FOOD AND DRUG ADMINSITRATION

FIELD MANAGEMENT DIRECTIVE No. 13

Subject: International Travel	Area: Operations Management	Date Revised October 2002

PURPOSE

This Field Management Directive (FMD 13) describes the development, administration, and execution of FDA/ORA's International Travel Plan (ITP). It explains how and upon what basis the ITP is developed and provides procedures that must be followed when ORA personnel are requesting approval and after it has been approved. It demonstrates FDA/ORA's commitment to public health on the international arena, furthering its mission through international inspections, sharing of expertise and knowledge, and allowing FDA personnel to participate in international forums.

The Food and Drug Administration encourages person-to-person contact with international scientists and health officials to improve U.S. consumer protection and to raise the standards of food, drugs, medical devices, and biological products throughout the world. However, it is essential that international travel be conducted in full compliance with regulations established by FDA, DHHS, Department of State, and with Executive Orders.

Group travel to visit the same location or to attend the same international meeting should be limited to a minimum number of persons required to accomplish the assignment. Similarly, all international travel should be mission critical and coordinated so as to assure effective use of agency resources.

DEFINITION

The DHHS Travel Manual (Section 6-00-00) defines international travel as all official travel outside the United States, Canal Zone, Guam, American Samoa, Wake Island and the Trust Territory of the Pacific Islands, Puerto Rico and the U.S. Virgin Islands, and any other territory under U.S. jurisdiction. However, some travel to Canada and Mexico are considered as domestic (detail see page 3).

THE ORA INTERNATIONAL TRAVEL PLAN

The ORA ITP is developed annually to meet the needs and goals in performing the Agency's mission in foreign countries. The majority of the funds in ORA's International Travel budget are used for inspections, investigations, and bilateral activities, e.g., Memoranda of Understandings (MOUs). Each year, a certain amount is allocated for ORA personnel to attend and participate in international technical/scientific meetings, conferences, and workshops.

Distribution:	**Regional Food and Drug Directors and District Directors** **FDA Headquarters Offices**
Issued by:	**ORA/ORO/Division of Field Investigations (HFC-130)**
Authority:	**ORA**
Publication Date:	**November 2002**

During the fourth quarter of each fiscal year, ORA units submit requests for international travel for the up coming year to ORA/ORO/Division of Field Investigations (DFI), HFC-130. DFI reviews and categorizes each request and makes recommendations to ORO, HFC-100. ORO review all requests and develops a plan based on considerations including goals set by the Commissioner, Agency commitments, regulatory needs, new products approval requirements, Congressional interests, established MOUs, and emerging issues. When more than one traveler participates in the same program, justification is required. Each traveler is to have a different purpose for participating in a program. An example of Programs requested, are listed below.

Each field office will receive a copy of the final plan approved by ORO that shows the status of each request (approved, disapproved, or approved with local funding or other modifications):

ORA has established the following priorities for international travel:

1. Inspections and Investigations – to assure that international standards for food, drugs, biologics (including blood and blood components), and medical devices intended for import into the U.S. meet the requirements of the FD&C Act. This travel is necessary to provide assurance that products exported to the U.S. comply with Good Manufacturing Practices, and for those products subject to a pending application before the Agency, whether they should be approved or disapproved. This travel may also include extension of domestic investigations to the international arena

2. Travel in response to international emergencies where FDA expertise is requested by a foreign government or international health organization. Examples of emergency situations are the contamination of glycerin with diethylene glycol in Haiti and problems with pathogens in imported fruits and vegetables.

3. The establishment of new MOUs and Mutual Recognition Agreements (MRA) with foreign countries and the maintenance of existing agreements. These activities relate directly to regulatory issues; and may involve international counterpart agencies that conduct regulatory work for FDA. The Office of International Programs has the lead on the MRA and will coordinate all related foreign travel.

4. Participation in technical and scientific meetings, conferences, and workshops. Attendance at a meeting or conference which relates directly to the employee's job responsibilities and has direct benefit to the individual's program, and to furthering one or more of FDA's priority initiatives.

5. Assistance to international organizations, such as Food and Agriculture Organization (FAO), Pan American Health Organization (PAHO), and World Health Organization (WHO), etc., where expertise within FDA is requested and necessary for the effective implementation or understanding of a project. The project clearly relates to the employee's job responsibilities and will benefit to both FDA and the international organization. The Office of International Programs should be apprised of all requests for assistance, in order to coordinate on behalf of the Agency, and obtain OC clearance, when warranted.

