SMG 9111

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

BUSINESS PRACTICES AND AGREEMENTS

SHARING OF INFORMATION RELATED TO CRIMINAL VIOLATIONS

Effective Date: 08/20/2010

1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to foster effective communication for the sharing of information between the Office of Criminal Investigations (OCI) and other Food and Drug Administration (FDA) components. The information set forth in this document does not replace previous procedures set forth in the Regulatory Procedures Manual (RPM) or the Investigations Operations Manual (IOM), but is intended to supplement those policies. This SMG is not meant to restrict communications, but to facilitate information-sharing, and the timely processing of criminal referrals and to provide an established mechanism for OCI to provide updates regarding criminal cases.

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.

C. OCI has a responsibility to provide regular updates to the Centers and ORA District Offices about those investigations/criminal cases in which the Centers and District Offices have a significant interest.

3. RESPONSIBILITIES/CONTACTS

It is crucial that FDA components inform OCI about all potential criminal activity involving FDA regulated products. Potential criminal activity includes, but is not limited to, any reasonable suspicion of fraud, false statements, counterfeit products, or incidences of tampering, as well as any matters that meet criteria developed between OCI and other components in strategic discussions. When there is a question as to whether it is appropriate to refer a matter to OCI, it is recommended to err on the side of caution, discuss the matter with OCI, and reach agreement on the best course of action. In general:

1. Designated points of contact (POC) from each of the Centers will be responsible for informing their respective OCI Headquarters (HQ) Senior Operations Manager (SOM) of potential criminal violations. If there is a question as to which SOM is covering the respective Center, please call OCI HQ at 240-276-9500 and you will be directed to the appropriate personnel.

2. The SOM will be the primary point of contact between OCI and the Centers. The SOM can assist the Centers with the identification of suspected criminal activity and the referral of criminal cases to field agents. The SOMs will also work with their Center counterparts to keep them apprised of developments in cases in which the Centers have a specified interest.

3. District Office managers and OCI Field Offices will establish and maintain working relationships in order to facilitate effective communications on matters concerning FDA regulated products.

4. ORA and FDA HQ Offices will inform their respective OCI SOM of cases identified as having a potential criminal violation.

4. AGENCY-WIDE PROCEDURES

Any notifications between relevant parties will take place immediately if there is an imminent threat to public health and within 10 business days in all other cases.

1. Center Referrals to OCI:

   Upon determination by a Center that there might be a potential criminal violation, the Center POC will contact the respective OCI SOM via telephone to discuss the issue. If there is sufficient information for possibly opening a criminal case, the SOM will send the referral to the appropriate OCI Field Office for further investigation. After the initial referral, the SOM, Center personnel and OCI field agents are encouraged to keep each other apprised of relevant information as the case progresses. To avoid jeopardizing a criminal case, agents are cautioned against releasing law enforcement sensitive information although in certain cases, information gathered in criminal investigations may be shared, considered, and used for regulatory purposes. If

an individual from the Center feels he/she is not getting necessary information related to a criminal case, the individual shall bring the matter to the attention of the SOM.

2. District Office Referrals to OCI:

When a potential criminal matter is identified by an ORA District Office, the RPM states it must be brought to the attention of the local OCI Field Office. District Management, i.e., the District Director (DD), Director of Compliance Branch (DCB), Director of Investigations Branch (DIB) or Director of Import Operations Branch (DIOB) will serve as the principal point of contact for all initial OCI interaction. District management should relay the information via telephone to the local Special Agent in Charge (SAIC), Assistant Special Agent in Charge (ASAIC) or Resident Agent in Charge (RAIC).

District and OCI personnel should maintain effective communications on all matters related to FDA regulated products. OCI will be responsible for evaluating the information within 10 business days and notifying the District Office of its initial assessment. Both parties will discuss appropriate next steps.

When the local OCI Field Office informs ORA District Management of its decision, District Management will notify the relevant Director of the Office of Compliance or designee in the respective Center (a) if OCI is pursuing a criminal case or (b) if the local District Office will be pursuing a case. If OCI declines pursuing a criminal case, the District Office can proceed with the criminal case in accordance with the procedures in Chapter 6 of the RPM.

