Advisory Committee. This action is being taken to more accurately describe this committee.

EFFECTIVE DATE: June 4, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Fertility and Maternal Health Drugs Advisory Committee has been changed. After reestablishment of this committee, on March 23, 1978, the agency decided that the name "Advisory Committee for Reproductive Health Drugs" would more accurately describe the subject areas for which the committee is

responsible. The mandate of the committee has expanded significantly in recent years to include drugs for menopausal women and drugs used in the practice of andrology. The change is consistent with the growing use of this term by specialists in the field of reproductive health, which includes obstetrics, gynecology, endocrinology, andrology, epidemiology, and related specialties. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

The Fertility and Maternal Health Drugs Advisory Committee's name was changed in the charter renewal dated March 23, 1996. In this document, FDA is hereby formally changing the name and the function of the committee by revising 21 CFR 14.100(c)(9).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely a clarifying amendment to existing regulations and when effective will reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394; 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by revising the heading of paragraph (c)(9) and paragraph (c)(9)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(9) *Advisory Committee for Reproductive Health Drugs.*

* * * * *

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

* * * * *

Dated: May 28, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–13978 Filed 6–3–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 14

Standing Advisory Committees; Change of Name and Function

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and the function of the Generic Drugs Advisory Committee to the Advisory Committee for Pharmaceutical Science. This action is being taken to more accurately describe this committee.

EFFECTIVE DATE: June 4, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Generic Drugs Advisory Committee has been changed. After establishment of this committee, on January 22, 1990, the agency decided that the name "Advisory Committee for Pharmaceutical Science" would more accurately describe the committee. The Committee reviews primary scientific issues dealing with pharmaceutical science including testing, research, biopharmaceutics, pharmacology, and new chemistry. The Committee also gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases. Therefore, the agency feels the name change will more accurately describe this Committee to the public. In the Federal Register of February 21, 1996 (61 FR 6644 at 6645), FDA published a notice that indicated that the name of the Generic Drugs Advisory Committee had been changed in the charter renewal dated January 22, 1996. In this document, FDA is hereby formally changing the name and function of the committee by revising 21 CFR 14.100(c)(16).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and under 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure, and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely a clarifying amendment to existing regulations and when effective will reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394; 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by revising the heading for paragraph (c)(16) and paragraph (c)(16)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(16) *Advisory Committee for Pharmaceutical Science.*

* * * * *

(ii) Function: Gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

* * * * *

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date June 20, 1996

From Executive Secretary (HFD-510)
Advisory Committee for Reproductive Health Drugs

Subject Notice of Scheduled Advisory Committee Meeting

To Committee Management Office (HFA-306)
Through: _____, Division of ~~Metabolism and Endocrine~~ Reproductive and Urologic
Drug Products, HFD-580 /S/ 6-21-96
_____ Office of Drug Evaluation II, HFD-102
/S/ 6/21/96

We have scheduled an advisory committee meeting as described below and request that a notice be published in the Federal Register as follows:

ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS

Date, time, and place. July 19, 1996, 9 a.m., FDA Technical Center, 16071 Industrial Drive, Gaithersburg, MD. Attenders should allow time to proceed through security procedures. Admission to the facility by public participants will available on a first come, first serve, basis, and will be limited to 200, the number of seats available to the public in the conference room.

Type of meeting and contact person. Open public hearing, July 19, 1996, 1:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Philip A. Corfman, M.D., Center for Drug Evaluation and Research, HFD-510, Food and Drug Administration, Rm. 14B-04, 5600 Fishers Lane, Rockville, MD 20857, phone 301-443-3510, fax 301-443-9282, email ~~July~~ july19@cder.fda.~~19@cder.fda.gov~~. (please keep email add on one lin Information concerning the meeting is available from FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Advisory Committe for Reproductive Health Dr s, code 12537.

MIF 002827

[redacted]

Please call the Hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics and gynecology, and related specialties.

Agenda--Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person in writing by mail, email, or fax no later than 5 p.m., EDT on July 12, 1996, with a brief statement of the general nature of the evidence or arguments they wish to present, the names, telephone numbers, and addresses of proposed speakers, and an indication of the approximate time required to make their comments. The time for presentations will be allotted equitably, and will depend on how many individuals give advance notice within the time indicated of their intention to speak. In the interest of time, the Agency may require persons with common interests to make joint presentations.

Open committee discussion. The committee will discuss the new drug application for mifepristone for the interruption for early pregnancy.

/S/

E L E C T R O N I C M A I L M E S S A G E

Date: 13-Jun-1996 10:39am EDT
From: [redacted]

Dept: HFD-510 PKLN
Tel No: 301- FAX 301-

TO: ( )

Subject: RE: Info on July meeting

The product is mifepristone. There are no competitors.

The other questions have yet to be answered by the Commissioner's office. Check in later or ask [redacted] office.

APPEARS THIS WAY
ON ORIGINAL

E L E C T R O N I C M A I L M E S S A G E

Date: 13-Jun-1996 09:29am EDT
From: [redacted]
Dept: HFD-510 PKLN
Tel No: 301-[redacted]

TO: ( )

Subject: RE: July 1996 meeting

Yes, it's scheduled for 19 July and the topic will be the NDA for mifepristone for the interruption of early pregnancy.

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date .2 July 1996 (Tuesday)

From Executive Secretary

Subject NOTICE CONCERNING JULY MEETING

To Members of the Advisory Committee for Reproductive Health Drugs

First, thanks to all of you who attended the meeting last Friday. Attached find a copy of a front page article in yesterday's New York Times concerning the meeting.

Concerning the meeting on 19 July, please arrange your travel to be able to attend a working dinner meeting at the hotel. _____, who is in charge of committee affairs, will review arrangements that will be made for your security. We are not, however, to discuss the medical issue before the Committee; that must be done in public.

_____ may also attend the working dinner. The hotel has arranged for us to order off the menu, so a copy of the menu is attached for your information.

Please let us know if you plan to attend the dinner so we can give the restaurant an accurate count. The room will accommodate a maximum of 20 people and the meal is booked for 8 pm (to accomodate to members on Pacific and Hawaiian time). Some of us may want to gather in the restaurant before the meal begins, starting about 7:30.

I look forward to seeing you again soon.

/S/

_____
Food and Drug Administration

APPEARS THIS WAY
ON ORIGINAL

DOCUMENTS CONNECTED WITH THIS MEETING MUST BE REQUESTED
IN WRITING FROM THE
FREEDOM OF INFORMATION OFFICE

Mail written request specifying date of meeting, name of committee, and a description of the documents requested to:

Food and Drug Administration
Freedom of Information Staff
HFI-35, Room 12A-16
5600 Fisher's Lane
Rockville, MD 20857

or fax to (301) 443-1726

Invoices are sent monthly by the Freedom of Information (FOI) Staff.
If requested, FOI will inform you of fees in advance.

TRANSCRIPTS OF THE OPEN SESSION WILL BE AVAILABLE FROM FOI FIFTEEN WORKING DAYS AFTER THE MEETING.

YOU MAY ALSO PURCHASE TRANSCRIPTS DIRECTLY FROM THE TRANSCRIBING COMPANY.

SUMMARY MINUTES WILL BE AVAILABLE APPROXIMATELY NINETY DAYS AFTER THE MEETING. PLEASE WAIT UNTIL THIS TIME PERIOD HAS ELAPSED BEFORE YOU PLACE YOUR ORDER.

This will allow time for the minutes to be written, edited, approved, and photocopied for distribution. You may phone (301) 443-5455 for status of minutes.

American Victims of Abortion

419 7th Street, N.W. Suite 500
Washington, D.C. 20004

202/626-8800
202/737-9189 (FAX)

STATEMENT OF OLIVIA L. GANS
TO THE FDA REPRODUCTIVE HEALTH DRUGS ADVISORY COMMITTEE
JULY 19, 1996

My name is Olivia Gans. I am the director of American Victims of Abortion, a national organization developed by women who have suffered from the aftermath of an abortion decision. I have held this position for over ten years and have addressed this issue in all fifty states. In addition to my work here in the USA, I have worked with women and professionals to establish similar programs in fifteen other countries.

I had a surgical abortion in 1981. I know all too well the grief, anger and pain which defined my personal experience with abortion. I am also accustomed to having those feelings and memories ignored by those who have supported legal abortion. However, after twelve years of involvement with women throughout our own country and abroad, I have learned that my experience is not unique.

Emotional difficulties following abortion are well-documented. Several long-term studies of women who have had abortions indicate that there are a wide range of emotional repercussions that affect women often as long as five to seven years following their abortions (Reardon, 1986; Speckhard, 1987; Speckhard & Rue, 1990). These emotional repercussions include intense grief, pain and guilt.

Abortions performed using RU 486 have already produced evidence of having effects on women similar to those of surgical abortions, although good long-term studies are not yet available. However, the particular method associated with this chemical abortion technique provides a different set of experiences that may create a different and possibly more troubling pattern of negative reactions.

When women are aware that the abortion causes them to participate in the deaths of their children, they often feel more guilt and pain. Any patient who sees the results of the abortion, that is, the developing child, is more apt to suffer than others. This is one reason why women who have late abortions are traumatized, since they will see a fully developed baby.

With RU 486 abortions, it is important that the woman identify the results of the abortion. She must look at these results. Seeing her dead baby can be traumatic. Even abortionists like Dr. Judy Tyson of Planned Parenthood of New England have reported that patients are "somewhat shocked at the tissue they passed" (New York Times, 1/30/95). Thus, the "privacy and control" which is used to sell RU 486 may actually lead to greater trauma.

In a surgical abortion, the woman generally does not see the baby. Women taking RU 486 see their aborted babies. *Newsweek* magazine spoke of "Sarah" who saw her baby swirling around in the shower drain; and "Becky", who kept talking about her baby's little fists. There have been similar accounts in *Time*, the *Boston Globe*, *Health* magazine and the Des Moines *City View* magazine. There is little doubt among those of us who work with post-abortion peer support groups that a woman who takes, by her own hand, the RU 486 drug cocktail which will kill her child could experience an emotional backlash of devastating proportions.

Women in peer support groups around the world share stories of nightmares and flashbacks to surgical abortion experiences which they cannot erase. Given the horrible dreams that are commonly experienced by women who have survived surgical abortions, one can only shudder to think what nightmares will someday visit those who actually see the tiny, emaciated bodies of their aborted children. Women who have surgical abortions speak of physical pain during the operation as well as after. They complain of humiliating treatment from facility personnel and degrading responses to their needs and requests for more information. We are afraid that the already careless treatment women receive in abortion facilities will only worsen with the approval of RU 486.

Common themes of alienation and isolation are reported in peer groups of post-abortive women. There has been little encouragement for women to share publicly any negative feelings they believe are related to their abortions. In order to cope with these feelings, many of us have denied that what we have aborted is our unborn children. In fact, most of us have felt silenced for years. Will RU 486 only serve to close the circle of isolation and silence all the more?

My sincere request to this committee today, on behalf of the thousands of women across the country struggling with complications and grief from abortion, is that we do not recklessly disregard their pain. It is imperative that the locomotive of the pro-abortion agenda not be allowed to supersede the rights of American women to have safety and honesty in their medical treatment. We are not guinea pigs. Women deserve truly life-affirming answers for themselves and their children. Please halt the approval of RU 486 in the USA.

References

Reardon, D. (1986). Women Exploited: A Nation Deceived, Chicago, Il: Loyola University Press.

Speckard, A. (1987). The Psycho-social Aspects of Stress Following Abortion. Kansas City, MO: Sheed & Ward.

Speckard, A. & Rue, V. (1990). Post Abortion Syndrome: An emerging public health concern. Journal of Social Issues, 48 (3), 95-120.

NATIONAL ABORTION FEDERATION

Testimony of Dr. Paul Blumenthal Before the Food & Drug Administration's Advisory Committee For Reproductive Health Drugs On Behalf of the National Abortion Federation[1]
July 19, 1996

My name is Paul Blumenthal. I am a Board-Certified Obstetrician-Gynecologist practicing at Johns Hopkins' Bayview Medical Center. I am an Associate Professor of Gynecology and Obstetrics at The Johns Hopkins University School of Medicine and am the Medical Director of Planned Parenthood of Maryland. I am also a specialist in epidemiology and reproductive health care and am a Fellow of the American College of Obstetricians and Gynecologists (ACOG). In addition, I am an advisor to the World Health Organization and the United States Agency for International Development on issues relating to safe motherhood, contraception, reproductive health care and quality assurance. I am here today speaking for the National Abortion Federation, the national organization of abortion providers, and to share with you our experiences with mifepristone.

The National Abortion Federation (NAF) was established in 1977 as a professional association of abortion providers committed to ensuring that abortion services remain legal, safe,

[1]The opinions expressed here are those of Dr. Blumenthal and not necessarily those of the Johns Hopkins University, the Johns Hopkins Health System or the Johns Hopkins Bayview Medical Center.

1436 U Street, NW Suite 103 Washington, DC 20009 Telephone: 202.667.5881 Fax: 202.667.589

may result in improved health care for millions of women who are exposed to and die from unsafe and ineffective abortions. Approval by the FDA of mifepristone, would undoubtedly improve access to a safe and effective abortion method worldwide.

