SMG 2810.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

AGREEMENTS WITH OTHER GOVERNMENT AGENCIES

INTERAGENCY AGREEMENTS

Transmittal Number 99-27 -- Date: 04/05/1999

1. PURPOSE

This guide establishes policies and areas of responsibility for the development and administration of Interagency Agreements between the Food and Drug Administration (FDA) and other Federal agencies. It establishes an FDA central point for information and control. This guide also includes:

1. the format for a HHS-393, which is the official obligating document; and,

2. the format for a FDA-3443, which is the official Interagency Agreement form required for a new or modified Interagency Agreement.

   For Domestic Memorandums of Understanding, see Staff Manual Guide FDA 2820.1. For Foreign Memorandums of Understanding, see Staff Manual Guide FDA 2830.1.

2. REFERENCE

This list provides citations for regulations regarding Interagency Agreements. Procedures for the execution of these agreements are summarized in this Staff Manual Guide.

A. Economy Act approved June 30, 1932, as amended by 31 USC 1535 (formerly 31 USC 686).

B. Section 301 of the Public Health Service Act (42 USC 241).

C. Section 1702 of Title XVII of the Public Health Service Act (42 USC 300 U et seq.).

D. Section 1704 of Title XVII of the Public Health Service Act (42 USC 300 U et seq.).

E. Comptroller General Decision B-190020 (Jan. 31, 1978).

F. HHS General Administration Manual, Chapter 8-77, "Agency Agreements."

G. Staff Manual Guide FDA 2111.3, "FDA Research Involving Human Subjects Committee (RIHSC)."

H. Staff Manual Guide FDA 2470.2, "Obtaining Clearances Under the Paperwork Reduction Act of 1980."

I. Staff Manual Guide FDA 2470.1, "FDA Reports Management Program."

J. Staff Manual Guide FDA 2113.2, "FDA Scientific Review of Research and Development Projects."

K. Federal Acquisition Regulation Subpart 17.5 "Interagency Acquisitions under the Economy Act."

L. Comptroller General Decision B-136318.

M. Comptroller General Decision B-104354.

N. Comptroller General Decision B-176209.

O. Public Health Service Policy on Care and Use of Laboratory Animals (March 1996 or most current edition).

P. Negotiated Contracts Branch memorandum dated September 18, 1974 entitled "Numbering of Procurement Documents."

3. POLICY

It is the policy of the Food and Drug Administration to initiate and enter into agreements with other Federal agencies whenever collaboration for the

purposes of sharing knowledge, personnel, services or other resources would:

1. strengthen programs of mutual concern in the public interest,

2. extend overall consumer protection through more effective use of the collective resources, and

3. eliminate overlapping or duplication of effort.

The Food and Drug Administration will engage in such collaboration with other agencies whenever it is within our program capabilities and legislative authority. The FDA will also determine the availability of services and facilities of other agencies prior to utilizing nongovernmental sources.

4. DEFINITIONS

A. Interagency Agreement. The term "Interagency Agreement," (IAG) as used herein, means any formal agreement between the Food and Drug Administration and another Federal agency concerning a transfer of funds, provision of services, loan of staff, use of property, facilities or equipment, or exchange of information. FDA Form 3443 should be submitted for the initiation of a new or a modified IAG. This document should be submitted in accordance with Attachment B of this issuance.

The term "Interagency Agreement" should not be confused with the term "Memorandum of Understanding (MOU)." The term "Memorandum of Understanding" refers to a formal agreement between the Food and Drug Administration and another Government agency (Federal, State, or local) or a formal agreement with foreign governments or other foreign institutions. A "Memorandum of Understanding" may not be used when it involves a transfer of personnel, transfer of funds, or real property. See Staff Manual Guide FDA 2820.1 and 2830.1 for additional instructions.

B. Sponsoring Office. The term "sponsoring office," as used herein, means the center or office having predominant interest in the agreement, and which initiates the proposed agreement and will assume responsibility for its administration.

C. Liaison Officer. The term "liaison officer," as used herein, means the person designated by the sponsor to be responsible for monitoring the technical requirements of the agreement.

D. Modification. The term "modification," as used herein, means a written revision (addition or deletion) to an existing agreement.

E. Reimbursable Agreement. The term "Reimbursable Agreement," as used herein, means an agreement in which FDA agrees to provide services to another agency for which payment will be credited to an FDA appropriation.

