MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 4641.4

MANAGEMENT

ACCEPTANCE OF PAYMENT FOR TRAVEL EXPENSES FROM NON-FEDERAL SOURCES

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PURPOSE This MAPP defines the policies and procedures of the Center for Drug Evaluation and Research with respect to the acceptance of cash or services in-kind from non-Federal sources to defray, in whole or in part, travel or related expenses. It applies to all officers and employees of CDER, both civilian and commissioned corps.

REFERENCES

- DHHS Travel Manual, Chapter 1-70, August 7, 1992
- FDA, Staff Manual Guide 2342.2, Acceptance of Payment for Travel Expenses from Non-Federal Sources, May 31, 1990.

DEFINITIONS

- **Non-Federal Sources.** Refers to any organization, corporation, association, individual, or any governmental unit other than the United States Federal Government.
- Services in-Kind. Refers to transportation, meals, lodgings, registration fees, and other items related to travel, paid by either direct reimbursement by the sponsor (preferred method) or by the prepayment of these items (rare instances).
- **Cash.** Currency, coin, checks, drafts, or other commercial paper which is convertible into currency or coin. (Cash is paid directly to the Office of Financial Management).
- It is the policy of the Center for Drug Evaluation and Research to proceed with great caution in the acceptance of funds from non-federal sources. This is to ensure that CDER employees are not accepting funds from prohibited or what appears to be a prohibited source. The underlying principle of the Department is that if an employee's participation warrants the expenditure of official time, it also warrants the expenditure of travel funds. Employees shall not solicit the payment of travel expenses from non-federal sources; indication of solicitation of support may result in denial of an offer of support that might otherwise be acceptable.
 - Acceptance of travel reimbursements in cash or in-kind will not be accepted under any circumstances when there is the potential for real or perceived conflict of interest. Such circumstances include, but are not limited to, the following:
 - 1. If the proposed sponsor is an FDA regulated firm such as a drug, biologic, or device manufacturer, food processor or retail grocery chain, or a trade association of such regulated firms. (In the case of foreign firms or trade associations that may represent them, reimbursement may not be accepted, even if the firms do not currently ship regulated products to the U.S.);
 - 2. If the reimbursement for travel expenses is to be made from funds received from the regulated industry or trade associations of regulated firms;
 - 3. If the reimbursement for travel expenses is to be made from funds received under any federal grant, or from funds received from a contract

or cooperative agreement with FDA or other DHHS components;

- 4. If CDER has a contract, grant, or cooperative agreement with the sponsoring organization;
- 5. If the employee is an officer, board-member, trustee, or employee of the sponsoring organization;
- 6. If any other situation exists that could be perceived as resulting in a conflict of interest. Responsibility for this judgment should be shared initially by the traveler, his or her supervisor and the travel authorizing authority. Any decision made in this judgment should be on the side of caution so that even the appearance of any impropriety or potential impropriety is avoided.
- HHS travel regulations state that payments from non-federal sources, when accepted, may not exceed those expenses that would otherwise be covered by government travel regulations. If hotel rooms, meals, and airline ticket costs are provided to employees, there is no way to assure that their cost does not exceed government allowed amounts. To protect employees from unknowingly violating this regulation, FDA policy precludes acceptance of prepaid travel support, such as hotel accommodations, meals, or airline tickets. Instead, FDA will pay for all travel costs and subsequently bill the sponsor. (One general exception to this policy is international travel supported by one of the United Nations family of organizations, such as WHO, PAHO, and FAO; FDA routinely permits acceptance of in kind support from these organizations, in accordance with their own travel regulations.)
- An organization volunteering to pay all or part of an employee's travel cost must assure that it does not put the employee in a difficult situation by contributing to the costs of accommodations other than paying the bill sent upon completion of travel. Sponsors are required to include standard paragraphs of the assurances (Attachment A) in the letter of invitation (Attachment B). If these assurances are not in the letter of invitation, they must still be made by the sponsor in writing, including the sponsors signature, before the offer can be considered for acceptance. If an employee believes that an organization has attempted to make unapproved contributions to defray travel expenses, the situation should be reported to the employee's supervisor and to the Director, Office of Financial Management.
- Employees are prohibited from accepting honoraria in relation to travel funded by non-federal sources.