As you know, mifepristone is the culmination of many years of research. It has been tested in both developing and industrialized countries by the Population Council and the World Health Organization. The governments of France, England and Sweden have all approved the use of mifepristone after their own rigorous clinical trials, and worldwide, over 200,000 women have used this non-surgical abortion method. Moreover, mifepristone has many other potential uses besides that of an abortifacient. It has been tested as an emergency/postcoital contraceptive with promising results. Mifepristone could also be used in treating several other conditions related to pregnancy (induction of labor and cervical dilation); gynecological disorders (infertility, endometriosis, and uterine fibroids); and other medical problems such as breast cancer. With so many potential uses and an impressive and efficacious record, we hope that mifepristone will be favorably reviewed by the Food and Drug Administration (FDA). Mifepristone is an important option for women faced with unwanted pregnancies, and I urge you to approve it for use in the United States.

University of Colorado Health Sciences Center

Department of Medicine
Division of Endocrinology, Metabolism and Diabetes

Campus Box B151
4200 East Ninth Avenue
Denver, Colorado 80262
(303) 270 8443
FAX: (303) 270-4525

July 11, 1996

The FDA Advisory Committee on
Reproductive Health Drugs

RE: Hearing on Mifepristone (RU486)
Friday, July 19, 1996

Ladies and Gentlemen:

I am a Professor of Medicine at the University of Colorado School of Medicine, engaged in basic research on the role of progesterone and antiprogestins on the growth of breast cancers.

I have two comments about the impact of current federal policies on my ability to conduct basic research on breast cancer using RU486:

1). Despite many years of discussions, THERE IS STILL NO AMERICAN SOURCE FOR THIS DRUG. Research scientists either have to network with foreign colleagues and institutions in order to obtain paltry supplies of RU486, or they can not get it at all. I urge the FDA to rectify this problem expeditiously.

2). Some Members of Congress continue to request detailed information from National Institutes of Health (NIH) administrators about 1) individual scientists who are using RU486 for research; 2) the type of research being done with RU486; 3) dollar amounts of grants, etc. I doubt that these individuals are requesting similar information from NIH about funding of Testosterone research.

I find these congressional inquisitions frightening, and needless to say, such tactics have a chilling effect on the progress of research into the uses of antiprogestins to improve the reproductive health of American women.

Thank you for the opportunity to air my views.

Sincerely yours,

Kathryn B. Horwitz, Ph.D.
Professor of Medicine and Pathology
University of Colorado Health Sciences Center

writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person in writing by mail, e-mail, or fax no later than 5 p.m., EDT on July 12, 1996, with a brief statement of the general nature of the evidence or arguments they wish to present, the names, telephone numbers, and addresses of proposed participants, and an indication of the approximate time required to make their comments. The time for presentations will be allotted equitably, and will depend on how many individuals give advance notice within the time indicated of their intention to speak. In the interest of time, the agency may require persons with common interests to make joint presentations.

Open committee discussion. The committee will discuss the new drug application for mifepristone for the interruption of early pregnancy.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above in writing, prior to the meeting.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: June 25, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-16770 Filed 6-28-96; 8:45 am]

BILLING CODE 4160-01-F

THE POPULATION COUNCIL

ANNUAL REPORT 1994

The Population Council, a nonprofit, nongovernmental research organization established in 1952, seeks to improve the wellbeing and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources.

The Council analyzes population issues and trends; conducts research in the reproductive sciences; develops new contraceptives; works with public and private agencies to improve the quality and outreach of family planning and reproductive health services; helps governments design and implement effective population policies; communicates the results of research in the population field to diverse audiences; and helps strengthen professional resources in developing countries through collaborative research and programs, technical exchange, awards, and fellowships.

Research and programs are carried out by three divisions—the Center for Biomedical Research, the Research Division, and the Programs Division—and two Distinguished Colleagues. Council headquarters and the Center for Biomedical Research are located in New York City; the Council also has four regional and 14 country offices overseas. About 365 women and men from 62 countries work for the Council, more than a third of whom hold advanced degrees. Roughly 40 percent are based in developing countries. Council staff collaborate with developing country colleagues to conduct research and programs in some 50 countries in South and East Asia, West Asia and North Africa, sub-Saharan Africa, and Latin America and the Caribbean.

The Council is governed by a board of trustees composed of men and women from 12 countries. This group includes leaders in international family planning, development activists, business people, physicians, and social scientists.

The organization's funds come from governments, foundations and other nongovernmental organizations, internal sources, multilateral organizations, corporations, and individuals. The Council's current budget is US$49 million.

THE POPULATION COUNCIL

CENTER FOR BIOMEDICAL RESEARCH

The Center for Biomedical Research undertakes basic research in the reproductive sciences and develops technologies that enable individuals to have safe, planned pregnancies and that promote their reproductive health. The Center is one of the world's leading institutions in the fields of contraceptive development and male reproductive physiology.

Staff in the Contraceptive Development Program conduct applied research and develop new methods of contraception to meet the needs of women and men. Clinical trials of drug formulations and devices developed at the Center are conducted by the Council's International Committee for Contraception Research (ICCR), a group of investigators from several countries who serve as consultants in the clinical evaluation of experimental contraceptive methods. The Contraceptive Development Program collaborates with the Council's Programs Division in contraceptive introduction and postmarketing activities.

Staff in the Reproductive Physiology Program conduct basic research on reproductive processes in women and men. Investigations focus on male reproductive physiology, with the goal of understanding the coordinated sequence of events associated with male hormonal action, sperm maturation, and fertilization. This research, results of which are published in respected scientific journals, complements the Contraceptive Development Program by increasing the prospects for developing safe and effective contraceptives.

Through its postdoctoral training program in reproductive biomedicine, the Center sustains and enlarges the community of scientists whose research leads to advances in reproductive health care and new and improved contraception. This program helps train the next generation of reproductive scientists from developing countries, enhancing the capacity of those countries to address reproductive health issues.

C. Wayne Bardin, Vice President, heads the Center for Biomedical Research; James Catterall is Director of Reproductive Physiology, and Rosemarie Thau is Director of Contraceptive Research. The staff of 85 includes 25 principal investigators; in addition to staff, 26 postdoctoral fellows work at the Center, which is located on the campus of the Rockefeller University.

AREAS OF RESEARCH IN 1994

CONTRACEPTIVE DEVELOPMENT vaginal rings • spermicides and microbicides • abortifacients • subdermal implants for women and men • intrauterine devices • antifertility vaccines • probing studies in female and male contraception REPRODUCTIVE PHYSIOLOGY receptors and transcription • genetic mechanisms of androgen action • steroid metabolism • physiology of Sertoli cells • development and physiology of Leydig cells • testicular proteins • biology of gametes • transmission of HIV

RESEARCH DIVISION

The Research Division's broad aims are to marshal social science expertise toward a better understanding of population issues and to promote applications of that knowledge to the design and implementation of policies and programs responsive to individual and societal needs in developing countries. The division undertakes analyses of population policy, demographic behavior, and interrelationships between population and socioeconomic change, often in collaboration with colleagues in developing countries. It administers the Population Council Fellowships in the Social Sciences, a program that plays a major role in strengthening developing countries' professional resources in the population field.

Population policy is defined broadly as the full range of government actions with a potential population impact. In addition to analyzing policy, division staff study critical inputs into policy formation, such as consequences of population change at the individual and societal level.

The largest share of the division's research is on fertility and family planning, which includes analysis of fertility determinants and the factors underlying the unmet need for contraception, as well as experimental research to improve program design and performance. Work in these areas goes beyond narrow demographic issues, reflecting a deep concern for individual rights, health, and well-being.

The division's research on gender and family examines how family structure and function and men's and women's roles affect fertility outcomes and parental investment in children. Particular attention is given to adolescence as a critical social, economic, and reproductive phase in the life cycle.

John Bongaarts, Vice President, heads the Research Division; Cynthia B. Lloyd is Director of Social Science Research. The division's staff of 19 includes demographers, economists, sociologists, and anthropologists with expertise in the population issues of developing countries.

AREAS OF RESEARCH IN 1994

POPULATION POLICY redefining population policy • family, development, and population policy • population and environment • population and economic development • population policy in China and India • consequences of rural-urban migration FAMILY PLANNING experimental studies in family planning • monitoring and analysis of family planning programs • determinants of reproductive behavior • unmet need for contraception • evaluation of program impact GENDER, FAMILY, AND DEVELOPMENT investing in children • child mortality in China • adolescence and the transition to adulthood • women's roles

PROGRAMS DIVISION

The Programs Division collaborates with governments, nongovernmental organizations, and scientific institutions in developing countries to design and implement population policies, improve delivery of family planning and related health services, enhance understanding of the determinants of reproductive behavior, and improve the conditions of women. This collaboration includes professional exchanges and research, training, awards, technical assistance, and dissemination of information.

The division's activities are divided into four programs: Population Policy, Reproductive Health, Family Planning, and Gender, Family, and Development. Work in these areas is developed, implemented, and evaluated by an interregional office in New York; regional offices in Cairo (West Asia and North Africa), Mexico City (Latin America and the Caribbean), Nairobi (sub-Saharan Africa), and New Delhi (South and East Asia); and 14 country offices.

Strengthening professional resources in developing countries is an objective of all programmatic activities. The division sponsors special programs to further this aim in the Middle East, Bangladesh, Mali, and Vietnam through awards, training, and institutional development.

George Brown, Vice President, heads the Programs Division; Anrudh Jain is Director, Programs, and Louise Kantrow is Director, Operations. Program Directors are: Judith Bruce (Gender, Family, and Development), Andrew Fisher (Family Planning), and Beverly Winikoff (Reproductive Health). Regional Directors are: Ayorinde Ajayi (sub-Saharan Africa), Barbara Ibrahim (West Asia and North Africa), Ana Langer (Latin America and the Caribbean), and Saroj Pachauri (South and East Asia). The division's staff of 183 includes 68 health and social scientists and other professionals.

AREAS OF RESEARCH AND PROGRAMS IN 1994

POPULATION POLICY population policies in Egypt, India, Kenya, and Mexico • population policy issues in the Middle East REPRODUCTIVE HEALTH quality of services in reproductive health programs • managing unwanted pregnancy and preventing the consequences of unsafe abortion • new approaches to postpartum care • programs that address sexually transmitted diseases, including AIDS, within the context of improving women's reproductive health • safe motherhood • acceptability of reproductive health technologies FAMILY PLANNING operations research and technical assistance (OR/TA) regional programs in Africa, Asia, and Latin America • family planning research and technical assistance in Bangladesh, Mali, Pakistan, and Vietnam • improving quality of care in Indonesia, Peru, and Vietnam • expanding contraceptive choice in Africa, Asia, and Latin America GENDER, FAMILY, AND DEVELOPMENT family structure and women's economic contributions to families • fathers' roles and responsibilities • family policy • gender training

DISTINGUISHED COLLEAGUES

The Population Council staff includes two Distinguished Colleagues, who provide an additional source of expertise in areas of relevance to the Council and represent the organization in their fields internationally.

Paul Demeny, Distinguished Scholar, investigates the consequences of population change and analyzes public policy debates on population issues. He also serves as Editor of the Council's quarterly journal, *Population and Development Review*.

Sheldon Segal, Distinguished Scientist, conducts and coordinates biomedical research bearing on fertility regulation and reproductive health. He is also a scientific advisor to other organizations on matters related to family planning, reproductive rights, and ethical issues in population.

CORPORATE AFFAIRS

Corporate Affairs encompasses the office of Finance, Computer Services, Information Systems, Personnel and Office Services, and the External Relations Group, which includes Development, Public Information, Publications, the Library, and Grants and Contracts.

The division provides supporting services to the Council and, through its Publications and Public Information offices, communicates work by Council staff, consultants, and colleagues to an international community of policymakers, government planners, activists, teachers, media professionals, and the general public. Council publications include two scholarly journals, *Population and Development Review* and *Studies in Family Planning*, as well as newsletters, working papers, pamphlets, and books.

Sandra Arnold, Vice President, heads Corporate Affairs, overseeing a staff of 74. Donald Abrams is Treasurer and Director of Finance, and Monica Knorr is Corporate Secretary and Senior Director of the External Relations Group.