F. Refund Agreement. The term "Refund Agreement," as used herein, means an agreement whereby FDA uses its own funds to pay for services performed under the IAG with the understanding that the other agency will refund the funds to FDA.

5. ADVANCE COORDINATION

For those Interagency Agreements requiring advanced intra-Center/office coordination, anapproval/signature page attached to the 393 will indicate that such coordination has been accomplished. Advanced coordination by the appropriate office is recommended for the following activities:

1. **Research Involving Human Subjects.** In accordance with paragraph 4 of Staff Manual Guide FDA 2111.3, Interagency Agreements involving investigational activities that will require utilization of human subjects will not be executed prior to review and full approval of the IAG by the Research Involving Human Subjects Committee (RIHSC). In accordance with paragraph 6.a. of Staff Manual Guide FDA 2113.2, a scientific review of all research and development projects will be conducted prior to submission of the IAG for final approval.

2. **Research/Other Activities Involving Live Animal Subjects.** Interagency Agreements involving any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes shall be coordinated through the Director, Office of Animal Care and Use (OACU). The OACU Director shall coordinate and verify review and full approval of the IAG by the Institutional Animal Care and Use Committee (IACUC), that oversees animal care and use at performance site, prior to execution. There is an IACUC in each FDA Center and the Office of Regulatory Affairs (ORA) whose function is to ensure that the care and use of animals in PHS-conducted or supported activities is appropriate and humane in accordance with the Public Health Service Policy on the Care and Use of Laboratory Animals.

3. **Compliance Activities.** Any proposed Interagency Agreement of a compliance nature such as inspection, monitoring, etc., will be coordinated through the Associate Commissioner for Regulatory Affairs.

4. **Activities Requiring Regional Participation.** Any Interagency Agreement that requires regional office participation will be coordinated through the Associate Commissioner for Regulatory Affairs.

5. **Activities Involving Automated Data Processing.** Any Interagency Agreement relating to computer systems analysis, applications of computer systems, and computer and word processing equipment and/or services will be coordinated through the Office of Information Resources Management.

6. **Consumer Statistics Collection Activities.** Any Interagency Agreement which requires the collection of information through surveys of consumers or other specialized audiences or similar means will be coordinated through the FDA Statistician in the Office of Planning and Evaluation (HFP-10), and the FDA Reports Clearance Officer, as described in Staff Manual Guide FDA 2470.2. Survey statistics activities are defined to include data collected from or about U.S. consumers, specifically, groups (physicians and dentists) and institutions (hospitals, universities, businesses, etc.).

7. **Activities Involving the Detail of Personnel.** Any Interagency Agreement which requires the detail of personnel between FDA and another Federal agency will be coordinated through the Director, Office of Human Resources and Management Services.

8. **Activities Requiring the Approval of the Office of the Secretary, DHHS.** The Office of the Secretary should be apprised of and approve agreements that have an impact on a major Secretarial or policy initiative or an agreement that may have an impact on relations between the Department and State and local governments, HHS grantees, or the public. This is in accordance with Chapter 8-77 of the General Administration Manual.

6. RESPONSIBILITIES

A. Sponsoring Office.

1. Maintains an awareness of program areas of other Federal agencies where cooperation and exchange of information or services would be beneficial to the mission of the Food and Drug Administration.

2. Prepares FDA Form 3443 "Interagency Agreement" attaching the Scope of Work specific to that agreement (see Attachment B of this Guide). Prepares the HHS 393 with the necessary approval signature page attached (see Attachment A of this Guide). The HHS 393 also indicates the type of funds being used, e.g., service or extramural.

Both of these documents are forwarded through necessary approval channels as indicated in paragraph 5 and paragraph 6(3) of this Guide.

3. Accomplishes all required intra-Center/office coordination. It is important that administrative delays be avoided in the processing of the IAGs. It is the responsibility of the sponsor to ensure that all the necessary coordination sign-offs be accomplished before the IAG package reaches the Office of Facilities, Acquisitions, and Central Services (see Section 5. **ADVANCE COORDINATION**). Numbering of the document will be accomplished in accordance with Negotiated Contracts Branch memorandum dated September 18, 1974, "Numbering of Procurement Documents." If the IAG package has not been coordinated in accordance with paragraph 5 of this Guide, the Office of Facilities, Acquisitions, and Central Services will return the package to the sponsor for the proper coordination and sign-off.