CONTACT POINT

The contact point for all ORA international travel is the DFI/International Operations Branch (IOB), HFC-130, Telephone:(301) 827-5653.

INQUIRIES RELATED TO INTERNATIONAL ASSIGNMENTS

Foreign governments and international organizations requesting FDA assistance should submit a formal written request to the Director, Office of International Programs (OIP), HFG-1.

All ORA headquarters and field personnel contacted by foreign governments and representatives of international organizations regarding FDA assistance will inform the requestor of the proper channels to follow and refer them to the OIP. No commitments should be made during these contacts under any circumstances.

As required by Staff Manual Guide 2342.2(2), the person receiving the inquiry or request will prepare a memo indicating the nature of the request. The memo should be forwarded to the Director of OIA, with copies to ORO and the appropriate District and Regional Directors.

TRAVEL TO CANADA AND MEXICO

When there is no overnight lodging for routine inspections and investigations, travel to Canada and Mexico is considered as domestic rather than international by the current HHS Travel Manual (Section 1-20-20). The occasional or recurring meetings of FDA field staff with our counterparts in Canada to discuss matters related to supporting FDA's inspection program has been interpreted by the Deputy Commissioner for Management and Operations to fall within the domestic classification (**when there is no overnight lodging**). Therefore, meetings that typically occur on relatively short notice and do not require overnight lodging in Canada and or Mexico will need only be authorized on the signature of the Associate Commissioner for Regulatory Affairs (ACRA) or his designee, which includes Regional Food and Drug Directors (RFDD) and/or District Directors (DD). Contact DFI to determine if costs of such trip will come from domestic or international travel funds.

PERSONAL SAFETY AND SECURITY

Travelers are encouraged to make every effort to ensure their safety while in international travel status and should provide their office with a detailed itinerary so that they can be contacted in an emergency. Travelers should also check in with their office on a routine basis. ORA personnel who encounter an emergency situation while traveling abroad should immediately contact FDA's 24-hour emergency number, +1 (301) 443-1240. International cell phones will be provided to international travelers, so they can be contacted during an emergency.

The following web sites will provide useful information for the international traveler.

- **Centers for Disease Control**

  http://www.cdc.gov

  Information on diseases in specific countries, inoculations and preventive measures.

- **CIA Fact Book**

  http://www.odci.gov

  Information on climate; population; political parties; and the economy for all countries. There are two ways to access "Fact Book": 1) Click on the "World Fact Book," click on "Country Listing;" 2) Click on "Publications and Reports," click on "World Fact Book," click on "Country Listing."

- **State Department Travel Warnings**

  http://www.state.gov

  Click on search and type in Travel Warnings, click on Travel Warnings and Consular Information and Consular Information, click on the letter for the country about which you would like information.

  The site has information on more than 160 countries and describes entry requirements, travel conditions, available medical facilities, areas of instability and more.

  For more information, return to the search page and type in "publications."

PROCEDURES

1. Each request for international activities should be based on the funds requested and approved in the annual ORA International Travel Plan.

2. Each request will be given careful scrutiny at all levels within the organization to determine that the trip is necessary. The person making the trip must be qualified for the assignment, as each FDA employee traveling abroad represents the U.S. Food and Drug Administration.

3. The Department of State now requires four weeks for processing a request for an official passport. Therefore, a request for issuance or renewal of an official passport must be received by DFI at least eight weeks prior to the travel. Additional time will be needed if one or more visas are required for the country(s) to be visited. Official passports may not be issued for some international activities, such as FAO, WHO, and PAHO consultancies. This type of assignment may be performed using a personal passport, which also requires four weeks to process.

4. The Notification of Foreign Travel (NFT) form is used to obtain HHS Department of State and Embassy clearance. This is the first document that needs to be completed and processed. The request should have the concurrence of the Regional Food and Drug Director or District Director, or the ORA Office Director and be forwarded to DFI/International Operations Branch (IOB), HFC-130. The purpose of travel in relation to departmental objectives should be described. In addition, an in-country contact name and telephone number is required.

5. The NFT is submitted to the Office of International Programs electronically via website: http://ogha.psc.gov/ogha/ftform.html. NFTs must be submitted 45 calendars days before the anticipated departure date. The NFT can be submitted by the field office or by IOB personnel. Any NFT received less than 2 weeks before departure will not be accepted.