BOARD OF TRUSTEES

McGEORGE BUNDY
Chair
Scholar-in-Residence
Carnegie Corporation of New York
New York, New York

ROBERT H. EBERT
Chair Emeritus
Caroline Shields Walker Professor of Medicine Emeritus
Harvard University;
Consultant to the President and to the Chairman
Milbank Memorial Fund
New York, New York

MARGARET CATLEY-CARLSON
President
The Population Council
New York, New York

JORGE BALÁN
Senior Researcher
Centro de Estudios de Estado y Sociedad
Buenos Aires, Argentina

GEORGE BENNEH
Vice Chancellor
University of Ghana
Legon, Ghana

JOHN C. CALDWELL
Coordinator
Health Transition Centre
Australian National University
Canberra, Australia

LAURA CHASIN[1]
Faculty
Family Institute of Cambridge
Watertown, Massachusetts

EDDAH GACHUKIA
Executive Director
Forum for African Women Educationalists
Nairobi, Kenya

WERNER HOLZER
Washington, DC

AZIZA HUSSEIN[2]
Chair of the Board
Cairo Family Planning Association
Cairo, Egypt

LUCILLE MATHURIN MAIR[1]
Ambassador–Permanent Representative of Jamaica to the United Nations
New York, New York

ELIZABETH J. McCORMACK[2]
Associate
Rockefeller Family and Associates
New York, New York

ROBERT B. MILLARD
Managing Director
Lehman Brothers Inc.
New York, New York

FREDERICK T. SAI[2]
President
International Planned Parenthood Federation
London, England

SHOICHI SAKAMOTO[2]
Professor and Director
Aiiku Maternal and Child Health and Welfare Center
Tokyo, Japan

GUILLERMO SOBERÓN ACEVEDO
Executive President
Fundación Mexicana para la Salud
Mexico City, D.F. Mexico

KRISTER STENDAHL
Professor and Dean Emeritus
Harvard Divinity School
Cambridge, Massachusetts;
Former Bishop of Stockholm, Sweden

HALDOR TOPSØE[2]
Chair
Haldor Topsøe A/S
Copenhagen, Denmark

AMINATA TRAORE
Regional Coordinator
PROWESS/AFRICA, United Nations Development Programme
Abidjan, Ivory Coast

MECHAI VIRAVAIDYA
Chair
Population and Community Development Association
Bangkok, Thailand

Executive Committee
McGeorge Bundy, *Chair*
Margaret Catley-Carlson
Robert H. Ebert
Werner Holzer[3]
Robert B. Millard[3]
Guillermo Soberón Acevedo[3]

Finance Committee
Robert B. Millard, *Chair*
Margaret Catley-Carlson
James D. Wolfensohn[4]

Audit Committee
George Benneh,[3] *Chair*
Eddah Gachukia
Krister Stendahl[3]

Nominating Committee
McGeorge Bundy, *Chair*
Jorge Balán[3]
John C. Caldwell[3]
Margaret Catley-Carlson
Laura Chasin[1,3]
Robert H. Ebert
Aminata Traore
Mechai Viravaidya[3]

Salary Committee
McGeorge Bundy, *Chair*
Margaret Catley-Carlson
Robert H. Ebert

[1] Until December 1, 1994
[2] Until June 30, 1994
[3] As of July 1, 1994
[4] As a non-trustee member

OFFICERS

McGEORGE BUNDY
Chair of the Board

MARGARET CATLEY-CARLSON
President

SANDRA ARNOLD[1]
Vice President, Corporate Affairs

C. WAYNE BARDIN
Vice President, Center for Biomedical Research

JOHN BONGAARTS
Vice President, Research Division

GEORGE F. BROWN
Vice President, Programs Division

SHIRLEY ALEXANDER[2]
Secretary

MONICA KNORR
Corporate Secretary[3]*/Senior Director, External Relations Group*

DONALD J. ABRAMS
Treasurer and Director of Finance

[1] As of July 5, 1994
[2] Until October 26, 1994
[3] As of December 8, 1994

Seated (l to r): ***Benneh, Catley-Carlson, Bundy, Millard, Gachukia*** *Standing (l to r):* ***Holser, Caldwell, Stendahl, Balán, Viravaidya***

Seated (l to r): ***Bardin, Catley-Carlson, Bundy, Abrams*** *Standing (l to r):* ***Brown, Knorr, Bongaarts, Arnold***

I dare to think that a new global realization was attained at the International Conference on Population and Development in Cairo in September 1994. It is this: Demographic and development objectives will not be reached without improving people's—particularly women's—lives. Population policy must concern itself with more than family planning services.

This is precisely the agenda that the Population Council has been exploring, expanding, and implementing for many years.

For several decades policymakers have emphasized numbers—slowing the rate of population growth to accelerate economic development and alleviate poverty. At Cairo, the need to stabilize world population sooner rather than later was ever present, but the accent was on improving people's lives and future prospects. Issues related to the quality of men's and women's lives permeate the conference's Programme of Action: the value of education for all, but especially for young girls (who now comprise 70 percent of children not in school), of women's access to income and credit, and of men's involvement in caring for children. Improvement in these areas is a worthy end in itself, but it would also have a substantial, positive impact on our global demographic situation by changing people's childbearing decisions and reproductive behavior.

While several issues at Cairo were highly contentious, family planning was so widely accepted that its value was hardly questioned. In this area the Cairo conference focused on improving quality of care and responding to individual needs, in part by recommending that appropriate reproductive health measures be integrated into family planning programs. Although the subject of abortion generated controversy that grabbed worldwide media attention, unsafe abortion was, for the first time, quietly acknowledged as a global public health problem

PRESIDENT'S MESSAGE

CHARTING A POST-CAIRO COURSE

responsible for hundreds of thousands of maternal deaths, disabilities, and illnesses every year.

Reflecting these concerns, Council programs stress safe contraception for women and men and improved quality and evaluation of family planning services. Council researchers continue to investigate ways to meet the vast unmet need for contraception and safe abortion around the world. The Council has been instrumental in testing the safety and acceptability of medical abortion using mifepristone (formerly RU 486). Medical abortion can save women's lives by providing a more private, noninvasive alternative to surgical abortion.

The Council also addresses several issues that were somewhat sidestepped at Cairo. These include the special needs of adolescents—the subject of a new Council initiative investigating ways to improve girls' prospects by increasing their educational and employment opportunities and fostering conditions that promote later, voluntary sexual and marital relationships and childbearing. On another front, the Council is pursuing research on preventing the spread of AIDS and other even more prevalent sexually transmitted diseases. Council scientists are developing a woman-controlled microbicide that would protect the user against a range of sexually transmitted diseases, including AIDS.

With global population quickly approaching 6 billion, we must not forget the impact of rapid population growth on development and the environment. Population is projected to increase until it stabilizes at less than 8 billion or reaches about 12 billion—depending on what we do in the next decade—by the year 2050, with most of the growth occurring in the developing world. Our research on the determinants and consequences of high fertility and rapid population growth, and our policy recommendations based on this research, have never been more needed.

There is now both exceptional promise and peril in the population field. On one side, we have global agreement on so many policies relevant to women. The Programme of Action sets quantitative goals for reducing infant, child, and maternal mortality rates by the year 2015. It also sets a price for a package of services in maternal health care, family planning, prevention of sexually transmitted diseases, and data collection: $17 billion annually by the year 2000, $21.7 billion by 2015. The world spends a good deal more than this every year playing golf or preparing for war. As a global civilization, we have choices to make.

Post-Cairo, the horizon of the population field is nebulous. The Council is confronted with deep budget cutbacks in institutional and government spending—and even more proposed cuts—which threaten continuation of current programs and development of new initiatives. We need to reach out to a wider audience to make the case for continued progress in population-related work. The next few years will test our programming and fundraising abilities to build on and surpass the spirit of Cairo.

March 1995

MARGARET CATLEY-CARLSON

There is now both exceptional promise and peril in the population field.

As a global civilization, we have choices to make.

The Population Council is dedicated to two broad, closely linked goals: 1) improve the wellbeing and reproductive health of current and future generations and 2) achieve a humane, equitable, and sustainable balance between people and resources. This dual mission guides Council staff in pursuing five practical, overlapping objectives: broaden the population agenda, improve reproductive health, reduce unplanned and unwanted pregnancies safely, create conditions favorable for smaller families, and alleviate pressures for early sexual activity and marriage.

The wide scope of Council activities in these areas—ranging from molecular biology to demography, from contraceptive development to on-site analyses of family planning programs and clinical trials—distinguishes the Council in the population field. The work described in the following pages represents a cross-section of the diverse projects underway at the Population Council.

RESEARCH AND PROGRAM

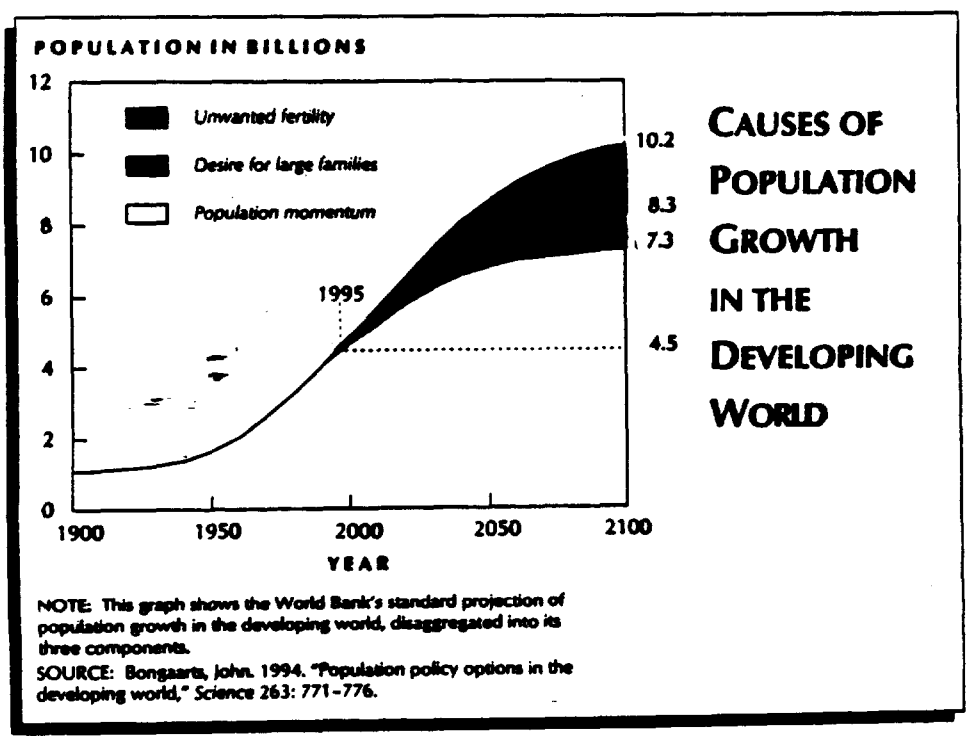
HIGHLIGHTS

Broaden the Population Agenda

The population field, once focused largely on family planning programs, has expanded to embrace a wide range of social and economic issues now understood to have a significant impact on reproductive behavior and demographic change. This broadened perspective was reflected in the agenda of the 1994 International Conference on Population and Development in Cairo—an agenda the Population Council played an important role in shaping. Indeed, the Council has for many years led the movement toward a broad-based approach to population issues.

The Council has also taken the lead in advocating a shift in focus from numbers to people—another tenet now widely held in the population field. The Council believes that family planning programs ought to help individuals meet their own reproductive goals in a healthful manner by focusing on reducing *unwanted* fertility safely. This rationale for family planning programs suggests that the population agenda must address issues related to individual wellbeing—notably reproductive health and freedom of choice—that may be minimized or excluded when family planning programs are designed to meet demographic targets.

In Cairo, the Council had many opportunities to communicate these views to the large international community of government leaders, policymakers, scholars, activists, and representatives of other nongovernmental organizations (NGOs) attending the population conference. Preparing for this event was a major institutional priority for the Council: Much work in 1994 was undertaken with an eye to



Causes of Population Growth in the Developing World

NOTE: This graph shows the World Bank's standard projection of population growth in the developing world, disaggregated into its three components.

SOURCE: Bongaarts, John. 1994. "Population policy options in the developing world," *Science* 263: 771–776.

Cairo. The Council's activities at the conference included two official presentations by Council President Margaret Catley-Carlson; three panels at the NGO Forum addressing aspects of reproductive health, population policy, and quality of family planning services; a media briefing on women's lives in Islamic countries and related policy issues; and staff participation in several events sponsored by other organizations, including the Distinguished Lecture Series on Population and Development presented by the International Union for the Scientific Study of Population. Results of Council research and programs were widely disseminated through these channels and through publications distributed at the Council's information booth at the NGO Forum.

Population policy

One of the Council publications that circulated at the Cairo conference was a 1994 "issues paper" titled *Population Growth and Our Caring Capacity*, which articulates the Council's argument for broadening the population agenda. The paper presents an approach to population policy developed by John Bongaarts (Vice President, Research Division) and Judith Bruce (Program Director, Gender, Family, and Development, Programs Division) that builds on Bongaarts's analysis of population policy options in "Population Policy Options in the Developing World," a 1994 article in the journal *Science*.

The issues paper explains that, while unwanted fertility remains a key cause of rapid population growth, a desire for large families and population momentum (a consequence of previously high fertility and a young population age structure) also contribute substantially to this growth. Thus, reducing overall fertility requires more than reducing unwanted fertility through family planning programs, vital as these programs are. Efforts are also needed to analyze and ameliorate the conditions that promote the other two components of population growth—efforts such as those underway at the Council to create conditions favorable for smaller families and to alleviate pressures for early sexual activity and marriage. This work aims to improve individual lives, but it will also contribute to stabilizing population—a goal the Council believes ought to be pursued in ways that do not jeopardize the health and wellbeing of individuals.

Effective implementation of population policy requires analysis of the evolution and performance of existing policies in various countries. Such analyses were presented at "Voices from the South—Population Policy Challenges: Case Studies from Africa, Asia, and Latin America," a panel at the Cairo conference NGO Forum, organized by Anrudh Jain (Director, Programs, Programs Division). The panel of social scientists discussed an ongoing comparative study of national policy evolution and performance in Egypt, India, Kenya, and Mexico. Country-specific studies were also undertaken in 1994 by staff in the Research Division, who investigated population policy in India and China.