- Employees may not accept travel expenses for a spouse or member of their family to accompany the employee on the travel.
- Acceptance of payment in cash or in-kind services must be authorized in advance by the Deputy Commissioner for Management and Systems on a properly completed Form HHS 348 (Attachment C). The prior approval procedures for this type of travel will include a determination of expected costs, and arrangement for reimbursement from the sponsor directly to FDA (allowance will be made for any reasonable cost deviations or for any unexpected or unavoidable occurrences or rearrangements beyond the control of the traveler).
- If a sponsor insists upon providing a check to the employee to defray travel costs, the employee should endorse it "Pay to the order of the Treasurer of the United States" and submit it to the Office of Financial Management, HFA 121, upon completion of the sponsored travel, accompanied with the travel voucher.

AUTHORIZING OFFICIALS

The Director, Office of Financial Manage has authority to approve the acceptance of cash or services in-kind from non-federal sources.

PROCEDURES

The following documents should be submitted as a package by the employee's office to their respective Program Specialist or Management Officer for the initial review. The Program Specialist or Management Officer will forward the package to the Office of Management, Administrative Management Team, HFD-61, for the final review, at least 21 days in advance of travel. The Administrative Management Team will obtain the necessary signatures/approvals within CDER (Executive Officer) then forward the package for authorization to the Accounts Receivable Branch, Office of Financial Management, HFA-121.

- Letter of Invitation (Attachment B): Comes from the sponsoring organization offering to reimburse all or part of the expenses of the employee concerned. The Letter of Invitation must contain the standard paragraphs of assurances (Attachment A).
- Form HHS-348 (Request and Approval for Acceptance of Travel Expenses in Cash or in Kind) (Attachment C): The traveler must complete sections 1

through 9 (block 10 is completed by the traveler upon completion of trip).

- **Background Information Sheet (Attachment D)**: The traveler must complete all information through item 8 and sign where indicated.
- Letter of Acceptance (Attachment E):
 - 1. The letter of acceptance sets forth the terms of agreement as stated in the Letter of Invitation, prepared by the traveling employee's office for the signature of the Director, Office of Financial Management. This is not needed for World Health Organizations such as WHO, FAO, PAHO.
 - 2. The acceptance letter must always include, as an attachment, the "General Information About FDA Employees Who Attend, Participate in and Speak at Non-Federal Meetings, Conferences and Symposiua" (Attachment G). If an honorarium has been offered in the Letter of Invitation, the Letter of Acceptance must state the following, "Your offer of an honorarium of \$_____ is greatly appreciated. However, agency policy does not allow the acceptance of an honorarium by our employees."

• Form HHS-1 - Travel Order (Attachment F):

- 1. Lists any expenses for the trip that are to be paid by the sponsoring organization in block 3 under the "OTHER" column. Any expenses to be paid by CDER should be listed in block 3 under the "DHHS" column.
- 2. For trips involving either international travel or acceptance of reimbursement for travel from foreign government (in any form), please also refer to FDA Staff Manual Guide FDA 2342.2.

Upon approval by the Deputy Commissioner for Management and Systems, the 348 package will be returned to the Accounts Receivable Section (HFA-120) for necessary fiscal action. The approved package will then be returned to the appropriate program office through the Administrative Management Team.

If authorization is not appropriate, staff from the Office of Financial Management will notify and return the package to the requesting office.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A

FDA REQUIRED ASSURANCES TO BE INCLUDED IN LETTERS OF INVITATION TO EMPLOYEES

None of the funds that will be used to support these travel costs come from any federal grants, or from any contracts with the Department of Health and Human Services, or from the regulated industry or trade associations.

We also understand that FDA requires that its employees pay directly for all of their travel costs, and that we will be billed for these costs by FDA after the trip has been completed and the traveler's claim has been submitted to FDA. We further understand FDA's requirements that costs of employee travel accommodations may not be subsidized in any way, and assure that we will comply with that policy.

Any room charges that are arranged for FDA employees by our organization will not be less than the hotel would normally charge to the traveling public, with the sole exception of volume discounts made available to us by the hotel. Our organization will not otherwise arrange for or make any additional payments to the hotel to defray room costs for FDA employees.

Attachment B

SAMPLE LETTER OF INVITATION

[DATE]

John Doe, M. D., Director Division of Domestic Activity Center for Drug Evaluation Food and Drug Administration 5600 Fishers Lane, HFD-000, Room 000 Rockville, Maryland 20857

Dear Dr. Doe:

On behalf of the (LIST SPONSORS NAME) I would like to invite you to attend a workshop on (LIST NAME OF WORKSHOP) to be held in Orlando, Florida, on June 10-14, 1996. (LIST SPONSORS NAME) is a not for profit 501(C) organization and you will be reimbursed out of the general registration fees paid by workshop participants. Our organization will reimburse to the Food and Drug Administration all costs for airfare, lodging, meals and miscellaneous expenses upon receipt of an invoice by your agency.

