

Attachment A - Guidelines for Follow-up of Tampering

I. Introduction

The Federal Anti-Tampering Act (FATA) passed by Congress in 1983 makes it a Federal crime to tamper with certain consumer products and to commit certain other related acts. The Act provides specific statutory authority to the FDA to investigate tampering and alleged tampering of products that the agency regulates. There are five violations of the FATA:

- (a) Tampering, or attempted tampering, with a consumer product with reckless disregard for the risk of death or bodily injury.
- (b) Tainting a consumer product with intent to cause serious injury to the business of any person.
- (c) Knowingly communicating false information that a consumer product has been tainted.
- (d) Knowingly threatening to tamper with a consumer product.
- (e) Conspiracy to tamper with a consumer product.

A more detailed discussion of these violations can be found in the FATA (Title 18, United States Code, Section 1365).

II. Guidelines

1. The FDA Emergency Operations Center (EOC), 866-300-4374 (HFA-615), must be promptly alerted to all tampering/threat incidents. This is in addition to the prompt reporting of incidents outlined in the *Emergency Procedures* section of the RPM, Chapter 8.
2. District offices should immediately notify the appropriate Office of Criminal Investigations (OCI) Field office upon receiving information concerning a tampering/threat incident. This notification will enable the OCI Field office and the District office to coordinate operations.
3. OCI Field offices have primary responsibility for liaison with law-enforcement agencies (i.e., FBI, state police, sheriff departments, and local police). In certain situations, OCI may request the District offices to maintain contact with and offer assistance to cooperating officials who investigate tampering incidents (i.e., FBI, USDA, state and local police, health department, coroner, and medical examiners).
 - (a) The FBI expressed an interest in being notified in all tampering investigations involving extortion, serious injury or death, terrorism, and significant false reports. In all but critical circumstances such notifications will be done through the OCI Field office. In some situations the District office may be asked by OCI to notify the FBI.
 - (b) All requests for assistance from other law-enforcement agencies, including status briefings and notifications, regarding criminal investigations must be coordinated through OCI Field office.
 - (c) Complaints/reports concerning products subject to USDA regulations should be immediately referred to their local contact of USDA for their follow-up. The District office should promptly notify the OCI Field office and EOC of all such referrals.
4. When an alleged or suspected tampering incident is reported to FDA, the Agency must attempt to determine whether tampering has actually occurred or whether some other

problem such as a manufacturing or distribution defect is involved. EOC and the centers are available to offer expert advice on possible manufacturing defects. The manufacturer can also provide information on defects. In addition, we should seek to determine where the tampering occurred (e.g., in the retail store, at the manufacturing site, etc.)

5. The OCI Field office will have primary responsibility for all criminal investigations of tampering/threats incidents. In those incidents where OCI does not or cannot initiate a criminal investigation because of resource limitations, the District offices must continue the investigation. District offices must closely coordinate their efforts with OCI Field offices. In these special situations the District office must keep the EOC and OCI Field office advised of their progress. Any referrals to law-enforcement agencies, other than OCI, may be made only after obtaining the concurrence of OCI Field office. The OCI Headquarters will provide details on tampering cases investigated by the OCI Field office to EOC for forwarding to the proper centers for their information and any action they may have to take.
6. The Office of Chief Counsel/FDA (OCC) should be notified as soon as an FDA component determines that a case will be referred to a United States attorney in the following circumstances:
 - (a) Where there is a conspiracy.
 - (b) When an FDA regulated entity is included as a defendant.
 - (c) When Title 21 charges are contemplated.

In the absence of one of these three circumstances OCC need not be notified prior to referral to a United States attorney; however, OCC should be sent a copy of the charging document that is filed with the court.