DOCUMENTED OR SUSPECTED PHARMACOLOGICAL ACTIONS OF RU486

Appendix A

		References
1.	Interference with pinopod function.	1
2.	Stimulation of steroidogenesis.	2
3.	Disruption of folliculogenesis.	3
4.	Inhibition of ovulation.	3
5.	Decreased intracellular calcium.	4
6.	Decreased penetration of oocytes by spermatazoa.	4
7.	Interference with progesterone receptor function.	5
8.	Inhibition of aldosterone effect.	6
9.	Altered ratios of LH:FSH.	7
10.	Altered ratios of testosterone:estradiol.	7
11.	Increased serum prolactin.	7
12.	Altered release of androgen.	7
13.	Increased testosterone.	7
14.	Relative deficiency of FSH.	14
15.	Decreased ovulatory LH release.	15
16.	Increased LH during follicular growth.	15
17.	Altered serum estrogen profiles.	16
18.	Suppressed progesterone levels.	8
19.	Inhibition of E2 secretion.	8
20.	Induction of cervical ripening during pregnancy.	9
21.	Delayed emergence of the periovulatory progesterone rise.	10
22.	Induced dilatation and softening of the uterus.	17
23.	Disruption of sexual development in rat embryos.	11
24.	Inhibition of in vitro development of mouse 2 celled embryos, morulae, and early blastocytes.	18
25.	Interference with egg transport.	19
26.	Reduced perivascular decidual cell hemostasis.	12
27.	Degradation of endometrial extracellular matrix	12
28.	Inhibition of normal secretory transformation of the endometrium.	13
29.	Inhibition of steroidogenesis.	2

CHARLES M. CARGILLE, MD
2486 Hyman Place
New Orleans, Louisiana 70131

REFERENCES

1. Edwards RG, Human Reproduction. Vol 9(Suppl. 2) (pp 73-87), 1994.
2. Curry Jr TE. Clinical Obstetrics & Gynecology. Vol 39(2) (pp *486-497), 1996.
3. Kekkonen R et al, Contraception. Vol 53(4) (pp193-195), 1996.
4. Yang J et al.International Journal of Andrology. Vol 19(1) (pp 61-66), 1996
5. Croxatto, HB et al, Human Reproduction. Vol 9(8) (pp 1442-1447) 1994.
6. Garty H. American Journal of Physiology. Vol 266(1 35-1) (pp F108-F116), 1994.
7. Sanchez-Criado JE et al. Journal of Reproduction & Fertility. Vol 99(1) (pp 173-179), 1993.
8. Spitz IM et al. Fertility & Sterility. Vol 59(5) (pp 971-975), 1993.
9. Bygdeman M et al. Annals of Medicine. Vol 25(1) (pp 61-64), 1993.
10. Batista MC et al. Journal of Clinical Endocrinology & Metabolism. Vol 74(3) (pp 565-570), 1992.
11. Weinstein MA et al. Pharmacology, Biochemistry & Behavior. Vol 41(1) (pp 69-74), 1992.
12. Lockwood CJ et al. MEDLINE: K=95229794.
13. Gemzell-Danielsson K. MEDLINE: K=95229895.
14. Sanchez-Criado JE et al. Biology of Reproduction. Vol 42(5-6) (pp 877-886), 1990.
15. Sanchez-Criado JE et al. Advances in Contraceptive Delivery Systems. Vol 9(2-3) (pp 151-163), 1993.
16. Kekkonen R et al. Fertility & Sterility. Vol 60(4) (pp 610-615), 1993.
17. Spitz IM. Bardin CW. Endocrinologist. Vol 3(1) (pp 58-66), 1993.
18. Juneja SC et al. Canadian Journal of Physiology & Pharmacology Vol 68(11) (pp 1457-1460), 1990.
19. Yang YQ et al. Contraception. Vol 41(5) (pp 551-556), 1990.

Contact:
Suzanne Delbanco
415/854-9400 ext. 123

1995 Kaiser Family Foundation Survey on Mifepristone: Knowledge and Attitudes Among Obstetrician-Gynecologists

Prepared for
Reproductive Health Drug Advisory Committee
U.S. Food and Drug Administration

July 19, 1996

Conducted by Fact Finders, Inc. for the Kaiser Family Foundation

2400 Sand Hill Road Menlo Park, California 94025 415 854-9400 Fax 415 854-4800
Washington, DC Office: 1450 G Street, NW, Suite 250 Washington, DC 20005 202 347-5270 Fax 202 347-5274

Abortion Delivery In the United States:
Half of Ob-Gyns Would Prescribe Mifepristone if Approved by the F.D.A.

One Third of Ob-Gyns Who Don't Currently Perform Surgical Abortions Say They Would Be Likely to Offer Mifepristone

A Kaiser survey found that six out of ten (59%) obstetrician-gynecologists (ob-gyns) familiar with mifepristone (also known as RU-486) -- or five out of ten (50%) of all ob-gyns -- say they would be "likely" to prescribe the drug for abortions if approved by the U.S. Food and Drug Administration (F.D.A.). (Sixteen percent of all ob-gyns surveyed said they were "not familiar" with mifepristone and therefore were unable to respond about their likelihood of prescribing the drug.)

Furthermore, many of the doctors who don't perform surgical abortions indicate that they would be likely to offer this non-surgical, or medical, method of abortion. Four out of ten (41%) ob-gyns who don't currently perform abortions and who are familiar with mifepristone -- or a third (33%) of all ob-gyns who don't perform abortions -- say they would be "very" or "somewhat" likely to prescribe the drug for abortions if approved by the F.D.A. (Nineteen percent of all ob-gyns surveyed who do not perform abortions said they were "not familiar" with mifepristone and therefore were unable to respond as to their likelihood of prescribing the drug.) Among ob-gyns who cite an "ethical," "moral," or "religious" reason for not performing surgical abortions, 2 out of 10 say they would be "likely" to prescribe mifepristone for abortions. Among ob-gyns who don't currently perform abortions, those most likely to say they would prescribe mifepristone are those who cite some reason other than "ethical," "moral," or "religious," such as community pressure, institutional barriers, or some other reason.

Ob-Gyns familiar with mifepristone consider it a "safe" and "effective" drug regimen to end a pregnancy. Ninety-seven percent of ob-gyns familiar with mifepristone say it is "effective," including three-quarters (76%) who say it is "very effective." The remaining three percent had "no opinion." Physicians are similarly confident about mifepristone's safety: more than nine out of ten ob-gyns familiar with mifepristone (94%) say it is "safe," including six out of ten (58%) who say it is "very safe." The remaining six percent had "no opinion." (The 16 percent of ob-gyns who said they "not familiar" with mifepristone were not asked about the effectiveness and safety of the mifepristone regimen.)

Methodology

The Kaiser Survey on Physicians' Attitudes and Practices Regarding Contraception and Unplanned Pregnancy was a telephone survey of 307 obstetricians/gynecologists drawn in a random-probability sample design from the American Medical Association's Physicians Masterfile. It was conducted for the Foundation by Fact Finders, Inc. between February 1 and March 21, 1995. The margin of sampling error for the national sample is plus or minus 5.7 percent. The margin of sampling error may be higher for some of the sub-sets looked at in this analysis, which have smaller populations.

The Kaiser Family Foundation, based in Menlo Park, California, is a non-profit, independent national health care philanthropy and is not associated with Kaiser Permanente or Kaiser Industries. The Foundation's work is focused on four main areas: health policy, reproductive health, HIV, and health and development in South Africa.

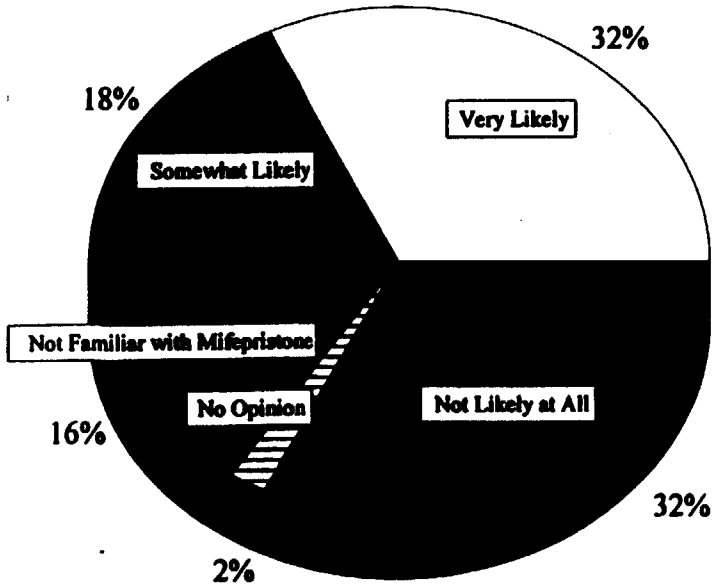
* * *

CHART 1

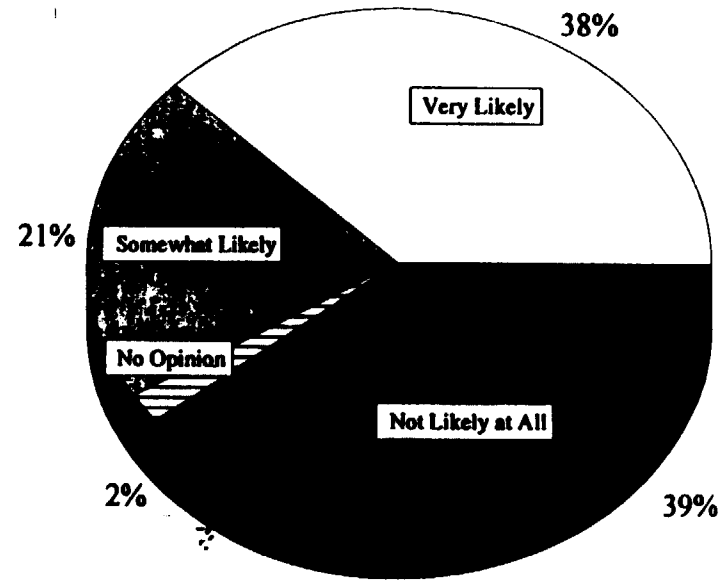
Many Ob-Gyns Say They Will Offer Medical Abortion

Likelihood to Prescribe Mifepristone (RU-486) if Approved by the F.D.A.

Among All Ob-Gyns
(N = 305)



Among Ob-Gyns Familiar with
Mifepristone
(N = 255)



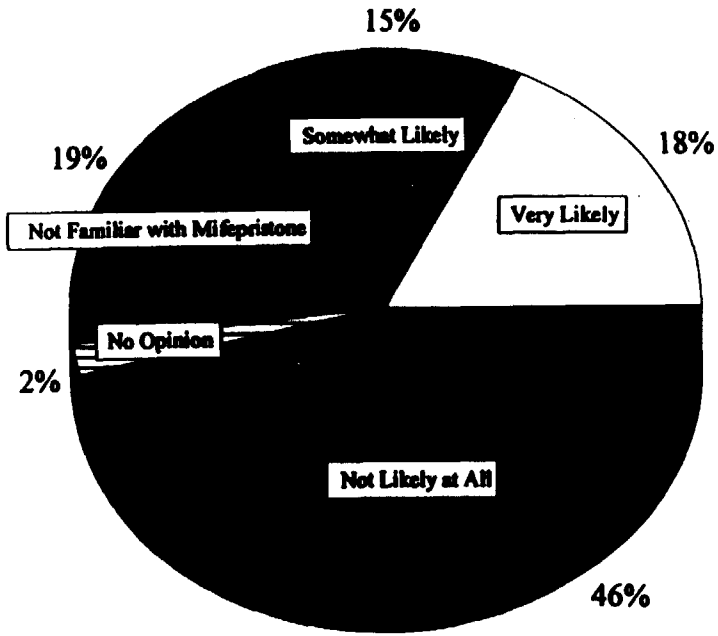
Source: 1995 Kaiser Family Foundation Survey on Physicians' Attitudes and Practices Regarding Contraception and Unplanned Pregnancy

CHART 2

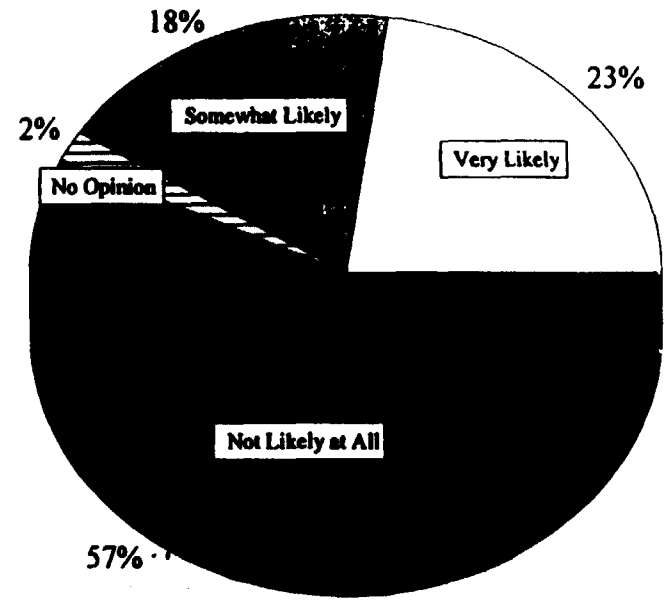
Medical Abortion May Expand Number of Providers

Likelihood of Ob-Gyns Who Don't Perform Surgical Abortion to Prescribe Mifepristone (RU-486) if Approved by the F.D.A.