None of the funds that will be used to support these travel costs come from any federal grants, or from any contracts with the Department of Health and Human Services, or from the regulated industry or trade associations.

We also understand that FDA requires that its employees pay directly for all of their travel costs, and that we will be billed for these costs by FDA after the trip has been completed and the traveler's claim has been submitted to FDA. We further understand FDA's requirements that costs of employee travel accommodations may not be subsidized in any way, and assure that we will comply with that policy.

Any room charges that are arranged for FDA employees by our organization will not be less than the hotel would normally charge to the traveling public, with the sole exception of volume discounts made available to us by the hotel. Our organization will not otherwise arrange for or make any additional payments to the hotel to defray room costs for FDA employees.

I look forward to seeing you in Orlando.

Sincerely,

John Smith Executive Director

HHS FORM 348

Attachment C

REQUEST AND APPROVAL FOR ACCEPTANCE OF PAYMENT OF TRAVEL EXPENSES IN CASH OR IN KIND

			(date)		
		d report acceptance of payments as provided in DHHS Travel N opies to recommending official at least 15 days before schedule			
1. NAME AND TITLE OF TRAVELER Dr. John Doe, Director Division of Domestic Activity		2. NAME AND ADDRESS OF SPONSORING ORGANIZATION John Smith, Executive Director (LIST SPONSORS NAME) 800 E. Northwest Highway			
3. Bureau, Division, Other (specify) DHHS/PHS/FDA/CDER/DDA/HFD-000		Palatine, Illinois 60067			
4. PURPOSE OF TRIP					
(LIST PURPOSE II	N ONE OR TWO SENTE	NCES)			
5. PAYMENT TO BE MADE FO					
	\bowtie TRAVEL	SUBSISTENCE			
$_{\rm A.}$ \boxtimes $_{\rm DIRECT}$	REIMBURSEMENT to appropriate \$ 1	207.00			
B. IN KIND \$ INDICATE VALUE OF PAYMENT:					
C. IN CASH for retention by traveler \$ TRAVEL \$ LOGDING \$ MEALS \$ OTHER \$					
	EITHER BOX "B" OR "C" ABOVE IS CH OVIDE AMOUNTS IN SPACE PROVIDE				
6. PAYMENT TO BE USED FO		X_ROUND TRIPONE WAY acc	ording to the following itinerary:		
STARTING DATE ENDING DATE		FROM	ТО		
6/10/96	6/14/96	Residence, Gaithersburg	Orlando, Florida		
		AND RETURN			
7. IS THE DEPARTMENT PAY YES, SALARY	ING PART OF THE TRAVEL COSTS? (if	any specify with part and amount)			
8. RECOMMENDATION see	reverse side of form				
	ereby certify that the acceptance of the above ord with the policies contained in Chapter 1				
OFFICIAL Don R. P (Signature)		ctor, Office of Financial Management	DATE		
10. TRAVELER'S CERTIFICA'	TION (Complete after trip)				
I certify that while	on official travel the above amounts are cor	rect and I did not receive:			
reimbursed by	a ions, meals, or incidental expenses not norm v Government travel regulations, or my retention from the sponsoring organizati	•			
EXPLAINED BEI	LOW ARE ANY DEVIATIONS FROM TH	E ABOVE STATEMENTS:			
TRAVELER		DATE			
			Attachment D		

BACKGROUND INFORMATION ON REQUEST FOR APPROVAL FOR ACCEPTANCE OF PAYMENT OF TRAVEL EXPENSES IN CASH OR IN KIND

TRAVELER'S NAME: John Doe, M. D. CENTER: CDER

TRAVELER'S POSITION: Director, Division of Domestic Activity

NAME OF SPONSORING ORGANIZATION: (LIST THE SPONSORS NAME)

MISSION OF SPONSORING ORGANIZATION: (LIST THE MISSION)

1. Is letter of invitation attached? Yes X No

2. Does the letter or other supporting documentation contain FDA required assurances? Yes_X_No____

3. Is the sponsoring organization using Federal funds to defray the cost of this trip? Yes No X

4. Is the traveler an officer, director, trustee, partner or an employee of the sponsoring organization? Yes____No__X__

5. Could the acceptance of expenses in this instance create a real or apparent conflict of interest? Yes___No_X__

I CERTIFY THAT THE ABOVE IS CORRECT TO THE BEST OF MY KNOWLEDGE.

