SMG 2129.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

EXTERNAL RELATIONS

GUIDELINES FOR RESPONDING TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL'S AUDITS AND INSPECTIONS

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1. PURPOSE

This guide establishes Agencywide policies and procedures for preparing responses to OIG contacts regarding audits and inspections of FDA programs, draft and final reports, inquiries, and progress made in implementing recommendations in the final reports. This guide replaces SMG 2129.2, dated 3/14/94, and the portions of SMG 2129.1, dated 8/6/81, that refer to the OIG.

2. DEFINITIONS

A. Audit. A structured review performed by Office of Audit Services, OIG in accordance with standards developed by the General Accounting Office.

B. Corrective Action Plan. A time-phased plan to implement recommendations in audits and inspections.

C. Draft Report. Initial, official report of findings and recommendations issued by the Inspector General to the Commissioner of Food and Drugs.

D. Entrance Conference. An official meeting of the OIG audit /inspection team with representatives of FDA Offices to discuss the purpose and scope of an audit or inspection, information sources, and other needs.

E. Exit Conference. An official meeting held to discuss audit or inspection results and conclusions, and solicit additional facts that could impact findings and report's recommendations. Sometimes, the practice allows for

a "working draft" to be provided before the conference for the review and initial comment of all participants.

F. **FDA Audit Follow-up Plan.** A semiannual status report provided to Centers/Offices showing the current status of all corrective actions underway in response to audits and/or inspections.

G. **Final Report.** The last version of the official report with any FDA comments on the draft OIG report attached.

H. **Inspection.** Short term analytical studies or evaluations performed by the Office of Evaluation and Inspections, OIG in accordance with standards developed by the President's Council for Integrity and Efficiency.

I. **Investigation.** A formal review by the Office of Investigations, OIG to determine and substantiate allegations of violations of criminal laws or administrative regulations.

J. **Management Advisory Report (MAR).** A high priority, narrowly focused OIG review that generally involves the analysis of existing information and does not generally include verification of data.

K. **Material Weakness.** Term used by government auditors to identify management control weaknesses which, in their opinion, pose a risk or a threat to the internal control systems of a program or operation.

L. **Non-concurred recommendation (in final report).** An OIG recommendation which is not agreed to by FDA and therefore goes to conflict resolution.

M. **Office of the Inspector General (OIG).** An independent arm within the Department of Health and Human Services (DHHS), comprised of three components: Office of Audit Services, Office of Investigations, and Office of Evaluation and Inspections. The OIG was established under the Inspector General Act of 1978.

3. POLICY

All FDA employees will cooperate fully with audit and inspection personnel while performing their official duties.

4. AUTHORITIES AND REFERENCES

A. **Inspector General Act of 1978 as Amended.** Created an independent Office of the Inspector General in DHHS and additional Federal agencies to carry out reviews of an agency's transactions, programs, and

administrative activities, and provide management with recommendations for corrections or improvements.

B. Inspector General Act Amendments of 1988 as Amended. Added the requirement to report twice a year to Congress on the actions taken and the amount of funds recovered or saved in response to the recommendations. Strengthens Inspector General authorities by revising reporting requirements to ensure agency accountability in implementation of recommendations.

C. Federal Managers' Financial Integrity Act of 1982 (PL 97-255). Mandated ongoing evaluations and reports on the adequacy of the system of internal accounting and administrative controls of each executive agency. It requires agencies to establish controls in accordance with standards prescribed by GAO and to evaluate them in accordance with the guidelines established by OMB.

D. Chief Financial Officer's Act of 1990 (PL 101- 576). Reformed financial management in the Federal Government, including establishment of an integrated financial management system, developing cost information, conducting systematic performance management, developing financial management budgets, and producing financial reports.

E. OMB Circular A-50, "Audit Follow-up". Established policies and procedures to be used where follow-up is necessary when responding to reports issued by the OIG, other executive branch audit organizations, the General Accounting Office (GAO), and non-Federal auditors.

F. DHHS General Administration Manual, Chapter 8-30, "Conflict Resolution Mechanism for Inspector General Report". Devised by DHHS' Assistant Secretary for Management and Budget to resolve differences concerning non-concurred recommendation(s) in a final report between an Operating Division, such as Food and Drug Administration (FDA), and the OIG (See Attachment B)

5. RESPONSIBILITIES

A. Office of Inspector General

Notifies FDA through the Senior Associate Commissioner for Management and Systems of the start of audits or inspections in agency programs or operations. Conducts reviews of FDA programmatic and financial activities. Conducts follow-up reviews to determine if FDA's implementation of corrective action was effective. Analyzes and responds to comments made by FDA on draft reports and prepares final reports.

B. Food and Drug Administration

1. Commissioner of Food and Drugs

Approves comments of a controversial or highly sensitive nature. Provides direction on contested recommendation(s) that may undergo conflict resolution.

2. Senior Associate Commissioner for Management and Systems

Serves as the Agency's audit follow-up official and approves FDA comments of a non-controversial nature. Refers comments of a controversial or highly sensitive nature to the Commissioner of Food and Drugs. Advises the Commissioner and his staff on audit/inspection issues. Approves follow-up report of corrective actions implemented by centers/offices in response to audit/inspection recommendations.

