

**FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM
DIRECTIVES**

BUSINESS PRACTICES AND AGREEMENTS

**ENHANCED COMMUNICATIONS WITH THE OFFICE OF CRIMINAL
INVESTIGATIONS (OCI) AND IMPROVED ALIGNMENT OF
CRIMINAL/REGULATORY PRIORITIES AND ACTIVITIES**

Effective Date: 08/20/2010

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1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to provide general procedures for the establishment of regularly scheduled senior level and staff level meetings between the Centers and OCI, Office of Regulatory Affairs (ORA) Headquarter (HQ)/District Offices and OCI, and other Food and Drug Administration (FDA) components and OCI. These meetings are expected to result in enhanced communications and improved alignment of criminal/regulatory priorities and activities.

2. POLICY

- A. OCI is committed to keeping the Centers and other FDA components up to date regarding emerging trends and criminal activities that could impact their regulatory decision-making. Likewise, the Centers, ORA District and HQ Offices, and other FDA components are committed to keeping OCI apprised of regulatory activities that could impact OCI.
- B. The Centers and OCI have a responsibility to keep each other informed of their respective initiatives and priorities which OCI investigates.
- C. OCI has a responsibility to provide regular updates to the Centers and District Offices about those investigations/criminal cases in which the Centers and District Offices have a significant interest.

3. RESPONSIBILITIES AND PROCEDURES

A. Information Sharing at Senior Levels

1. At the outset of each fiscal year, a joint meeting will be held that includes the Associate Commissioner for Regulatory Affairs (ACRA), Director of OCI and Center Directors, or their respective designees. Topics for discussion include but are not limited to the establishment of Agency-wide regulatory and criminal enforcement priorities and the alignment of criminal cases with other regulatory options in achieving the Agency's mission.
2. Following the yearly joint meeting described above, each Center Director, and the Director of OCI, or their respective designees, will also meet on additional occasions within the same fiscal year in a mutually agreed upon forum. Relevant staff members will also be invited to participate.
 - a. Topics for discussion include, but are not limited to, Center-specific regulatory and OCI criminal enforcement priorities, areas of mutual interest, status of criminal referrals forwarded to OCI from the respective Center, status of the regulatory referrals forwarded from OCI to the respective Center, and emerging trends that could impact either regulatory or criminal resources.
 - b. The ACRA will participate in these meetings.
3. The Office of the ACRA Affairs will bear the responsibility for setting up these meetings and will work with the appropriate Center Points of Contact (POC) and OCI HQ to establish an agenda, formalize meeting logistics, etc. The Center POC is the individual responsible for the day to day contact with the OCI Senior Operations Managers SOMs.
4. Each Center Director, the Director of OCI, or their designee, will share the outcomes of these meetings with relevant staff.

B. Information-Sharing at Staff Levels

1. At mutually established frequencies, and in addition to routine discussions:
 - a. The OCI SOMs and their respective Center POCs will meet to discuss areas of mutual interest/concern; the status of referrals, updates regarding criminal cases, etc.
 - b. District Office Managers and their respective OCI Field POCs will meet to discuss areas of mutual interest/concern; the status of referrals, updates regarding criminal cases, etc.

2. Staff Members should inform their chain of command when these meetings occur and keep them apprised of the outcomes of these discussions.

C. Other FDA components

Any other FDA component can request a meeting with OCI to discuss areas of mutual interest/concern, potential criminal activity, etc. at any time by contacting OCI HQ.

4. REFERENCES

This Staff Manual Guide complements SMG 9111, the "Standard Operating Procedure for the Sharing of Information Related to Criminal Violations."

5. EFFECTIVE DATE

The SMG is effective on August 20, 2010, except that the first joint meeting with the ACRA, OCI Director and Center Directors will commence at the beginning of FY 2011.

6. Document History - SMG 9110, "Enhanced Communications with the Office of Criminal Investigations (OCI) and Improved Alignment of Criminal/Regulatory Priorities and Activities"

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/20/2010	N/a	ORA/OCI HQ	John Taylor, Counselor to the Commissioner