Signature of employee traveling ______ Traveling Employee Date

6. Does the traveler's Center have a contract or grant with the sponsoring organization: Yes <u>No X</u>

--NOTE: IF ANSWER TO 2 IS NO OR IF ANSWER TO 3, 4, 5, OR 6 IS YES, FUNDS CANNOT BE ACCEPTED--

7. How does this trip meet Department's priorities and goals: (ANSWER THIS QUESTION)

8. Why can't this trip be paid for with DHHS funds and not be considered as an exception to the Department's general policy: The (LIST SPONSORS NAME) has invited Dr. Doe to participate in this workshop and as part of (LIST THE PURPOSE)

TO THE BEST OF MY KNOWLEDGE, I CERTIFY THAT ALL THE INFORMATION IS CORRECT, THAT THIS TRAVEL WILL BE COMPLETED IN ACCORD WITH THE TRAVEL POLICY ATTACHED TO THE JULY 6, 1989, MEMO FROM THE ASSOCIATE COMMISSIONER FOR MANAGEMENT AND OPERATIONS, AND THAT THE ACCEPTANCE OF THIS TRAVEL SUPPORT WILL NOT RESULT IN REAL OR APPARENT CONFLICT OF INTEREST.

Center Executive Officer or Center Director

Date

TO THE BEST OF MY KNOWLEDGE, I CERTIFY THAT FEDERAL GRANT OR CONTRACT FUNDS ARE NOT BEING USED TO DEFRAY IN WHOLE OR IN PART THE EXPENSES OF THIS REQUEST AND RECOMMEND APPROVAL OF THIS REQUEST AS IN THE BEST INTEREST OF THE GOVERNMENT.

	Director, Office o		
Recommending Official	Financial Management	Date	

Attachment E

SAMPLE LETTER OF ACCEPTANCE

USE HHS LETTERHEAD

[DATE]

John Smith Executive Director (LIST SPONORS NAME) 800 E. Northwest Highway Palatine, Illinois 60067

Dear Mr. Smith:

On behalf of the Food and Drug Administration, I am pleased to acknowledge your invitation to Dr. John Doe, Director, Office of Domestic Activity, Center for Drug Evaluation and Research, to participate in the workshop (LIST TITLE) to be held in Orlando, Florida, from June 10-14, 1996.

In accordance with your letter of (LIST DATE FROM THE LETTER OF INVITATION) we understand that your organization will reimburse the costs for airfare, lodging, meals, and miscellaneous expenses. When Dr. Doe has returned and presented his claim, you will be notified by our Accounts Receivable Branch of the amount to be reimbursed. Checks are to be made payable to the Food and Drug Administration.

Enclosed for your reference is some general information on guidelines for FDA employees who speak or participate in outside seminars and conferences.

Sincerely,

Don R. Peterson, Director Office of Financial Management

Enclosure

HHS FORM 1

Attachment F

DEPARTMENT OF HEALTH AND HUMAN SERVICES							
TRAVEL ORDER			2. денареци он ма. 7560600				
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(See HHS Travel Manual, Part 3, for Detailed Instruction							
4. NUME AND POSKION OR RANK	5. 35AN			RIVEL \$ \$ 447.00 510.00			
John Doe, M.D., Director	000-00-0000			THER 250.00			
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DHHS/FDA/CDER/DDA/HFD-000			a. APPROX.DATE OF DEPARTURE. 6/10/96				
F. PRESENT OF COLL STATION			2. APPROX.DATE OF REFURN				
Rockville, Maryland				96			
10. IFFEREN AND PLEFOXE OF FRANCE (New Cly, Main as manaly, data and an Travel from Residence in Gaithersburg, MD. To Orlando, F			2 97				
PURPOSE: PLEASE LIST PURPOSE							
American Express Card: YES_XNO NO Annual Leave: YESNOX Prepared by: Jane Smith 443-0000 NOTICE: TRAVELERS ARE RESPONSIBLE AND LIABLE FOR UNUSED GTR'S - TICKETS RECEIVED UNTIL THEY							
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Lodging = \$85.00, M&E = \$34.00			3.F G	RESPONSIBLE FOR SECURITY CLEARANCE OF TRIVELER ASSUMED BY			
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ACCOUNTING INFORMATIO	N COMPLETED			* Funds Available *			
	 						