Among All Ob-Gyns Who Don't Currently Perform Abortions (N = 201)



Among Ob-Gyns Who Don't Currently Perform Abortions and Who Are Familiar with Mifepristone (N = 155)



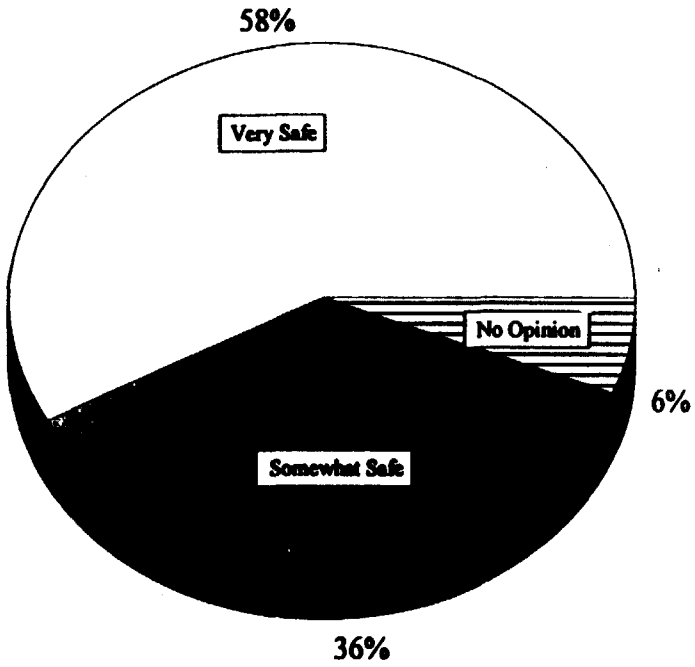
Source: 1995 Kaiser Family Foundation Survey on Physicians' Attitudes and Practices Regarding Contraception and Unplanned Pregnancy

CHART 3

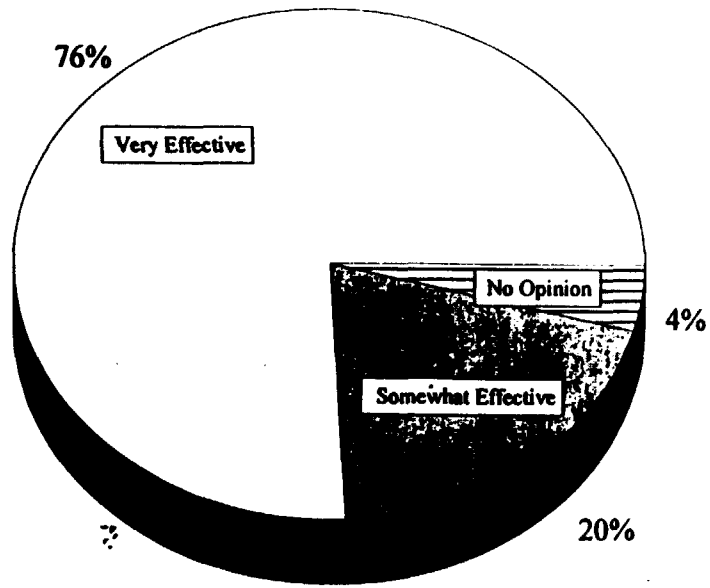
Ob-Gyns Consider Mifepristone "Safe" and "Effective"

Views Among Ob-Gyns Familiar with Mifepristone

Safety of Mifepristone



Effectiveness of Mifepristone



Source: 1995 Kaiser Family Foundation Survey on Physicians' Attitudes and Practices Regarding Contraception and Unplanned Pregnancy

STATEMENT OF

THE ALAN GUTTMACHER INSTITUTE

BEFORE THE

ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS

OF THE

FOOD AND DRUG ADMINISTRATION

JULY 19, 1996

Presented by

Lisa Kaeser, JD
Senior Public Policy Associate

Good afternoon. I am Lisa Kaeser, representing The Alan Guttmacher Institute (AGI), an independent, not-for-profit corporation for research, policy analysis and public education on issues relating to reproductive health. We appreciate the opportunity to make a statement regarding the committee's consideration of the use of mifepristone for the interruption of early pregnancy.

As you may know, six in 10 pregnancies in the United States are unintended. Nearly half of these end in abortion. Currently, abortion is a legal procedure used by almost half of all women in this country at some point in their lives. Any new method of abortion, including medical abortion such as mifepristone, should be judged and made available based on the scientific evidence of its safety and effectiveness, according to the criteria and processes applicable to other medical treatments. Thus, if the Food and Drug Administration (FDA) determines, based on the evidence presented and its own best judgement, that mifepristone is safe and effective, it should be approved, and a new option can be made available to women in the U.S.

Once the decision to have an abortion is made, time is of the essence. The risk of complications increases with the length of gestation, and most women who have made the decision to terminate pregnancy want to do so as soon as possible. Even though currently available surgical methods of abortion are very safe, medical methods of abortion, such as mifepristone, could be extremely useful to women who prefer not to have surgery.

Moreover, while 98% of abortion facilities will provide services at eight weeks' gestation, most providers of surgical abortion set minimum gestation limits before which

they will not perform the procedure. According to AGI's most recent abortion provider survey, conducted in 1993, the most common gestation requirement is six weeks since a woman's last menstrual period (LMP), the criterion used by 43% of nonhospital facilities. In fact, only 26% of surgical abortion providers offer care to women at four or five weeks LMP. Some 24% of facilities do not provider surgical abortion until women are at least seven weeks (19%) or eight weeks (five percent) from LMP, that is, at least five weeks since conception.

Many of these limitations continue to exist, despite the fact that the newest pregnancy tests are highly sensitive, some accurately predicting pregnancy as soon as ten days after conception, and allowing women who ultimately choose abortion to make their decisions earlier. For those who do not want to wait until later in the pregnancy to obtain surgical abortion, a medical method that can be used earlier could be highly beneficial.

While the availability of medical abortion has the potential to reduce some of the barriers to abortion services, at this time we do not know what kind of eventual impact the approval of mifepristone will have. It would be unrealistic to expect this new method to solve *all* problems of access. As it is, few providers are available to perform surgical abortions – particularly in some areas of the country. Currently, 66% of private fee-for-service and 77% of HMOs in the U.S. cover surgical abortion. If mifepristone is deemed by the FDA to be safe and effective for the termination of early pregnancy, and is approved, coverage for this new option should be at least the same as that for surgical abortion.

Clearly, the political pressures brought to bear against surgical abortion and its providers have already affected the development of medical abortion. Unfortunately,

these pressures have also served to slow research on mifepristone and related drugs for other purposes, including their possible use for contraception. Should the FDA approve mifepristone, we hope that these other avenues can be pursued.

FEMINIST MAJORITY FOUNDATION
Working for Women's Equality

Eleanor Smeal
President

Peg Yorkin
Chair of the Board

Katherine Spillar
National Coordinator

Washington D.C. Office
1600 Wilson Boulevard
Suite 801
Arlington, VA 22209
703 522 2214
703 522 2219 fx

West Coast Office
8105 West Third Street
Los Angeles, CA 90048
213 651 0495
213 653 2689 fx

Web Site:
http://www.feminist.org

E-mail:
femmaj@feminist.org

TESTIMONY BEFORE THE U.S. FOOD AND DRUG ADMINISTRATION ADVISORY COMMITTEE ON REPRODUCTIVE HEALTH

JULY 19, 1996

ELEANOR SMEAL, PRESIDENT FEMINIST MAJORITY FOUNDATION

My name is Eleanor Smeal. I am President of the Feminist Majority Foundation.

For the past eight years, French women and now women in Great Britain, Sweden, and China have had available to them the option of medical abortion. For eight long years, American women have fought to have this safe, effective choice available to them.

Every step of the way, rather than decisions being based on pure science and medicine, politics instead have blocked or slowed the distribution of Mifepristone. If the medical well-being of women were the only issue, Mifepristone would have been approved eight years ago.

The Feminist Majority Foundation has led the nation's largest public education campaign to make Mifepristone available in the United States. We began our Campaign for RU 486 and Contraceptive Research in 1988 after an exhaustive review of scientific data on Mifepristone, extensive consultations with leading scientists and health care providers in the United States and abroad, and visits to clinics in France where we spoke with women who had undergone medical abortions with Mifepristone. As women's health advocates, we wanted to make sure Mifepristone was as safe, effective, and acceptable to women as it appeared from news reports. Our conclusion: Mifepristone as a method of early abortion and as a potential treatment for diseases and conditions ranging from some forms of breast cancer to endometriosis is a major medical breakthrough in women's health care that must be made available to women in the United States.

The feminist and scientific communities in the United States share this very positive assessment of Mifepristone. Over the past seven years, we have delivered over 700,000 petitions from women and men in this country urging the French pharmaceutical company that developed RU 486 and its German parent company to license the compound in the United States. We also presented petitions from 3,000 scientists and academicians who were outraged at the "medical McCarthyism" of

clinical trials. He has published over 30 peer-reviewed articles on RU 486. In all of this research experience, Dr. Hodgen has found no scientific evidence of safety problems from Mifepristone. Even embryonic and fetal development progressed normally, despite early exposure to RU 486 either *in vitro* or *in utero*. Dr. Hodgen concludes, "I believe that this drug is safe for women!"

The Feminist Majority Foundation has fought long and hard to protect women's access to abortion and other medical services. In addition to our work to bring Mifepristone to this country, we lead a nationwide National Clinic Access Project to help protect clinics from anti-abortion violence and to help keep clinics open and accessible. We work closely with all types of clinics: for-profit and non-profit, independent and those affiliated with large organizations, and individual doctors that perform abortions. We also conduct an annual clinic violence survey. Our 1995 Survey found that violence at clinics declined overall, but 38.7% of clinics still faced one or more of the most severe forms of violence, including death threats, stalking, bomb threats and bombings, chemical attacks, blockades, invasions, arson and arson threats. Availability of Mifepristone could significantly curb anti-abortion violence. As more physicians begin to administer Mifepristone, abortion services will become more decentralized, significantly undermining anti-abortion violence at clinics.

The time for approval of Mifepristone is now -- and long overdue. Every day that Mifepristone is not available to American women is another day that some woman will suffer needlessly. Equally important, every day Mifepristone is not available is another day that scientific development of anti-progestins for a number of serious diseases and conditions primarily affecting women will be delayed.

Today's hearing is on the safety and efficacy of Mifepristone as a method of pregnancy termination. But your actions today and the FDA's ongoing review process of The Population Council's New Drug Application for Mifepristone as an abortifacient have even broader implications for women's health care.

In 1989, under the Bush Administration, the FDA issued an "import alert" on RU 486 that sent the message that the United States was hostile towards the research and development of Mifepristone. The import alert, as scientific researchers testified before Congress, effectively brought to a halt even non-abortion research on Mifepristone. It is time for the FDA to reverse this negative symbolism. With its approval of Mifepristone, the FDA will signal scientists and manufacturers that research on the compound's many indications for improving women's health can move forward at long last.

Here are just some of the promising uses of Mifepristone that result from the compound's properties as both as anti-progestin and an anti-glucocorticoid:

* Mifepristone shows promise as a treatment for progesterone-dependent breast cancers,[2] which account for some 40% of all breast cancer tumors. New research has found Mifepristone may inhibit the proliferation of ovarian cancer cells.[3]

ENDNOTES

[1]Kaiser Family Foundation, National Survey of Obstetricians and Gynecologists on Contraception and Unplanned Pregnancy, 1995.

[2]Klign JGM, *et al.* "Pre-clinical and Clinical Treatment of Breast Cancer with Antiprogestins." *Human Reproduction.* Vol. 9 Supp 1, 1994.

[3]*The Reuter Business Report.* "RU486 May Treat Ovarian Cancer, Researchers Say." February 19, 1995.

[4]Kettel M, Murphy AA, *et al.* "Clinical Efficacy of the Antiprogesterone RU486 in the Treatment of Endometriosis and Uterine Fibroids." *Human Reproduction.* Vol. 9 Supp 1, 1994; Murphy, et al. "Regression of Uterine Leiomyomata in Response to the Antiprogesterone RU486." *Journal of Clinical Endocrinology and Metabolism*, 76(2), 513-17: 1993.

[5]Grunberg, SM, *et al.* "Role of Antiprogestational Therapy for Meningiomas." *Human Reproduction.* Vol. 9 Supp 1, 1994; da-Motta LA, de-Motta LD. "Endocrine Treatment of Meningiomas: a Review." *Arq-neuropsiquiatr.* Vol53(2), June 1995; 324-32.

[6]Nieman, LK *et al.* "Successful Treatment of Cushing's Syndrome with the Glucocorticoid Antagonist RU486." *Journal of Clinical Endocriiology and Metabolism.* Vol 61 (3), 1985; 536-540.

[7]House of Representatives, Subcommittee on Regulation, Business Opportunities, and Energy, Committee on Small Business, RU 486: The Import Ban and its Effects on Medical Research, serial no. 101-85, November 19, 1990.

[8]Chivalisz, K and R Garfield. "Antiprogestins in the Induction of Labor." *Annals, New York Academy of Science.*

[9]Baird, DT, Dewar M, Glasier A, *et al.* "Mifepristone (RU486) Compared with High-Dose Estrogen and Progestogen for Emergency Postcoital Contraception." *New England Journal of Medicine.* Vol 327 N_15, October 8, 1992; 1041-1044.

[10]Weiner, *et al.* The glucocorticoid receptor type II complex is a target of the HIV-1 vpr gene product. *Proc. Natl. Acad. Science, USA*, 92, 3621-3625: (Apr) 1995; "New International Association Provides Evidence of Cortisol's Major Role in AIDS and Other Diseases." *PR Newswire, Financial News.* June 21, 1996.

Planned Parenthood®
Federation of America, Inc.

TESTIMONY OF
GLORIA FELDT, PRESIDENT,
PLANNED PARENTHOOD FEDERATION OF AMERICA,
BEFORE THE FOOD AND DRUG ADMINISTRATION'S
ADVISORY COMMITTEE ON REPRODUCTIVE HEALTH DRUGS

JULY 19, 1996

I am Gloria Feldt, President of the Planned Parenthood Federation of America. Each year, our nearly 1,000 health care centers across the country provide medical and educational services to more than five million patients. The first birth control clinic in the United States was opened 80 years ago by our founder, Margaret Sanger. Ever since, family planning to enable people to prevent unintended pregnancies and plan wanted ones has been the heart and soul of our work.

Planned Parenthood centers provide abortion services to about 130,000 women each year. Six of our centers were part of the US mifepristone clinical trials. The women we serve, and millions of other women, have a strong interest in the issue before you today. Every time there is a news story about medical abortion, women call Planned Parenthood. Often they are women who have just missed their periods -- they are early in an unintended pregnancy.