4. Performs a continuous evaluation of each agreement and initiates appropriate action for continuing, amending, or terminating those agreements. A Form FDA 3443 prepared in accordance with Attachment B of this issuance is also required for amending or extending an agreement. Termination of an agreement should be accomplished by the use of a formal memorandum addressed to the Division of Contracts and Procurement Management, HFA-520, through the Office of Financial Management.

5. Provides the Office of Financial Management, HFA-122, the proper operating and refund/reimbursable accounting information (transaction number) on invoices before sending to OFACS for final payment approval.

6. Approves billing submitted by other agencies.

7. Provides for the scientific peer review of proposed IAGs in accordance with paragraph 6.a. of Staff Manual Guide FDA 2113.2.

8. Prepares or obtains the necessary documentation in order to obtain RIHSC review and approval by the Center and Agency RIHSC Committees. The Center RIHSC Chairperson will coordinate review by the Agency RIHSC Committee.

9. When preparing reimbursable IAGs, includes the appropriate overhead and G&A expenses in the calculation of all applicable costs. If overhead is not to be charged, prepares a Request for Waiver for approval by the Office of Financial Management and OFACS, and submits it along with the initial IAG package. On reimbursable

agreements, a cost breakout is required. An example of this is included as part of Attachment A of this Staff Manual Guide.

10. Upon completion of the Interagency Agreement, completes the Project Officer Checklist forwarded to the Center by OFACS. The timely completion of this Checklist is necessary for closeout of the Agreement.

B. Office of Regulatory Affairs.

Reviews each Interagency Agreement involving compliance or regulatory matters for appropriateness and completeness. Upon approval, the Interagency Agreement will be forwarded through the Office of Financial Management (HFA-140) to the Division of Contracts and Procurement Management (HFA-520).

C. Office of Health Affairs.

Reviews each Interagency Agreement involving research involving human subjects for appropriateness and completeness and suitable peer review. Upon approval, the Interagency Agreement will be forwarded through the Office of Financial Management (HFA-140) to the Division of Contracts and Procurement Management (HFA-520).

D. Office of International Affairs.

Reviews each Interagency Agreement involving international affairs for appropriateness and completeness. Upon approval, the Interagency Agreement shall be forwarded through the Office of Financial Management (HFA-140) to the Division of Contracts and Procurement Management (HFA-520).

E. Office of Financial Management.

1. Reviews IAGs for compliance with all Agency program requirements and applicable appropriations.

2. Records obligations and/or sets up Accounts Receivable.

3. Receives requests to bill participating agencies, based on services performed.

4. Provides financial status reports of Interagency Agreements as required.

5. Reviews and approves/disapproves requests for overhead waivers as submitted by the Centers.

F. Office of Facilities, Acquisitions, and Central Services.

All Interagency Agreements are signed in the Office of Facilities, Acquisitions and Central Services, the Division of Contracts and Procurement Management.

1. The Division of Contracts and Procurement Management, ORA Support and Assistance Management Branch (OSAMB), receives all packages for proposed Interagency Agreements. Reviews packages for completeness of documentation, clarity of proposed requirement, and determines whether the requirement meets the criteria for eventual formalization of an Interagency Agreement.

2. OSAMB reviews reimbursable agreements ensuring that appropriate overhead (O/H) and general and administrative expenses (G&A) have been charged in accordance with the Comptroller General Decision B-136318. If overhead has not been charged, a Request for Waiver must be submitted, along with the IAG package, by the sponsoring office to the Office of Financial Management for approval. This Request for Waiver is then approved by the Director, Division of Contracts and Procurement Management, OFACS, or designee.

3. OSAMB reviews non-reimbursable agreements and prepares a Determination and Findings in accordance with the Federal Acquisition Regulation Subpart 17.5.

4. OSAMB may contact the other participating agency, as needed, for coordination of agreement.

5. OSAMB prepares all agreements for execution.

6. OSAMB assures that the necessary clearances have been obtained by the sponsoring office prior to execution of the agreement.

7. OSAMB provides for the distribution of all executed agreements including one copy to the Office of Enforcement, Division of Compliance Policy, ORA.

8. OSAMB provides on-going administration of all agreements. This includes processing and modification for administrative changes, renewals, and terminations.

9. OSAMB serves as central repository for all agreements and information relating to them. Prepares reports on the status of all agreements as required.

10. Upon completion of project, OSAMB performs closeout procedures. This is accomplished through coordination with the Center Liaison for confirmation of project completion, with the Office of Financial Management for billing completion and with the other participating agency for concurrence of closeout.