			_				
15. NUME AND TITLE OF OFFICER RECOMMENDING APOVE TRAVEL Name, Title, and Signature of Person Recommending abo	vc Travci						
Aurhenity is HEREY GRINTED TO PERSORM TRAVEL AND TO INCUR SUCH EXP Domestic: Director, Office of Management Foreign: Director, Office of Financial Management Aurhenited &	ENSES AS MAY BENED		ERT	HE CONDITIONS SET FOR THI ABOVE			
Vir Frankrauber "Fabe completed by Office Information Frank Order, Other Accounting Data to be Completed HHS-1 (REV, 7/89)		3		89			

Attachment G

General Information About Speakers and Participants in Conferences and Symposia Provided by the Department of Health and Human Services

The Department of Health and Human Services is pleased to provide officials and employees to speak on FDA programs and policies and to participate in conferences, symposia, and similar gatherings related to the programs and responsibilities of the Department. The following information is provided to assist sponsoring organizations in planning for participation by FDA officials and employees and to acquaint them with rules and regulations applicable to such participation by federal employees.

Honoraria and Gifts

Federal officials and employees who give speeches or participate in conferences in their official capacity are considered to be on duty for those purposes and are prohibited by federal law from accepting any fee, honorarium, gift or anything of monetary value in connection with their participation in the event. (However, they may accept a lunch or dinner that is held in conjunction with their participation in the event and they may accept a certificate or other token of appreciation directed to them personally.)

Where an official or employee is prohibited from accepting a fee, honorarium or other remuneration for his or her participation, the official or employee is also prohibited from designating a charity to receive the fee, honorarium or other remuneration. For the above reasons, and in order to prevent any misunderstanding or embarrassment in conjunction with the Department's participation in the event, please do not offer or provide any such fee or gift in conjunction with our speaker's participation in the event.

Payment of Travel Expenses by the Food and Drug Administration

Ordinarily, where it is deemed appropriate for official time to be used for an FDA official or employee to participate in an outside event, it is considered appropriate for the government to pay his or her travel expenses. Our regulations prohibit acceptance of any unapproved travel support, including free or subsidized hotel accommodations, meals, or airline tickets. As a result our employees may sometimes elect to stay in hotels separate from the primary meeting location, because of government limitations on hotel cost reimbursements. (If the accommodations chosen by our employee exceed amounts reimbursable under travel regulations, the employee is personally responsible for the difference in cost.) We appreciate your cooperation in assuring that your organization does not put our employees in a difficult situation by making unapproved contributions to the costs of travel or accommodations in any way.

Approval of Non-Federal Support for FDA Employee Travel

Although the Department has statutory authority to accept the payment of employees' travel expenses from outside organizations in connection with their attendance at meetings or in performing advisory services concerned with the functions or activities of the Department, employees are not allowed to solicit offers for such payments.

In limited circumstances, however, where an organization has initiated an offer to pay for the travel expenses of FDA's participant, such an offer may be accepted. If that is to be the case, please advise the speaker or participant well in advance of the arrangements that will be made, so that appropriate review of those arrangements can be made by FDA prior to the event.

Reimbursement for travel expenses will not be accepted if there is real or apparent conflict of interest between the traveler or FDA and the organization offering to pay, if the reimbursement for travel expenses is to be made from funds received under any federal grant or a DHHS contract, or where any other circumstances exists that would bring into question the propriety of the traveler for FDA accepting such reimbursement.

HHS regulations prohibit acceptance of travel support in excess of expenses that would otherwise be covered by government travel regulations. To assure conformance with these regulations, FDA policy prohibits acceptance of in-kind travel support, such as hotel accommodations, meals, or airline tickets, except in unusual and well justified circumstances. Instead, FDA will routinely pay for all travel costs and subsequently bill the offerer. An organization volunteering to pay all or part of an employee's travel cost must assure that it does not put our employees in a difficult situation by contributing to the costs of accommodations in any way other than paying the bill we send upon completion of travel. Sometimes our employees may elect to stay in hotels separate from the primary meeting location, because of government limits on hotel cost reimbursement.

The foregoing information is provided not to solicit such reimbursement, but merely to indicate clearly both the limited circumstances under which offers of reimbursement may be accepted, and the limitations on amounts that may be accepted to cover travel costs.

Spousal or Family Accompaniment

Where an official or employee of the Department is giving a speech or participating in an event as part of his or her official duties, he or she may not accept reimbursement from any outside source for the travel expenses of his or her spouse, family member, or associate. This prohibition applies whether the HHS official or employee is traveling at the expense of the government or at the expense of the sponsoring organization.

If you have any questions regarding any of the foregoing information, please contact the Food and Drug Administration, Office of Financial Management on 301-443-2884.

HHS/OmO/OFM 7/89