Many women want to end their unintended pregnancies without surgery or anesthesia. They want to have an abortion as early as possible. Mifepristone gives women the ability to do both these things. Women ask us about medical abortion, and we have to

1120 Connecticut Avenue, N.W., Suite 461, Washington, DC 20036 (202) 785-3351 FAX (202) 293-4349

tell them, "yes, we know it is available in Europe, but we cannot offer it to you here." These women are understandably frustrated.

Political reasons, not medical reasons, stood in the way of introducing mifepristone in France at first, until the Public Health Service declared it to be "the moral property of women" and went forward with it. It has taken us longer to overcome the political obstacles here in the United States. We are gratified that mifepristone, which has been used successfully by more than 200,000 women in Europe, has finally reached the point of FDA consideration. Mifepristone should be reviewed in the same manner as any other drug.

For many years, a small band of groups opposed to both family planning and abortion, has limited women's access to advances in reproductive health technology. Strident opposition, including threats of boycott, from these religious political extremists has chilled – indeed, frozen – critical research and testing for all kinds of health advances that would help protect the fertility and lives of women, and might also contribute to medical treatment for other conditions. I know you must be under tremendous political pressure from opponents of mifepristone. But I am convinced, from the experience that women had with mifepristone at Planned Parenthood centers, that mifepristone can be used safely and effectively in the United States as it is in Europe.

I hope this hearing today will mark the beginning of a new era for women as they strive to plan and space their children responsibly.

The acceptability study presented today by the Population Council backs up what our physicians, nurses, and counselors all experienced. They found that most women were quite satisfied with medical abortion. Women chose to participate in the test trial only after a thorough consultation, during which the expectation and events of the procedure were explained. Because of that in-depth counseling, women said they were prepared for the mifepristone process. The side effects some experienced did not surprise or

scare them. For most women in fact, the procedure was what they expected, or better than they expected. Some said they felt the mifepristone procedure was more natural. Certainly, there is no drug or medical procedure that comes without some level of risk, which is why we have the FDA, to determine the degree of risk associated with drugs and procedures.

Unintended pregnancy is a tremendous problem in the United States -- close to 60% of pregnancies are not intended. We at Planned Parenthood do our best to serve women with contraceptive information and services. But when women come to us with an unintended pregnancy, we offer them full information on all of their options, from prenatal care and adoption, to abortion. It is imperative that American women have access to the newest, safest methods of ending a pregnancy -- and as early as possible. Mifepristone should be an important part of that.

Making mifepristone available will also eventually increase women's access to abortion services, and make harassment and violence less effective as a weapon against women and the health care professionals who serve them. A survey of obstetrician/gynecologists by the Kaiser Family Foundation concluded that a third of the OB/GYNs who do not now offer surgical abortion would be likely to administer mifepristone. That would make a difference to women in areas with no surgical abortion provider, and that is what the opponents of mifepristone truly fear.

In summary, our experience with mifepristone was what we at Planned Parenthood, and the women we serve, expected. For the overwhelming majority of women, mifepristone proved safe and effective. The complications that arose were the ones we expected and were manageable. Serious ones were rare. Most women were satisfied.

We at Planned Parenthood look forward to offering medical abortion using mifepristone. We are ready. French women have had access to mifepristone since 1988. It is time to offer American women this new, safe choice. Thank you.

NATIONAL WOMEN'S LAW CENTER

STATEMENT BY ANN KOLKER
NATIONAL WOMEN'S LAW CENTER
BEFORE THE
FDA REPRODUCTIVE HEALTH DRUGS ADVISORY COMMITTEE
JULY 19, 1996

Mifepristone: A Potential Milestone for Women

I am Ann Kolker, Public Policy Director at the National Women's Law Center, a legal and public policy organization that for over twenty years, has been working to secure equality and equal opportunity for women in the workplace, in educational and family settings, and in their access to health care, income and family support services. I appreciate the opportunity to appear before you today.

Central to women's equality is access to safe and legal abortion. Unfortunately, in recent years, a vocal minority has waged a relentless battle to make abortion illegal again, to intimidate women seeking abortion, and to drive abortion providers out of practice, through harassment, violence, and threats to their families. The submission by the Population Council of a New Drug Application for mifepristone and the approval process now underway at the FDA have a chance to change this landscape dramatically. The Center strongly supports FDA's efforts to review carefully and thoroughly this NDA and determine whether mifepristone (in combination with misoprostol) is safe and effective. The Center is extremely hopeful that FDA will come to the same conclusion that has been reached in France, Great Britain and Sweden and approve mifepristone (in combination with misoprostol) for use as a method of terminating an unwanted pregnancy in the early weeks.

1 Dupont Circle, NW • Suite 800 • Washington, DC 20036 • (202) 588-5180 • FAX (202) 588-5185

We cannot overstate the value to women of the availability of safe medical abortion as an alternative to surgical abortion. Most important, use of an abortifacient drug can take place in a physician's office rather than at a clinic. Thus, women will be spared the trauma of harassment, blockades, outright violence and intimidation that have occurred at so many clinics around the country and made entering the clinic more frightening than the prospect of surgery for many women. The statistics alone are chilling. Although levels of clinic violence have declined since the enactment of the Freedom of Access to Clinic Entrances Act, they are still high. According to a survey by the Feminist Majority Foundation, last year nearly 40% of clinics experienced some form of severe violence, and nearly 20% of clinic staff reported death threats and home picketing. I often wonder if more people, and especially those in charge of national research, had to endure these tactics, whether a medical abortion method would have been developed earlier in this country. But that aside, the prospect that women will eventually be able to obtain an abortion in the same manner that they obtain other medical procedures - in the privacy of a physician's office, free from intimidating tactics - will be enhanced if mifepristone is approved. This would be a welcome development.

Assuming that FDA determines that mifepristone is safe - and the data from use by nearly 200,000 women in Europe seems to suggest that should be the case - this method of non-surgical abortion has important and favorable implications for the health of women seeking to terminate an unwanted pregnancy. First, many women seeking to terminate a pregnancy may fear the invasive nature of surgery, along with the prospect of anesthesia. Taking several pills induces the abortion which then occurs in the same way as a

miscarriage. Avoiding surgery will be a definite plus for some women. Second, the fact that mifepristone works early in pregnancy when abortion is safest is also advantageous. The availability of the drug for use only during the first seven weeks of pregnancy - or nine weeks at the most - will act as an incentive for women seeking to end an unwanted or unsafe pregnancy to seek medical help in the early weeks. Indeed, medical abortion with mifepristone is available as soon as a pregnancy can be confirmed, while a surgical abortion cannot be performed until several weeks later. Medical experts acknowledge that there are fewer risks to women's health when termination occurs early in the pregnancy.

The approval of mifepristone stands to have a beneficial effect on the number of providers willing to perform abortions in this country - a change that has positive implications for women's health as well. This panel knows all too well, I am certain, that there has been a dramatic decrease in the number of physicians willing to do abortions in recent years. Surveys show that over 84% of the counties have no abortion provider, - many having been driven out of practice by harassment and threats of violence to themselves and their families. However, a number of physicians who do not currently perform abortions have indicated that they would be willing to do so if they could prescribe mifepristone. A recent survey by the Kaiser Family Foundation found that one-third of Ob/Gyns would add abortion to their practice if it involved prescribing medication such as mifepristone rather than surgery. Ultimately, the availability of more physicians willing to provide abortions will reduce travel time and arrangements, particularly for women in rural areas, thus enabling these women to undergo the procedure at an earlier point in the pregnancy - when it is safest.

The National Women's Law Center has, over the years worked with the FDA to assure that drugs and devices of importance to women, especially newly developed methods of contraception, are safe and effective. We know that product approval decisions are based on careful review of clinical trials, scientific data and researched articles by physicians, medical scientists, and other experts. Others who appear before this advisory committee today may present claims and charges about mifepristone that are not supported by the clinical trials and the experiences of women both in this country and overseas who have successfully and safely used this non-surgical method of abortion for nearly seven years. Thus, we urge this committee to be guided in its decision-making about mifepristone by the scientific evidence presented in the Population Council's NDA and related materials and studies that the FDA may have assembled, and not on ideologically motivated claims that are without scientific merit.

American women eagerly await your recommendation and hope that before the year is over the FDA will render a favorable decision on the availability of mifepristone (in combination with mifepristol) as an alternative to surgical abortion in this country.

Testimony of Seymour L. Romney, M.D.

Chairman of

The Society of Physicians for Reproductive Choice and Health

Before the US Food & Drug Administration Advisory Committee for Reproductive Health Drugs

Concerning the New Drug Application for the Use of Mifepristone for the Interruption of Early Pregnancy

At the Center for Drug Evaluation and Research

July 19, 1996

I am Dr. Seymour L. Romney, the current Chair of the **Society of Physicians for Reproductive Choice and Health**. The Society of Physicians for Choice thanks the FDA for this opportunity to express our unqualified support for the new drug application that the Population Council has submitted concerning the safety of the antiprogesterone drug mifepristone. The Society of Physicians for Choice urges the FDA to promptly approve this application. It is vitally important to the reproductive health care of women and men that the known benefits of mifepristone and the to be-determined, safe and effective therapeutic usages of this agent, as well as other progestin analogues that can be synthesized, be carefully investigated and evaluated. The mission of The Society of Physicians for Reproductive Choice and Health is to enable concerned physicians to take a more active and visible role in support of universal reproductive health care. We are a national organization of physicians that works to ensure that everyone has the knowledge, access to quality services, and freedom of choice to make their own reproductive health care decisions. We educate and advocate that every pregnancy should be a wanted, intended pregnancy. We believe this condition is an essential component for the physical, mental and social well-being of women, men and children.

I am also here as an obstetrician-gynecologist of long standing duration, who has participated in the comprehensive health care of women as a clinician, a teacher and a researcher. I completed my training at two Boston institutions, the Boston Lying-In Hospital and the Free Hospital for Women in Brookline Massachusetts. Both no longer exist and have been fused into the now well known Brigham and Women's Hospital. My experience in Boston has been supplemented by more than 35 years in New York City where I was chair of the Department of Obstetrics and Gynecology at the Albert Einstein College of Medicine and currently serve as a Professor Emeritus. My credentials also include memberships in the American Gynecologic and Obstetric Society, the Society of Gynecologic Investigation, the American Association of Cancer Research, the American Association for the Advancement of Science and the American Association of Medical Colleges. The responsibility for teaching medical students and training residents, as well as maintaining high

quality standards for the health care of women is challenging and demanding. Many young motivated students want to know why mifepristone is not clinically available. In the past 45 years, significant progress has been made in almost eliminating maternal deaths, that we know are preventable. One of the most dramatic changes is the elimination of maternal deaths due to mismanaged septic abortions, back alley abortions or abortion complications including septic shock. Since Roe v. Wade, emergency rooms and hospital beds are not filled with dangerous or tragic self induced abortions. Mifepristone can be a valuable addition to this therapeutic armamentarium. It is one of the most important scientific advances in reproductive health care in decades.

My colleagues and I are acquainted with the details of the protocol and the implementation of the Population Council's multi-institutional mifepristone/misoprostol clinical trials. What we have learned in personal communications with responsible physicians participating in the trials in the United States, Sweden and England is that the clinical experience with mifepristone-misoprostol in this country is comparable to the ongoing and previously reported results recorded in the medical literature by well qualified physicians and investigators in France, Sweden, and Great Britain, where mifepristone was approved following clinical trials documenting its safety and effectiveness. More than 200,000 women in Europe have chosen to use mifepristone. The success rate for terminating early intrauterine pregnancy (up to 49 days from the beginning of the last menstrual period) is 95-97%. The side effects are equivalent to those encountered in a spontaneous miscarriage.

We have seen the informed consent form employed in the Population Council's sponsored clinical trials. It is accurately detailed, and can be easily understood by any woman seeking a non-invasive pharmacologic termination of pregnancy. That is her constitutional right. The exclusion criteria which need to be carefully evaluated in all patients is that the woman have no evidence of heart disease; is not a heavy smoker; does not have any ectopic tubal pregnancy nor any chronic liver or kidney disease which could complicate her care.

In support of the application, the Society of Physicians for Choice would like to include in this presentation, for the record, the extensive and detailed publication by the Institute of Medicine of the National Academy of Sciences entitled "**Clinical Applications of Mifepristone RU486 and Other Antiprogestins**" which is publicly available. This is a comprehensive report of a two day workshop involving the deliberations of a 7 member committee selected for their expertise in cell biology, pharmacology, epidemiology, reproductive endocrinology, care of women with hormone dependent clinical conditions and oncology. The workshop, convened in 1993, provided an unbiased evaluation of the science and potential clinical uses of antiprogestins for numerous diseases and conditions in addition to inducing abortion. The report identifies 20 recommendations of important work that should have been promptly undertaken at that time to further clarify the mechanisms of action of the antiprogestins and the potential for developing additional compounds involving the usefulness of inhibiting progesterone receptors. The FDA approval of this new drug application will predictably generate keen interest in possible other therapeutic uses of the antiprogestins that can be immediately pursued. If the drug is made available, there are a spectrum of important gynecologic problems including missed menses, term and post term labor induction, endometriosis and uterine leiomyomas that can hypothetically benefit therapeutically. Promising preliminary data has also been obtained in breast and endometrial cancer, meningiomas and antiglucocorticoid dependent conditions.