Nothing in this procedure precludes the pursuit of parallel civil, administrative and/or criminal enforcement action, if appropriate. When the public health is at stake, and both regulatory and criminal enforcement action is indicated, precedence should be placed on whichever remedy achieves effective action most expeditiously to mitigate any harm to the public. All parties are encouraged to maintain effective communications and to establish regular, mutually agreed upon timeframes to provide periodic updates regarding the case.

The procedure for the handling of referrals to OCI for parcels intercepted at International Mail Facilities is attached in Appendix I.

3. ORA and FDA HQ Referrals to OCI:

Upon receipt of information that may indicate potential criminal activity, the respective ORA or FDA HQ POC will contact their respective SOM to discuss the issue. If there is sufficient information for possibly opening a criminal case, the SOM will send the referral to the OCI Field Office for further investigation. After the initial referral from the OCI SOM, the

appropriate personnel and OCI field agents are encouraged to keep each other apprised of case progress through the use of the assigned case numbers. To avoid jeopardizing a criminal case, agents are cautioned against releasing law enforcement sensitive information although in certain cases, information gathered in criminal investigations may be shared, considered, and used for regulatory purposes. If individuals feel they are not getting necessary information related to a criminal case, it is requested that this matter be brought to the attention of the SOM.

4. OCI Communication with FDA counterparts:

OCI will keep the Centers, ORA District Offices, and HQ personnel up to date on any emerging trends or activities that could affect regulatory decision making via regular communication between the respective SOMs and their counterparts. As requested, the respective SOMs or OCI field agents will keep their Center and ORA District Office counterparts informed of significant case developments. If evidence is developed during a criminal investigation that could be beneficial in a civil or administrative action or an investigation of a regulatory issue currently being conducted by the Agency, agents will communicate with their counterparts and provide the information in a timely manner. Additionally, OCI may encounter evidence that reveals a potential or ongoing public health risk that may be addressed in an administrative or civil proceeding. If OCI encounters such evidence, including, for example, a medical or product safety issue, a question of data integrity in a manufacturing or clinical investigation, or other evidence that a product may present a public health risk, OCI will provide all information that is not subject to legal confidentiality rules to the Director of the Office of Compliance in the appropriate product Center or the appropriate ORA District Director. Any information received by OCI from Federal, state or local law enforcement sources that could affect or assist in a regulatory or administrative action by the Agency will be forwarded to the appropriate people in a timely manner.

All components are encouraged to meet on a regular basis with their OCI counterparts to discuss relevant issues as described in SMG 9110.1, "Enhanced Communications with the Office of Criminal Investigations & Improved Alignment of Criminal/Regulatory Priorities and Activities". If at any point during a criminal case there is the need for technical expertise or support, OCI will communicate with the appropriate POC.

OCI will keep the Centers, ORA District Offices, and HQ personnel up to date on any emerging trends or activities that could affect regulatory decision making via constant communication between the respective SOMs and their counterparts. As requested, the respective SOMs or OCI field agents will keep their counterparts informed of significant case developments. All components are encouraged to meet on a regular basis with their OCI counterparts to discuss relevant issues as described in SMG 9110.1,

"Enhanced Communications with the Office of Criminal Investigations & Improved Alignment of Criminal/Regulatory Priorities and Activities". If at any point during a criminal case, there is the need for technical expertise or support, OCI will communicate with the appropriate ORA/Center POCs.

5. SCOPE

The SMG will address referrals from the Centers and ORA District Offices to OCI when potential criminal activity is identified. This SMG will also address the bi-lateral sharing of information between OCI and other FDA components that could affect the criminal or regulatory decision making process.

6. REFERENCES

A. The Regulatory Procedures Manual (RPM), Chapter 6, Section 6-5-2, states that "The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings."

B. The IOM, Chapter 8, Subchapter 8.9.1 states "The Office of Criminal Investigations (OCI) has the primary responsibility for all criminal investigations conducted by the FDA, including suspected tampering incidents and suspected counterfeit products. Similarly, OCI has primary responsibility and is the primary point of contact for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA regulated products."

C. This SMG complements SMG 9110, "Enhanced Communications with the Office of Criminal Investigations & Improved Alignment of Criminal/Regulatory Priorities and Activities".

7. EFFECTIVE DATE

The SMG is effective on August 20, 2010.

8. Document History – SMG 9111, Sharing of Information Related to Criminal Violations

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