   The following are examples of countries that require longer approval time:

   Seven weeks: Peru and India

   Four weeks: Russia, China, Colombia, Taiwan, Philippines, and all South American counties

Note: In an effort to assure that NFT memos are submitted to IOB on time, we are encouraging all offices to submit the NFT memo in advance of the other travel documents, especially if there is the chance of missing the established deadline. NFT memos for SES individuals require additional clearance.

6. If this time frame cannot be met, Staff Manual Guide 2342.2(2) requires a letter of late justification. The justification for late submission for international travel must relate to circumstances outside the control of the traveler and the Agency. Late travel request may be denied unless an emergency or public health crisis exists. An example is shown in Attachment A. If two or more travelers will be participating in a non-inspectional trip, a" Justification for Two or More Travelers" statement is required. An example is shown in Attachment B.

7. Travelers from field offices should send the Advance of Funds (SF-1038) and Travel Voucher (SF-1012), if applicable, to the designated Regional Payment Office.

8. DFI/IOB will prepare the majority of the necessary documents, such as travel reservations, travel order, obtain signatures on all documents; have accounting data placed on the travel order and return the signed documents to the traveler.

9. To assure timely processing of travel requests, send pertinent documents and questions of the proposed travel to DFI/IOB.

10. If for any reason, the traveler trip status changes prior to departure, they should notify DFI/IOB immediately.

11. Upon returning from an international trip, the traveler must submit the travel Voucher with supporting receipts within five working days per HHS travel Manual. If the amount of the advance exceeded the expenses incurred, a check or money order made payable to "U.S. Food and Drug Administration" must be attached when you submit the travel voucher. Additionally, if the traveler takes annual leave*, the traveler's timekeeper must verify the leave usage by placing their timekeeper number on the travel voucher, and signing or initialing the travel voucher. The voucher must be submitted directly to the first line supervisor who will review and submit the voucher to the designated international travel voucher auditor in the region. Send travel vouchers for travel paid by outside sources (travel orders designated with a "Z") to DFI/IOB for processing.

*Note: Annual Leave may only be taken during FDA funded trips. Up to two days of leave can be approved for every five days worked with a total not to exceed five working days for a multi-week trip. No Annual Leave will be approved for trips funded by outside sources.

FOR TRAVEL FUNDED BY OUTSIDE SOURCES

In addition to the NFT, the following documents are necessary for international travel that is funded by foreign government and international organizations:

1. Letters of Invitation from outside sources other than FAO, PAHO, WHO, must be submitted to Katherine Zink, HFI-1. This will ensure that FDA can accept travel funds from the organization in accordance to FDA laws and regulations and to assure no conflict of interest (Attachment C).

2. Organizations that wish to fund travel must complete and submit a Sponsor Certification Form (Attachment F). Form is not necessary for travel funded by FAO, PAHO and WHO. You can access the form via the intranet, Office of Financial Management website, under travel. This form must be submitted with the letter of invitation to Katherine Zink, HFI-1.

3. HHS 348 Form, Request and Approval for Acceptance of Payment of Travel Expenses In Cash or In Kind, including the background information on Request for Approval for Acceptance of Payment of Travel Expenses In Cash or In Kind Form. Page two of this form must be signed with an original signature and questions one to eight (1-8) completed, and submitted with your travel package.

   The HHS 348 Form can be downloaded and filled in PDF from the website below: http://forms.cit.nih.gov/adobe/travel/HS348.PDF

4. A letter of acceptance to the sponsoring organization (for signature of Director, Office of Resource Management) on Rockville letterhead stationery (Attachment D).

5. General information about FDA Employee Who Attend, Participate in or Speak at Non-Federal Meetings, Conferences and Symposiums (Attachment E).

The above documentation should be prepared by the traveler's district and must be received by DFI, International Operations Branch, HFC-130, as a package, at least five weeks before departure. A late travel package may be denied. Any request for travel received less than 2 weeks prior to the requested travel date with not be accepted.

ATTACHMENT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date:

From: Associate Director, Division of Field Investigations (HFC-130)

Subject: Justification for Late Submission of International Travel

To: Director, Office of International Programs (HFY-50)

(Insert justifications for submitting travel package to the Office of International Affairs less than 45 working days prior to the scheduled departure date. The justification should relate to circumstances outside the control of the traveler and FDA. Reasons relating to typing workload and obtaining organizational approval are, generally, not acceptable.)

ATTACHMENT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date:

From: Associate Director, Division of Field Investigations (HFC-130)

Subject: Justification for Two or More Travelers

To: Director, Office of International Programs (HFY-50)

It is advantageous for the Department and FDA to have active participation and leadership in the development of Thailand's Export Certificate Programs to assure exports are in compliance with existing FDA standards. U.S. influence in the development of these standards helps to assure safe and honestly labeled food products that are imported into and consumed in the U.S.