I am also providing for the hearing today, a resolution on mifepristone, identified here by its French brand name, RU 486 passed by the American Association for the Advancement of Science in April, 1991. The sense of this resolution is equally applicable today and comprehensively supports the Population Council's application. However, we now have the opportunity to make scientific and health care progress in 1996. The resolution reads:

"Whereas RU 486 a major new drug is both an antiglucocortiocid and antiprogesterone steroid that has many potential benefits for society, and whereas RU 486 is an effective treatment for Cushing Syndrome; it has shown effective activity in the treatment of some types of breast cancer; it has been used in France as a safe effective method for the termination of early pregnancy; and there is suggestive activity for its value in the treatment of endometriosis and difficult deliveries and whereas a hostile political climate has discouraged Roussel Uclaf, the French manufacturer of RU 486 from seeking a license to market the compound in the United States, and whereas the US Food and Drug Administration (FDA) has imposed an import alert on RU 486, and whereas AAAS is committed to freedom of scientific inquiry and the advancement of modern technology; be it resolved that the American Association of Advancement of Science encourages pharmaceutical companies and the FDA to make RU 486 and related agents available for further research and use as medically indicated."

Essential objective mifepristone clinical data is now available in the Population Council's new drug application that warrants FDA approval. The difficulties in obtaining the manufacture and distribution of RU 486 can be resolved. The Society of Physicians for Reproductive Choice and Health applauds the action of the Population Council and strongly urges the FDA to expedite the implementation of the manufacture and distribution of this important therapeutic molecule. We also encourage the submission of related therapeutic protocols to advance reproductive health care.

Thank you for your time.

SP71596

Invoice 1

F-D-C REPORTS, INC.
P.O. Box 7247-7999
Philadelphia, PA 19170-7999

PHONE (301) 657-9830
FAX (301) 664-7248

Laurie Harden

DATE	ACCOUNT NUMBER
07/29/96	133627

Date: 7/31/96
Attn:
Mail Symbol HFD-009
Bldg. Rm. No.
Transaction No. DS1783
This invoice requires receiving verification. If in order, sign, date and immediately return to HFA-120
If not in order attach explanation and return immediately.
Received
Date of Receipt

Requisitions re: 7/19/96 Meeting F+M

FDA ACS
5600 FISHERS LANE
ROCKVILLE, MD 20857

Product code	Quantity		
FTV07196A	1	FDA TV # 6992862	11800.00
Sales tax			0.00
Delivery			0.00
Total			11800.00

To insure uninterrupted delivery of the product ordered, please send payment with the remittance form at the bottom of the page.

If you have any questions concerning your invoic ou wish to pay by credit card, please call F-D-C Reports' Customer Service Department at 1(800) 332-2181; FAX (3(-7238.

07/29/96

PLEASE RETURN THIS PORTION WITH PAYMEN

PLEASE MAKE ANY ADDRESS CHANGES BELOW.

FDA ACS
5600 FISHERS LANE
ROCKVILLE, MD 20857

P.O. NUMBER 7560600
BEFF-1

8/14/96
OK to pay
/S/

ACCOUNT NUMBER 11800.00

AMOUNT:

PLEASE MAKE CHECKS PAYABLE TO: F-D-C REPORTS, INC.

NOTE: F-D-C REPORTS, INC. IS A CORPORATION NOT SUBJECT TO BACKUP WITHHOLDING OR 1099 REPORTING

**SEND INQUIRES TO:
F-D-C REPORTS, INC.
5550 FRIENDSHIP BLVD., SUITE ONE,
CHEVY CHASE, MD 20815-7278**

PLEASE COMPLETE THE READER PROFILE SURVEY ON REVERSE OF REMITTANCE FORM. *THANK YOU!*

F-D-C REPORTS, Inc.
5550 Friendship Blvd., Suite One, Chevy Chase, MD 20815
(301) 657-9830 ■ FAX: (301) 656-3094

HEALTHCARE PUBLICATIONS

Prescription Pharmaceuticals & Biotechnology "The Pink Sheet"®

Nonprescription Pharmaceuticals & Nutritionals "The Tan Sheet"®

Quality Control Reports "The Gold Sheet"®

Medical Devices, Diagnostics & Instrumentation "The Gray Sheet"®

Toiletries, Fragrances & Skin Care "The Rose Sheet"®

Weekly Pharmacy Reports "The Green Sheet"®

Health Policy & Biomedical Research "The Blue Sheet"®

Daily Healthcare Information Service "Health News Daily"®

The NDA Pipeline®

Pharmaceutical Approvals Monthly

August 14, 1996

To: [redacted]
From : Lori Hardin, Special Projects Manager
RE: Telecast of the July 19th invoice

The invoice for FTV07196A for $11,800 is the total cost for the uplink and downlink service rendered on July 19, 1996. The original quote of $13,100 has been decreased due to a lower charge for the days satellite service through Taurus Communications.

Thank YOu-

Lori Hardin

APPEARS THIS WAY ON ORIGINAL

F-D-C REPORTS, Inc.
5550 Friendship Blvd., Suite One, Chevy Chase, MD 20815
(301) 657-9830

FACSIMILE TRANSMISSION SHEET

TO:	[redacted]
COMPANY:	FDA
FAX NUMBER:	[redacted]
FROM:	*Lori Hardin, Manager, Special Projects*
OFFICE NUMBER/FAX:	*(301) 664-7210 / (301) 664-7245*
# OF PAGES: ONE	*(NOT INCLUDING COVER PAGE)*
SUBJECT:	
DATE:	8-14-96

MESSAGE:

per your request . . .

APPEARS THIS WAY
ON ORIGINAL

PURCHASE/SERVICE/STOCK REQUISITION

REQUISITION NUMBER: E [redacted]

BPA and Call No. _____

OFFICE CODE/SYMBOL: CDER/ACS/HFD-21

HS/PHS/FDA/Supply Contracts Sec. (HFA-513)

REQUEST FOR: ☐ PURCHASE ☐ SERVICE ☐ STOCK ISSUE ☒ RENTAL/LEASE

QUESTING ORGANIZATION: od and Drug Administration

CUSTODIAL AREA: CDER

DATE:

OBJECT CLASS: 25.9Z

R REFERENCE CALL:

EXTENSION:

APPROPRIATION: 7560600 22320Q 20

CAN: 6-6992862-D- 51783

ELIVER TO:
A/Center for Drug Evaluation and Research
S, Meeting Management Branch
hapman Building, Room 200
901 Chapman Avenue, Rockville, Maryland 20852

DATE REQUIRED: July 10, 1996

ITEM NO.	DESCRIPTION (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.)	QUANTITY REQUIRED	UNIT OF ISSUE	COST UNIT	COST TOTAL
	AMENDMENT ********** (see requisition no. E-094495) This amendment includes funds to cover costs of a one-day meeting. The charge is for the one-day telecast downlink at The Hilton, Gaithersburg, Maryland. (downlink truck and operator) Title of Meeting: Advisory Committee for Reproductive Health Drugs Date: July 19, 1996 Source Contacted: FDC Regulatory TV/Video Service 5550 Friendship Blvd. Suite One Chevy Chase, Maryland 20815 Lori Hardin/301-657-9830	Downlink services for one day			$3,300.00

I certify that the property/services requested are required for Government business, and are not available from excess or current assets.*

FUNDS AVAILABLE (S: /S/ SGE Program Officer

DATE: 7/10/96

TOTAL: $3,300.00

REQUESTED BY (Sig: /S/ Committee Mgmt. Ass't.

DATE: 7/9/96

RECEIVING OFFICIAL - I certify that the quantities indicated in the "Quantity Required" column above have been received in total or as annotated.

RECOMMEND APPROVAL (Signature/Title)*

DATE

RECEIVING OFFICIAL (Signature/Title)

DATE

APPROVED BY: /S/ SGE Program Officer

DATE: 7/10/96

ORDER NO. (PO, DO, FEDSTRIP, ETC.)

ORDER DATE

PROPERTY MANAGEMENT OFFICER (Signature)*

DATE

VOUCHER NO.

VOUCHER DATE

HHS-393 (Rev. 6/90)

DR 1

MIF 002890

Requisition # E-094495

JUSTIFICATION:

The Advisory Committee for Reproductive Health Drugs (ACRHD) scheduled a meeting on July 19, 1996. The Committee will discuss sensitive issues. Due to security, the meeting will not be held at the PKLN or NIH conference rooms, it will be held at the CDRH Building site. Limited public seating will be available therefore, we are providing an overflow room at the Gaithersburg Hilton.

We will need to procure a satellite service and technicians to down-link the meeting via satellite to the viewers at the Gaithersburg Hilton. FDC Regulatory TV/Video Service will Interface and "hook into" the satellite at the hotel.

FDC is familiar with what is required and have interfaced via satellite previously for other customers at other CDER meetings.

FDC is the owner of the Satellite truck and the direct source for this service. Therefore, FDC is the only source contacted for an estimate.

SOURCE CONTACTED:

FDC Regulatory TV/Video Service
5550 Friendship Blvd.
Suite One
Chevy Chase, MD 20815
301-657-9830
Contact: Lori Hardin

APPEARS THIS WAY
ON ORIGINAL

PORTANT: Mark all packages and papers with contract and/or order numbers

TE OF ORDER	2. CONTRACT NO. (If any)	3. ORDER NO.	4. REQUISITION NO.
11-JUL-96		FDA 094495 00 96 TR 01	094495

5. ISSUE OFFICE (Address correspondence to)	6. SHIP TO: (Consignee and address, ZIP Code)
DHHS/FDA/OFACS/COB 5600 Fishers Lane, HFA-512 Park Building, Room 3-32 Rockville, MD 20857	FDA/CDER CHAPMAN BUILDING, ROOM 200 1901 CHAPMAN AVE. ROCKVILLE, MD 20852

TO: CONTRACTOR (Name, address and ZIP Code)

F-D-C REGULATORY TV/VIDEO SERVICE
5550 FRIENDSHIP BLVD.
SUITE ONE
CHEVY CHASE, MD 20815

8. TYPE OF ORDER

[X] A. PURCHASE - Reference your WRITTEN

Please furnish the following on the terms and conditions specified on the attached sheets, including delivery as indicated.

[ ] B. DELIVERY - Except for attached billing instructions, this delivery order is subject to instructions contained on this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA

22320Q 20 259Z
6992862 D 51783 00

10. REQUISITIONING OFFICE: HFD 009

11. BUSINESS CLASSIFICATION

PURPOSE CODE: X142 | PREFERENCE PROGRAM CODE: | TYPE OF BUSINESS CODE: A3 | WOMAN-OWNED: 2

12. F.O.B. POINT	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
Destination		19-JUL-96	Net 30
13. PLACE OF INSPECTION AND ACCEPTANCE			

17. SCHEDULE

ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	THIS PURCHASE ORDER IS HEREBY AMENDED TO INCREASE THE AMOUNT BY $3300. THE INCREASE IS NEEEDED TO COVER ADDITIONAL CHARGES FOR THE DOWNLINK SERVICES FOR ONE DAY, FOR THE ADIVISORY COMMITTEE MEETING. THE ORIGINAL AMOUNT OF THIS ORDER WAS FOR $9,800, THE NEW TOTAL AMOUNT IS FOR $13,100. ALL OTHER TERMS AND CONDITONS OF THIS ORDER WILL REMAIN THE SAME. Effective July 26, 1996, in accordance with the Debt Collection Improvement Act of 1996, agencies of the Federal Government must use electronic funds transfer to make all payments. You are required to include the following information	1	EA	3300.00	3300.00

18. SHIPPING POINT	19. GROSS SHIP WEIGHT	20. INVOICE NO.	17(H) TOTAL (Cont. pages)
			0.00

21. MAIL INVOICE TO: (Include ZIP Code)
DHHS/FDA/Commercial Accts Phone:
5600 FISHERS LANE, HFA-122, ROCKVILLE, MD. 20857

17(I) GRAND TOTAL: 3300.00

22. UNITED STATES OF AMERICA BY (Signature) /S/

23. NAME (Typed)

TITLE: CONTRACTING/ORDERING OFFICER

FORM FDA 3303 (10-88)

MIF 002892

ORTANT: Mark all packages and papers with contract and/or order numbers

E OF ORDER	CONTRACT NO.	ORDER NO.
11-JUL-96		FDA 094495 00 96 TR 01

M NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	on your invoice in order to receive payment: 1. Routing transit number of the financial institution receiving payment. 2. Number of account to which funds are to be deposited. 3. Type of depositor account C for checking, S for savings. Should you have any questions, you may contact the Food and Drug Administration, Office of Financial Management, Systems Accounting Branch at: APPEARS THIS WAY ON ORIGINAL				

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17 (H)) ▶ 0.00

ORM FDA 3304

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
PURCHASE/SERVICE/STOCK REQUISITION

REQUISITION NUMBER: E 094495

BPA and Call No. _____

OFFICE CODE/SYMBOL: ACS/HFD-21

DHHS/PHS/FDA/Supply Contracts Sec. HFA-513

REQUEST FOR: ☐ PURCHASE ☐ SERVICE ☐ STOCK ISSUE ☒ RENTAL/LEASE

QUESTING ORGANIZATION	CUSTODIAL AREA	DATE	OBJECT CLASS
Food and Drug Administration	CDER	7/5/96	25.92

R REFERENCE CALL	EXTENSION	APPROPRIATION
		7560600 223200 20

LIVER TO

FDA/Center for Drug Evaluation and Research
ACS, Meeting Management Branch
Chapman Building, Room 200
1901 Chapman Avenue, Rockville, Maryland 20852

CAN: 6-6992862-D-51783

DATE REQUIRED: ASAP

ITEM NO.	DESCRIPTION (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.)	QUANTITY REQUIRED	UNIT OF ISSUE	COST UNIT	COST TOTAL
	F-D-C Regulatory TV/VIDEO Service Telecast at the Reproductive Health Advisory Committee Meeting July 19, 1996 Gaithersburg Hilton 620 Perry Parkway Gaithersburg, Maryland 20877 301-977-8900 7:30 am to 7:00 pm				9,800.00

certify that the property/services requested are required or Government business, and are not available from ...ces or current assets.*

FUNDS AVAILAB... /S/ SGE Progr... Officer for — DATE 7-5-96 — TOTAL 9,800.00

REQUESTED BY (Signatu... /S/ Committee Management Assistant — DATE

RECOMMEND APPROVAL (Signature/Title)* — DATE

RECEIVING OFFICIAL - I certify that the quantities indicated in the "Quantity Required" column above have been received in total or as annotated.

