SMG 2129.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

EXTERNAL RELATIONS

GUIDELINES FOR RESPONDING TO GAO AND HHS/IG AUDITS

Transmittal Number 81-81 -- Date: 08/06/1981

1. PURPOSE

The purpose of this Guide is to provide guidance to FDA employees in responding to contacts from the General Accounting Office (GAO) and the HHS Office of the Inspector General (HHS/IG) relative to inquiries and audits of FDA programs, procedures, and policies; for responding to draft and final audit reports; and for reporting Agency progress in implementing FDA commitments on recommendations made in reports.

2. POLICY/PROCEDURES

The policy of the Food and Drug Administration regarding contact with the General Accounting Office and the HHS Office of the Inspector General relative to audits of FDA programs, procedures, and policies is set forth below.

1. Audits are considered as initiated only when:

   a. GAO or HHS/IG auditors have officially contacted either the Commissioner (HF-1), Deputy Commissioner (HF-2), Associate Commissioner for Management and Operations (HFA-1), and/or the Operations Coordination Staff (OCS) (HFA-10), and informed the Agency of their intention to conduct an audit on the particular subject; and

   b. An entrance conference has been held between the auditors and appropriate FDA officials

2. The OCS will arrange for an entrance conference between the auditors and appropriate FDA officials. This is the first step in any audit. The purpose of the entrance conference is to provide the auditors with an overview of the program that is the subject of the audit; to elicit from the auditors their plan and approximate timeframe for conducting the audit; and, to direct the auditors to the appropriate knowledgeable employees to assist with the audit. A Memorandum for the Record (MFR) of the entrance conference will be provided by OCS to GAO and the bureau/office involved.

3. Following the entrance conference, auditors may contact and meet with any Agency employees and follow any leads until their investigation is completed. OCS may assist in the scheduling of meetings, and will attend such meetings as necessary.

4. Any employee in the Agency who is contacted by GAO or IG auditors should immediately inform their bureau/office contact for GAO matters (see Attachment B) and OCS.

5. Bureau/office contacts should inform OCS in advance of all planned meetings between employees and GAO or IG auditors. They should also inform OCS of the progress of the audit, and any issues or problems which are, or appear to be, developing during the audit.

6. Following each substantive contact with an auditor, FDA employees must appropriately document the content of the exchange as well as any transmittal of materials as follows:

    a. An MFR should be prepared (handwritten is acceptable) which succinctly captures the subject matter discussed and documents conveyed. MFRs of meetings and telephone calls should describe:

        (1) Subjects discussed.

        (2) Important matters that were brought out.

        (3) Decisions reached.

        (4) Conclusions stated.

        (5) Requests for information or documents.

            These procedures are similar to those in the administrative regulations regarding meetings with persons outside the Agency (21 CFR 10.65).

b. Copies of the MFR should be sent to OCS, the bureau/office contact and/or the bureau executive officer.

c. Individual MFRs should be prepared on one-time substantive exchanges (telephone conversation or interview wherein substantive information about FDA programs or operations is provided). However, documenting a series of contacts during a period of continuing interaction may he accomplished by a summary MFR as long as the substance of each contact is accurately recorded. Contacts in which no substantive exchange occurs (e.g., incorrect referrals to an individual who knows nothing about the subject of interest) need not be documented.

7. Individual organizational units may establish additional internal policies and procedures regarding audits. Such policies and procedures should be communicated to OCS as information only, not for approval.

8. Upon completion of a GAO audit, a draft report will usually be provided to the Department. An official Department response must be submitted within 30 days. To facilitate coordination of the necessary clearances through PHS and the Department, the following procedures are to be observed:

   a. OCS receives and forwards all draft reports to appropriate FDA officials for review and comment.

   b. OCS, in conjunction with representatives of involved organizations and other appropriate Agency personnel, prepares a response which will be circulated to appropriate officials for concurrence.

   c. The Associate Commissioner for Management and Operations, with the Food and Drug Division Assistant General Counsel's concurrence, forwards the Agency's response through PHS to HHS.

   d. PHS and HHS review the response and resolve any problems through OCS.

   e. HHS forwards the final response to GAO as official Department comments.

9. GAO, upon receipt of the Department's comments, puts the report in final form and issues it to the Congress with copies to the Department for comment.

10. The Department is required by law to respond to the final report within 60 days. The procedures listed in 2.8. above will be followed in responding to final reports.

3. FOLLOW-UP TO AUDIT RECOMMENDATIONS

Whenever the Agency concurs with recommendations made in final audit reports or makes any commitments for actions to be taken, HHS requires an implementation plan and quarterly progress reports until the recommendations are fully implemented. To meet the Department's requirement, the following procedures will be observed:

1. After the Agency submits comments to the final report, OCS will provide a list of Agency commitments to the bureau executive officer/GAO contact and other appropriate officials. They, in conjunction with OCS, will develop an implementation plan and submit it to OCS by the indicated date.