Sydney H. Rogers, Director, Investigations Branch. He will cover aspects of seafood issues and laboratory operations, and discuss analytical concerns of the seafood area.

John Poe is the recently designated Director, Division of Shellfish Products, Food Safety and Applied Nutrition. He is responsible for all shellfish activities and will be discussing implementation of standards with his foreign counterparts.

Mr. Charles Smith is an ORA Expert in the area of Shellfish Processing, and his expertise was specifically requested by the government of Thailand.

Mr. John F. Smith is an advisor on FDA policies in the area of international activities. He will meet with officials to discuss technical assistance to foreign government provided by FDA.

ATTACHMENT C

Model Letter of Invitation

Mr. Sidney H. Rogers
Director, Investigation Branch
Baltimore District
900 Madison Ave.
Baltimore, MD 21201

Dear Mr. Rogers:

On behalf of the Food and Agriculture Organization, I would like to invite you to work with staff from our office in Rome, Italy on a review of the National Export Certification Program and its application in the field of exports, determine its effectiveness in assuring adequate quality control practices, and study the feasibility of establishing memoranda of understanding between Thailand and other countries for the certification of foods intended for export. The meeting will take place in Thailand from July 10-27.

It would be advantageous for the Food and Drug Administration to have active participation and leadership in the development of this program. The influence of the United States in the development of these standards helps to assure safe and honestly labeled food products that are imported into and consumed in the United States.

The Food and Agriculture Organization will reimburse to the Food and Drug Administration all costs for travel, lodging, meals, and miscellaneous expenses upon receiving an invoice from your Accounting Office.

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 am looking forward to working with you on this very interesting and exciting project.

Sincerely,

Dennis Brydges
Executive Officer

ATTACHMENT D

Model Letter of Acceptance

Food and Drug Administration

Rockville MD 20857

Dennis Brydges
Executive Officer
Food and Agriculture Organization
1001 22nd Street, N.W.
Washington, D.C. 20437

Dear Mr. Bridges:

On behalf of the Food and Drug Administration, I am pleased to acknowledge your invitation to Mr. Sidney H. Rogers, Director, Investigation Branch to review the Food and Agriculture Organizations National Export Certification Program and its application in the field of export practices. The travel will take place in Thailand from July 10-27, 2002.

In accordance with your letter of May 12, 2002, we understand that your organization will reimburse the costs for air fare, lodging, meals, and miscellaneous expenses. When Mr. Rogers has returned and presented his claim, you will be notified by our Accounting 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,

Malcolm L. Frazier
Director, Office of Resource Management

Enclosure

ATTACHMENT E

General Information about FDA Employee Who Attend, Participate in or Speak at Non-Federal Meetings, Conferences, and Symposiums

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, symposiums, 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.

Honorariums 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 for 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 participation, 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 organizations 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 or 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 that 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 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, Division of Financial Management on 301-443-2884.

ATTACHMENT F

Office of Financial Management

SPONSOR CERTIFICATION

The Food and Drug Administration requires the following information to be completed by sponsoring organizations requesting FDA employees to attend, participate in, or speak at non-federal meetings, conferences, and symposiums.

NAME OF SPONSOR ISSUING INVITATION: _____

_____

SPONSOR MISSION STATEMENT: _____

_____

_____

_____

TARGET AUDIENCE: _____

_____

PURPOSE FOR WHICH THE FDA EMPLOYEE IS BEING INVITED: _____

_____

_____

NAME OF FDA EMPLOYEE: _____

NATURE OF COSTS TO BE REIMBURSED TO FDA (i.e., airfare, lodging, meals. miscellaneous expenses): _____

Additional Certification:

Yes ___ No___ Is the traveler an officer, director, trustee, board member, partner or an employee of the sponsoring organization?

Yes ___ No___ Does the traveler's Center/Office have a contract or grant with the sponsoring organization?

Yes ___ No___ Is the sponsor (or a component of this sponsoring organization) a party to a matter, which is pending before the FDA?

Yes ___ No___ Is the sponsor a for-profit organization?

Yes ___ No___ Does the sponsor engage in any lobbying activities?

Yes ___ No___ Does the sponsor include corporate as well as individual membership? if so, how many and what is the percentage of corporate members?

WE ALSO AGREE TO THE FOLLOWING:

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.

Name: _____
Please Print

Title: _____

Signature:_____Date: _____