3. Division of Management and Policy (DMP)

Schedules meetings between FDA Centers and Offices and the personnel conducting audits or inspections. Prepares final comments on audit and inspection reports for FDA Centers and Offices. Prepares FDA position and briefs appropriate senior FDA management on non-concurred recommendations. Assists FDA Centers and Offices in preparing semi-annual status reports on planned corrective actions and briefing appropriate senior FDA management on the results.

4. FDA Centers, Office of Regulatory Affairs, Office of the Commissioner Staff Offices

Designates a contact who is responsible for acting as the component's liaison with DMP. Responsibilities include: (a) scheduling meetings with staff during audits or inspections, (b) coordinating responses to audit and inspection reports, and corrective action plans, (c) coordinates responses for briefing the Commissioner on non-concurred recommendation, (d) coordinates with DMP in the preparation of agency response based on Commissioner's direction.

6. PROCEDURES

A. Entrance Conference and Exit Conference Coordination

DMP schedules entrance or exit conferences upon notification of a new or closing audit/inspection. For exit conferences, the OIG may provide a working draft report prior to the meeting for review and comment. The working draft may include tentative findings and recommendations.

B. Review Procedure

Following the entrance conference, the OIG, or its representative, may contact and meet with anyone and follow any leads until their work is completed.

1. Following each substantive and significant contact with a representative during the course of an audit/inspection, FDA employees must document the content of the exchange and any transmittal of materials. Contacts with no substantive exchange (e.g., incorrect referrals to an individual who knows nothing about the subject matter) need not be documented.

2. A memorandum for the record (MFR) describing the matter discussed and documents conveyed will be prepared and provided to the appropriate Center/Office liaison. A copy of any such memoranda will be given to DMP.

   Memoranda of meetings and telephone calls should include:

   - ❖ Names of staff involved,
   - ❖ subjects discussed,
   - ❖ decisions and conclusions reached, and
   - ❖ any requests for information or documents.

C. Reporting Procedures

1. Draft Comments

DMP will transmit a copy of the draft report to the appropriate centers/offices with a request for comments. OIG provides FDA forty-five calendar days to respond beginning with the date on its report transmittal memorandum. Comments may include:

general comments - *address overall tone of the report or concerns about findings;*

technical comments - *address factual errors; and*

comments on the recommendations - *address the FDA's position on the recommendation, how it intends to implement corrective actions, or provide its rationale for disagreeing with it.*

2. Commenting on Draft Reports

Comments on the recommendations are reviewed and analyzed by DMP to determine responsiveness.

In particular, the lead Center/Office's liaison ensures:

(1) If there is agreement, whether the comments describe in general terms how the office intends to implement the recommendation;

(2) If there is partial agreement, whether the comments provide sufficient detail to support its position.

(3) If there is disagreement, whether the comments adequately describe the rationale for not agreeing. They should include whether or not the disagreement is based on interpretation of law, regulation, or the authority to or not take the action recommended.

DMP develops Agency comments to OIG's recommendations from Center/Office's comments. This draft is given to each appropriate office for review and concurrence. Necessary changes are made to obtain concurrence. Final Agency comments are sent to OIG's audit/inspection Office.

3. Preparation of Agency Comments

After receiving requested comments from liaisons of the appropriate Centers/Offices, DMP will draft the Agency response.

To draft a response which accurately and fairly reflects the Agency's position, DMP may seek clarification from an appropriate office, work to negotiate consensus from conflicting Agency responses, seek legal counsel on interpretation of FDA law or regulation, or seek support from the Office of Policy on a requested new policy or regulation.

If an extension is requested, DMP will work with Center/Office liaisons to determine the amount of time needed.

4. Disputed Agency Response

DMP, in coordination with the appropriate officials develops the Agency position for recommendations from FDA components having different positions. If necessary, DMP will elevate the matter to the

appropriate Senior Associate Commissioner for resolution.

5. Commenting on Final Reports

a. Comments are obtained within 20 working days from those offices which will be implementing the audit/inspection recommendations.

b. The format used consists of general comments and status of actions taken or planned regarding on the recommendations.

c. The final comments are sent to the Senior Associate Commissioner for Management and Systems or higher for approval. The signed comments are then sent to the appropriate OIG audit/inspection office.

d. If there is a position of non-concurrence for a recommendation as stated in the draft report, a conflict resolution process will be started.

6. Conflict Resolution

When a position of non-concurrence for a recommendation exists, DMP will initiate a conflict resolution briefing to the Commissioner or designee.

a. The appropriate Agency contact coordinates and prepares briefings to the Commissioner or other designated official.

b. The Commissioner or designated official will be briefed on the recommendation, its position of non-concurrence, and available alternatives.

c. After the briefing, an appropriate Agency official will assist DMP in formulating the Agency's position regarding contested recommendation.

D. Corrective Action Plans

After FDA submits comments to OIG final reports, DMP will request a plan of corrective action for each recommendation FDA agreed to implement.

1. A report of corrective actions will be provided to DMP from the Centers/Offices having responsibility over the particular recommendation. This report will contain two parts:

a. *Completed Actions* - Center/Office reports completed action on a particular recommendation.

b. *Corrective Action Plan* - a time-phased action plan with discernable milestones (describing one organization, one action step, one estimated completion date, and a status section).

2. DMP will send a consolidated report to the appropriate audit/inspection office.

E. Program Management and Analysis

Not later than July 31 of each year, the Centers/Offices will provide DMP with a report showing an analysis of audit recommendations, resolutions, and corrective actions for their respective office to determine trends, identify system-wide problems, and recommend solutions.