RECEIVING OFFICIAL (Signature/Title) — DATE

APPROVED BY (Sig... /S/ SGE Program ...Officer for — DATE 7-5-96

ORDER NO. (PO, DO, FEDSTRIP, ETC.) — ORDER DATE

...OPERTY MANA... MENT OFFICER (S...nature)* — DATE

VOUCHER NO. — VOUCHER DATE

MIF 002894

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PA

IMPORTANT: Mark all packages and papers with contract and/or order numbers

DATE OF ORDER	2. CONTRACT NO. (If any)	3. ORDER NO.	4. REQUISITION NO.
05-JUL-96		FDA 094495 00 96 TR 00	094495

5. ISSUING OFFICE (Address correspondence to)
DHHS/FDA/OFACS/COB
5600 Fishers Lane, HFA-512
Park Building, Room 3-32
Rockville, MD 20857

6. SHIP TO: (Consignee and address, ZIP Code)
FDA/CDER
CHAPMAN BUILDING, ROOM 200
1901 CHAPMAN AVE.
ROCKVILLE, MD 20852

7. TO: CONTRACTOR (Name, address and ZIP Code)
F-D-C REGULATORY TV/VIDEO SERVICE
5550 FRIENDSHIP BLVD.
SUITE 1
CHEVY CHASE, MD 20815

8. TYPE OF ORDER
[X] A. PURCHASE - Reference your
Please furnish the following on the terms and condi specified on the attached sheets, including delivery indicated.
[ ] B. DELIVERY - Except for attached billing in tions, this delivery order is subject to instructions contained on this form and is issued subject to the terms and conditions of the above-numbered contr

9. ACCOUNTING AND APPROPRIATION DATA
22320Q 20 259Z
6992862 D 51783 00

10. REQUISITIONING OFFICE
HFD 009

11. BUSINESS CLASSIFICATION
PURPOSE CODE X142 | PREFERENCE PROGRAM CODE | TYPE-OF BUSINESS CODE A3 | WOMAN-OWNED

12. F.O.B. POINT	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
Destination		19-JUL-96	Net 30
13. PLACE OF INSPECTION AND ACCEPTANCE			

17. SCHEDULE

ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	F-D-C REGULATORY TV/VIDEO SERVICE TELECAST AT THE REPRODUCTIVE HEALTH ADVISORY COMMITTEE MEETING. DATE: JULY 19, 1996 TIME: 7:30 AM TO 7:00 PM Effective July 26, 1996, in accordance with the Debt Collection Improvement Act of 1996, agencies of the Federal Government must use electronic funds transfer to make all payments. You are required to include the following information on your invoice in order to receive payment: 1. Routing transit number of the financial institution receiving payment. 2. Number of account to which	1	EA	9800.00	9800.00

18. SHIPPING POINT	19. GROSS SHIP WEIGHT	20. INVOICE NO.	17(h) 0.00
21. MAIL INVOICE TO: (Include ZIP Code) DHHS/FDA/Commercial Accts Phone: 5600 FISHERS LANE, HFA-122, ROCKVILLE, MD. 20857			9800.00

22. UNITED STATES OF AMERICA BY (Signature) /S/

23. NAME (Typed)
TITLE: CONTRACTING/ORDERING OFFICER

FORM FDA 3303 (10-88)

MIF 002895

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
PURCHASE/SERVICE/STOCK REQUISITION

REQUISITION NUMBER: E 095779

BPA and Call No. _____

OFFICE CODE/SYMBOL: CDER/ACS/HFD-21

TO: DHHS/PHS/FDA/Supply Contracts Sec. (HFA-513)	REQUEST FOR: ☐ PURCHASE ☐ SERVICE ☐ STOCK ISSUE ☒ RENTAL/LEASE		
REQUESTING ORGANIZATION: Food and Drug Administration	CUSTODIAL AREA	DATE	OBJECT CLASS: 25.9Z
FOR REFERENCE CALL:	EXTENSION	APPROPRIATION: 7560600 223200 20	
DELIVER TO: FDA/Center for Drug Evaluation and Research ACS, Meeting Management Branch (HFD-21) Chapman Building, Room 200 1901 Chapman Avenue, Rockville, MD 20852		CAN: 6-6992862-D-51782 DATE REQUIRED: July 10, 1996	

ITEM NO.	DESCRIPTION (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.)	QUANTITY REQUIRED	UNIT OF ISSUE	COST UNIT	COST TOTAL
	Request is made for the use of (2) Gray Line Buses for an advisory committee meeting. (1 day at $975 per bus)	rental	for (2) buses		$1,950.0
	Title of Meeting: Advisory Committee for Reproductive Health Drugs Date: July 19, 1996 Location: The Hilton/Montgomery County Fairgrounds 620 Perry Parkway Gaithersburg, MD 20877 The buses will pick up and deliver passengers beginning at 6:30 a.m. and ending at 7:30 p.m. The buses will provide back and forth shuttle service for the public all day. The passengers will be bused from the Hilton/Montgomery County Fairgrounds to the FDA Technical Center, 16071 Industrial Drive, Gaithersburg, MD.				

I certify that the property/services requested are required for Government business, and are not available from excess or current assets.*

FUNDS AVAILABLE: SGE Programs /S/

DATE: 7-5-96 TOTAL: $1,950.(

REQUESTED BY (Signature)* /S/ DATE

Committee Mgmt. Ass't.

RECOMMEND APPROVAL (Signature/Title)* DATE

APPROVED BY (Signature) /S/ DATE 7-5-96

SGE Programs PROPERTY MA(ure)* DATE

RECEIVING OFFICIAL - I certify that the quantities indicated in the "Quantity Required" column above have been received in total or as annotated.

RECEIVING OFFICIAL (Signature/Title) DATE

ORDER NO. (PO, DO, FEDSTRIP, ETC.) ORDER DATE

VOUCHER NO. VOUCHER DAT

MIF 002896

Gray Line
(Gold Line)
5500 Tuxedo Road
Tuxedo, Maryland 20781-1389

phone: 1-800-862-1400
or 301/386-8300
fax: 301/386-2024

APPEARS THIS WAY
ON ORIGINAL

GRAY LINE
GOLD LINE

FAX: 301-386-2024
TOLL FREE: 800-862-1400
(301) 386-8300
5500 TUXEDO ROAD
TUXEDO, MARYLAND 20781-1389

MEMBER AMERICAN SIGHTSEEING INTERNATIONAL

07/05/96 14:02 CHARTER BUS ORDER PAGE 1

Charter Number: 095602

Charter Date: 07/19/96 FRI Status: ESTIMATE Entry Date: 07/05/96

Customer Number: [redacted]
FDA
5600 FISHERS LANE
CEDER ACS HFD21 "CHAPMAN BLDG"
ROCKVILLE, MD 20857

Home Phone: [redacted]
Work Phone: [redacted] FAX

Group:

Contact: [redacted]

NBHCA Name:
Tour Number:
Remarks:
Bus Type: M 47 PASSENGER

Agent Number:
P.O. Number:
Number of Passengers: 0
Number of Buses: 1

LEAVE CITY	ST	DATE	TIME	TYPE	ARRIVE CITY	ST	DATE	TIME
GAITHERSBURG	MD	07/19/96	6:30am	LOCL	NON-LECTURED	DC	07/19/96	7:30pm

PICKUP INFORMATION
GAITHERSBURG HILTON, 620 PERRY PARKWAY, GAITHERSBURG MARYLAND

ITINERARY
P/U AT 0630 HRS FROM GAITHERSBURG HILTON AND TAKE TO ROUTE 355 & 270. (SHUTTLE BACK & FORTH) SERVICE TO END BY 1930 HRS.

Total D.H. Miles	0	.00
Total Live Miles	0	.00
Total Time 0 Days + .00 Hours		.00
Total Additional Charges		975.00
Charter Grand Total		975.00
Payments Received		.00
Balance Due		975.00

PAYMENT POLICY: $100.00 DEPOSIT REQUIRED PER BUS TO CONFIRM SERVICE, UNLESS CREDIT HAS BEEN APPROVED. CONFIRMATION WILL BE BASED ON AVAILABILITY AT TIME DEPOSIT IS RECEIVED. FULL PAYMENT IS DUE TWO (2) WEEKS PRIOR TO DATE OF SERVICE. CANCELLATIONS RECEIVED WITHIN 7 DAYS OF BEGINNING DATE OF SERVICE WILL RESULT IN FORFEITURE OF TOTAL CHARTER RATE.

NO SMOKING ALLOWED ON COACH AT ANY TIME. NO EATING OR DRINKING ALLOWED ON COACH WITHIN 2 HOUR DRIVING RADIUS OF WASHINGTON, D.C. WITHOUT SPECIAL ARRANGEMENTS AND CLEANING DEPOSIT.

ALL LECTURED SERVICE IS PERFORMED BY ENGLISH SPEAKING LICENSED DRIVER/GUIDE. ARLINGTON CEMETERY PARKING, IF CHARGED, WAS CHARGED FOR UP TO 2 HOURS. ADDITIONAL TIME WILL BE RESPONSIBILITY OF CUSTOMER. VIDEOS FOR VIDEO COACHES WILL BE SUPPLIED BY GOLD LINE.

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 2

IMPORTANT: Mark all packages and papers with contract and/or order numbers

1. DATE OF ORDER	2. CONTRACT NO. (If any)	3. ORDER NO.	4. REQUISITION NO.
10-JUL-96		FDA 095779 00 96 BD 00	095779

5. ISSUING OFFICE (Address correspondence to)
DHHS/FDA/OFACS/COB
5600 Fishers Lane, HFA-512
Park Building, Room 3-32
Rockville, MD 20857

6. SHIP TO: (Consignee and address, ZIP Code)
DHHS/PHS/FDA
NICHOLSON RESEARCH CENTER00
5516 NICHOLSON LANE
KENSINGTON, MD 20895

7. TO: CONTRACTOR (Name, address and ZIP Code)
GRY LINE (GOLD LINE)
5500 TUXEDO ROAD
TUXEDO, MD 20781-1389
ATT: LAURA

530181665

8. TYPE OF ORDER
[X] A. PURCHASE - Reference your WRITTEN
Please furnish the following on the terms and conditions specified on the attached sheets, including delivery as indicated.

[ ] B. DELIVERY - Except for attached billing instructions, this delivery order is subject to instructions contained on this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA
22320Q 20 259Z
6992862 D 51782 00

10. REQUISITIONING OFFICE
HFD 009

11. BUSINESS CLASSIFICATION
PURPOSE CODE V122 PREFERENCE PROGRAM CODE TYPE OF BUSINESS CODE A3 WOMAN-OWNED 2

12. F.O.B. POINT	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
Destination		19-JUL-96	Net 30
13. PLACE OF INSPECTION AND ACCEPTANCE			

17. SCHEDULE

ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	PROVIDE SERVICE FOR THE USE OF TWO (2) GRAY LINE BUSES FOR AN ADVISORY COMMITTEE MEETING TITLE: ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUG DATE: JULY 19, 1996 FROM: THE HILTON/MONTGOMERY COUNTY FAIRGROUNDS 620 PERRY PARKWAY GAITHERSBURG, MD 20877 TO: FDA TECHNICAL CENTER 16071 INDUSTRIAL DRIVE GAITHERSBURG, MD 20877 TIME: PICK UP AND DELIVER PASSENGERS ALL DAY: 6:30 AM - 7:30 PM	2	EA	910.00	1820.00

CHARTER #95789
(per Laura on 7/18/96)
(301) 386-8300

18. SHIPPING POINT	19. GROSS SHIP WEIGHT	20. INVOICE NO.	17(H) TOTAL (Cont. pages)	0.00

21. MAIL INVOICE TO: (Include ZIP Code)
DHHS/FDA/Commercial Accts Phone:
5600 FISHERS LANE, HFA-122, ROCKVILLE, MD. 20857

17(I) GRAND TOTAL 1820.00

22. UNITED STATES OF AMERICA BY (Signature) /S/

23. NAME (Typed)
TITLE: CONTRACTING / ORDERING OFFICER

IMPORTANT: Mark all packages and papers with contract and/or order numbers

DATE OF ORDER	CONTRACT NO.	ORDER NO.
10-JUL-96		FDA 095779 00 96 BD 00

ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	The dollar value reflected on the purchase order is estimated. It cannot be exceeded without the authority the contracting/ordering officer. Effective July 26, 1996, in accordance with the Debt Collection Improvement Act of 1996, agencies of the Federal Government must use electronic funds transfer to make all payments. You are required to include the following information on your invoice in order to receive payment: 1. Routing transit number of the financial institution receiving payment. 2. Number of account to which funds are to be deposited. 3. Type of depositor account C for checking, S for savings. Should you have any questions, you may contact the Food and Drug Administration, Office of Financial Management, Systems Accounting Branch at:				

APPEARS THIS WAY
ON ORIGINAL

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17 (H)) ▶ 0.00