2. OCS will forward the implementation plan to HHS through PHS.

3. Ten days prior to the close of each subsequent quarter and continuing until the plan has been completed or terminated, the bureau executive officers will submit a status report to OCS.

4. OCS will compile all status reports and submit the Agency's quarterly progress report to HHS through PHS.

5. If problems in implementing audit recommendations occur, OCS will request that the issues be discussed and resolved at a bureau staff meeting or in another appropriate forum. Alternatively, if the bureau recognizes that a problem is developing, the bureau should request that it be the subject of a staff meeting or other appropriate forum with the Commissioner.

ATTACHMENT 1

Answers to Frequently Asked Questions

Question:

What do I do if I'm contacted by a GAD Auditor?

Answer:

When you are contacted about a subject that is not presently under audit or you are unsure about whether an audit has been initiated, contact your bureau/office contact, the Operations Coordination Staff, or refer the auditor to the OCS (301-443-4116). When you are contacted in connection with audits that have been initiated through proper channels, you should cooperate fully with the auditors to the best of your ability. When you have concerns about how to deal with a particular GAO auditor or a particular question, contact your bureau/office GAO contact or the OCS for guidance.

Question:

How do I respond to GAO questions?

Answer:

You should answer questions forthrightly and honestly. While you are free to discuss anything you choose with GAO, we believe it is most helpful to the auditors and to the Agency if you confine your discussions to the subject of the audit and specific facts which you may be able to provide. Individual GAO auditor's knowledge of FDA will range from limited to quite extensive. Your responses will, therefore, need to be tailored to the level of knowledge you perceive the auditors to have and what they will need to know to understand the scientific, legal, and procedural ramifications of the information you are providing. In general, you may confine your discussions with GAO auditors to your specialty area. Rather than respond to questions outside of your area of expertise with personal opinions, refer them to other FDA employees.

Question:

What do I do when I am concerned about how to respond to the GAO auditor's questions?

Answer:

You should seek guidance from OCS or your bureau/office contact. You may decline to give personal opinions about the actions of other employees. When responding to GAO questions, you should identify any personal opinions you express which differ from Agency policy.

ATTACHMENT 1

Question:

What do I do if asked for documentation from or access to FDA files?

Answer:

GAO auditors will normally want to look at memoranda, registers, regulations, logs, guidelines, written procedures, and other documents that relate to the area under audit. Subject to the qualifications stated below, copies of such documents should be made available to them. However, they should not be given the original of any document except to copy it. All official record copies contained in FDA files must remain in the custody of FDA. You must contact the bureau/office GAO contact and OCS for guidance when the auditors request access to documents or files that:

1. May contain material prohibited from release under section 301(j) of the Federal Food, Drug and Cosmetic Act.

2. Are drafts of policies or regulations that contain or represent unresolved issues.

3. Relate either to unresolved legal actions against an establishment or to matters under litigation.

4. Contain information subject to the Privacy Act, patient names, personnel information, or financial interests.

Question:

Under what circumstances do we photocopy for GAO and/or ask them to sign for documents they take if they volunteer to photocopy them?

Answer:

It is generally preferable for FDA employees to make copies of documents requested by GAO, if circumstances allow (workload, volume of document, material prohibited from release has been purged, etc.). Should GAO take copies of documents to photocopy, a sign-out system should be used. Under no circumstances are original documents to be removed from Agency possession.

Question:

What records should I keep regarding my conversations with GAO?

Answer:

You should prepare a Memorandum for the Record (see 2.f. of SMG).

Question:

Is it appropriate for employees to ask GAO to make appointments in advance and to state the general nature/purpose of the contact?

Answer:

Yes. This will enable employees to (1) judge whether or not they are the appropriate person to discuss the subject matter and (2) prepare and research records and files so that the interview is productive. Should auditors appear in your office without an appointment, and if you have the time available to meet with them, you should do so. This is not required, however.

Question:

What if a GAO auditor gives me a draft report and/or asks me for informal comments on it?

Answer:

If, in the unusual event, you receive a copy of a draft report from GAO, you should contact OCS immediately. Under no circumstances are official comments to be provided other than through official FDA, PHS and HHS channels (see 2.h.).

ATTACHMENT 2

List of Bureau/Office GAO Contacts.

Bureau/office GAO Contacts

Names and Telephone Numbers

- OFFICE OF THE COMMISSIONER
  Lois P. Adams 443-4116
  Beatrice K. Anderson 443-4116

- EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS
  Ronald T. Ottes 443-6230

- BUREAU OF BIOLOGICS
  Russell J. Abbott 496-5394

- BUREAU OF DRUGS
  Walter M. Batts 443-4181

- BUREAU OF FOODS
  Taylor Quinn 245-1243

- BUREAU OF MEDICAL DEVICES
  Robert W. Sauer 427-7167

- BUREAU OF RADIOLOGICAL HEALTH
  J. Arthur Lazell 443-4690

- BUREAU OF VETERINARY MEDICINE
  Beulah M. Sink 443-2795

- NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH
  Arthur R. Norris 8-542-4516