7. FISCAL REQUIREMENTS

A. Funding.

1. Interagency Agreements Performed by Other Federal Agencies.

Interagency Agreements with Federal agencies shall be written on a fiscal year basis only; therefore the IAG must end on the last day of the fiscal year. **If the work is performed by a Federal facility, the facility can only bill for services performed through the last day of the fiscal year. Work performed by the recipient agency after the close of the fiscal year would have to be funded from the following fiscal year's appropriation.** Fiscal planning should be in consonance with the Comptroller General's Decision (B-104354) which reads, in part, as follows: "... an order for the work or service placed by one agency with another no longer obligates the appropriation of the ordering agency in the same manner as orders or contracts placed with private contractors; therefore, work or services covering more than one fiscal year are to be charged to the appropriation for the fiscal year in which the work is performed or the services rendered."

2. Interagency Agreements Contracted Out by Other Federal Agencies.

It should be noted that, if the recipient agency in turn awards a contract to a non-Federal source, then the fund availability is the same as that of of a contract. An additional statement should be included in the Interagency Agreement advising the Office of Financial Management that the agency will be using the services of a private contractor.

3. Interagency Agreements Contracted Out by FDA.

If the Interagency Agreement is put in place for the purpose of another agency to contribute funding toward an FDA contract, the funds can be collected immediately. Each FDA Center/Office may indicate on the HHS 393 that this need exists and should cite the FDA contract

involved. The appropriate language will then be added to the billing section of the IAG when the agreement is prepared.

a. Billing. Billing will be made through The Treasury OPAC (On-Line Payment and Collections) system. The FDA ALC Code (75060099) will be included in the Interagency Agreement. The participating agency ALC Code and accounting information will be requested. Any agency not under the OPAC billing method may still request billing under Standard Form 1080, "Voucher for Transfer Between Appropriations and/or Funds," or Standard Form 1081, "Voucher and Schedule of Withdrawals and Credits," or any appropriate billing documents specified in the agreement.

b. Cost Determination. At the end of each quarter, Center budget officers must submit to the Office of Financial Management a schedule of actual work completed for each reimbursable IAG and only those refund IAGs for which payment has been collected in advance.

8. AUTHORITY

There are several statutes which authorize the use of Interagency Agreements. This section addresses only the basic authority under the Economy Act and the most frequently used authorities under the Public Health Service Act. The Food, Drug, and Cosmetic Act and other statutes may contain language which authorizes the FDA to achieve its objectives through the use of agreements to cooperate and to coordinate its actions with other Federal agencies. However, this section will not list those authorities due to their infrequent usage.

A. The Economy Act. The basic authority for Interagency Agreements is the Economy Act (approved June 30, 1932, as amended by 31 U.S.C. 1535 (formerly 31 U.S.C. 686)) which permits the requisitioning of goods and services between Federal agencies. The Economy Act provides in pertinent part:

"Any executive department or independent establishment of the Government, or any bureau or office thereof, if funds are available therefor, and if it is determined by the head of such executive department, establishment, bureau or office to be in the interest of the Government so to do, may place orders with any other such department, establishment, bureau, or office for materials, supplies, equipment, work, or services, of any kind that such requisitioned Federal agency may be in a position to supply or equipped to render. . ."

It is FDA's position that the Economy Act will not be used for an agreement involving a third party.

B. The Public Health Service Act. The Comptroller General has ruled (Comptroller General's Opinion B-176209, September 11, 1972), that the Economy Act does not apply to Interagency Agreements entered into pursuant to an agency's cooperation function established by statute. According to the Comptroller General's opinion, FDA may enter into an agreement with another agency for work to be performed under contract with that agency or with FDA, provided that both agencies have a need for the work to be performed, and that both agencies share in the total cost of the work.

Therefore, in view of the foregoing Comptroller General's decision, the following statutes contain language authorizing cooperation and coordination by FDA with other agencies. Any of these statutes may be used, as applicable, to enter into Interagency Agreements involving contracts.

1. Section 301 of the Public Health Service Act provides in pertinent part:

   "The Secretary shall conduct in the service, and encourage, cooperate with, and render assistance to other appropriate public authorities . . . in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.... In carrying out the foregoing the Secretary is authorized to...enter into contracts, including contracts for research...."

2. Section 1702 of Title XVII of the Public Health Service Act (42 U.S.C. 300 U et seq) as amended, authorizes FDA to conduct and support by grant or contract (and encourage others to support) research in health information and health promotion, preventive health services, and education in the appropriate use of health care.

3. Section 1704 of Title XVII of the Public Health Service Act (42 U.S.C. 300 U et seq) as amended, authorizes FDA to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventative health services, and education in the appropriate use of health care available to the consumers of such care, schools, and others who are or should be informed respecting such matters.

These authorities will be used only when each agency has a need for the work to be performed and will share in the total cost of the work. (Sharing in the total cost refers to the cost under the contract. Efforts on the part of agency personnel related to establishing and monitoring the agreement do not apply to the cost sharing requirement.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Memorandum

Date

From

Subject Memorandum of Need - Request for Establishment of an Interagency Agreement

To Division of Contracts and Grants Management, (HFA-500)

Through Associate Commissioner for Regulatory Affairs (HFC-1)
Associate Commissioner for Health Affairs (HFY-1)
Division of Financial Management (HFA-100)

1. State whether "New Agreement" or "Renewal Agreement", and the project title. If Renewal Agreement, identify agreement number.

2. Purpose of agreement, justification and rationale for the need, and expected benefit.

3. Comprehensive description of work to be performed by each party.

4. Name and address of participating Federal agency. Name, address and telephone number of liaison office of participating Federal agency.

5. Name of FDA participating unit. Name, address and telephone number of FDA liaison office.

6. Period of agreement.

7. Anticipated duration of agreement: year ( )1, ( )2, ( )3.

8. Funding:

   A. If funds are to be obligated, provide the following:

      (1) Cost first year: cost elements

      (2) Estimated cost second year

(3) Estimated cost third year

(4) Appropriation and Allotment Symbols.

B. If a "Reimbursable Agreement," identify dollar amount.

9. Estimated Cost of Performance.

Prepare a line item budget supporting the total estimated cost of performance. The following is a suggested format for preparation of this estimate.

Cost Element	1st Year	2nd Year	3rd Year	Total
(1) Salaries and Fringe Benefits	_____	_____	_____	_____
(2) Indirect Cost	_____	_____	_____	_____
(3) Materials & Supplies	_____	_____	_____	_____
(4) Travel	_____	_____	_____	_____
(5) Equipment	_____	_____	_____	_____
(6) Total Direct and Indirect Cost	_____	_____	_____	_____
(7) General and Administrative Expenses (G&A)	_____	_____	_____	_____
Total	_____	_____	_____	_____

10. Anticipated reporting requirements on the participating agency. When applicable, list the nature, format and frequency of the reports to be received by FDA.

11. The following checklist is provided for your convenience in the coordination and sign-off process. Approvals by the offices in items lla. through lld. are usually required for most Interagency Agreements. The approvals by the officials listed in items lle. through llg. are required only in the special circumstances cited in each item. Other offices may be added if needed.

Advanced Coordination and Sign-Off	Required	Not Required
a. Sponsoring Office of Bureau		
(1) Adequacy of MON and intra-bureau coordination		

Approved: _____ _____ _____
Bureau or Office Director

(2) All Research and Development Projects

Approved:_____ _____ _____
Review by Sponsoring Office of
Bureau's Scientific Review Group

Advanced Coordination and Sign-Off (Continued)	Required	Not Required

b. Office of Health Affairs

(1) Adequacy of MON involving science, professional progress, international affairs and health or related research

Approved:_____ _____ _____
Associate Commissioner Health
Affairs, HFY-1

(2) Human Subjects Involved

Approved:_____ _____ _____
Research Involving Human
Subjects Committee (RIHSC)

c. Office of Regulatory Affairs

Compliance or Regulatory Research

Approved:_____ _____ _____
Associate Commissioner for
Regulatory Affairs, HFC-1

d. Division of Financial Management, OMO

Adequacy of MON for compliance with all agency program requirements and applicable appropriations

Approved:_____ _____ _____
Director, Division of Financial
Management, HFA-100

e. Regional Office Participation

Approved:_____ _____ _____
Executive Director of Regional
Operations (EDRO), HFO-1

f. Surveys or Questionaires

Approved:_____ _____ _____
Assistant Director for Health
Program Research, Bureau of
Radiological Health, HFX-4

Advanced Coordination and Sign-Off (Continued)	Required	Not Required

g. Computer Systems Analysis

(1) Computer Systems Analysis by other than Parklawn Computer Center

Approved:_____ _____ _____
Director, Division of Management
Systems and Policy, HFA-300

(2) Computer Systems Analysis by the Parklawn Computer Center

Approved:_____ _____ _____
Parklawn Computer Center, HFA-50