
Manual of Standard Operating Procedures and Policies

Regulatory - Compliance

Procedures for Responding to a Counterfeit Product Event

SOPP 8507

Version #1

Date: March 9, 2004

1. Purpose

This SOPP describes the process that the Center for Biologics Evaluation and Research (CBER) follows in the agency's overall efforts to contain a potential counterfeit product event. Efforts are directed at preventing the further distribution of the potential counterfeit product, and protecting the public health by providing notice of the potential counterfeiting. This procedure provides the framework for more efficient communication within the Center and between appropriate FDA staff and those participants outside the agency.

2. Definitions

Counterfeit Drug Product

Federal law [21 USC 321(g)(2)] defines a counterfeit drug product as a drug sold under a product name, without proper authorization, that is represented, labeled, or packaged in a manner that suggests it is an authentic approved product. Counterfeit products may include products without active ingredient (contain only inactive ingredients), products with incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, insufficient quantity of active ingredient, the wrong active ingredient, or products that are contaminated.

3. Background

Over the last several years, there have been a number of incidents of counterfeit biological drug products. Counterfeit drugs pose significant public health and safety concerns. As a result, patients may be put at risk of serious adverse health consequences. CBER may receive reports of counterfeit products through various sources (e.g., physicians, healthcare providers, manufacturers, distributors, wholesalers, consumers, FDA personnel, and other governmental organizations). The Office of Compliance and Biologics Quality (OCBQ) coordinates the response to these counterfeit product events for CBER. The communications response to an event includes interaction within and outside CBER. FDA continues to believe that the quality of products in this country is high, and that the public can continue to have confidence that the products sold in the U.S. market are authentic. The Agency, however, takes very seriously any allegations or information regarding the counterfeiting of products. As the manufacturing and distribution system has become more global in nature, protecting against counterfeit products has become more challenging.

4. Policy

Upon receipt of a report of potential counterfeiting, CBER, through its OCBQ, forms an ad hoc internal response team that includes representatives from OCBQ; Office of Communication, Training and Manufacturers Assistance (OCTMA); Office of Regulatory Affairs (ORA), including the Office of Criminal Investigations (OCI), Office of Enforcement (OE), and district office(s) and laboratories; the appropriate CBER product Office, Office of Biostatistics and Epidemiology (OBE) and others, as needed, to develop an immediate action plan.

This SOPP will be followed by all assigned parties and encompasses all CBER regulated products.

5. Responsibilities

OCBQ

- Serves as the focal point within CBER to respond to a potential counterfeit event. For more information on this SOPP, contact the Assistant to the Director for Policy in the Office of Compliance and Biologics Quality (OCBQ) on 301-827-6197.
- Communicates with the manufacturer regarding the event to obtain relevant information.
- Assesses the public health aspects, in close collaboration with the appropriate product office.
- Coordinates with ORA (OCI, OE and district offices and laboratories) to investigate the report.
- Reviews the counterfeiting information provided to CBER.
- Organizes reports and tracks information, including the firm's review of its adverse experience/event information.
- Coordinates the interpretation of the data with the ad hoc response team focal points.
- Provides guidance to manufacturer on regulatory submissions that may be needed to support implementation of changes to packaging systems to introduce anti-counterfeiting or tamper-evident measures.
- Notifies the appropriate FDA contacts, including the Emergency Operations Center (EOC), as necessary.

ORA (Including OCI)

- Directs and implements all field activities relating to counterfeit products in consultation with OCBQ.
- Coordinates efforts for accurate testing of the potential counterfeit product with the appropriate FDA laboratory (e.g. National Forensic Chemistry Center (FCC) and Winchester Engineering and Analytical Center (WEAC)), CBER OCBQ, and the product manufacturer.
- Collects and retains samples of potentially counterfeit product.
- Office of Criminal Investigations (OCI) directs criminal investigation activities for counterfeit products in coordination with other agency components and with other Federal, State, and local law enforcement. Works with and keeps OCBQ fully apprised of ongoing counterfeit investigation efforts and results.

National Forensic Chemistry Center (FCC), Winchester Engineering and Analytic Center (WEAC), and other ORA analytical laboratories

With input from CBER and the product manufacturer, identifies and performs appropriate testing to establish content of potential counterfeit product.

OCBQ/OCTMA/FDA Press Office

- Coordinates with manufacturers to post on CBER's website the manufacturers notices to the medical community, distributors, wholesalers, and the public with a link to the manufacturers' web site. CBER expects manufacturers to cooperate with the agency in efforts to notify healthcare providers, patients, wholesalers, distributors, and other public health officials.
- Develops a Question & Answer (Q&A) or other document, as appropriate, for consumers, for handling calls and/or for posting on CBER's website and/or FDA's website.

OCTMA

- Obtains relevant information in consultation with OCBQ and articulates the Center's public information.
- Receives and responds to incoming calls from consumers, healthcare providers, and others.
- Distributes incoming, relevant information to appropriate ad hoc response team focal points.
- Coordinates with the manufacturer to issue website information and other important public health notifications.

Product Office

Provides to OCBQ an assessment of health hazard and patient specific concerns that may be associated with the potentially counterfeit product.

OBE

Reviews adverse event reports for the potential counterfeit product and provides this information to the product offices and OCBQ.

Product Manufacturer

- It is expected that the manufacturer will routinely cooperate with FDA to promptly notify healthcare providers, patients, wholesalers, distributors and other public health officials, and to retrieve and retain potentially counterfeit product in distribution.
- OCBQ assists the manufacturer in developing these communications about a potential counterfeit product event.

6. Procedures

1. After receiving information about a potential counterfeit product event, the CBER contact communicates the information to the Director, OCBQ. OCBQ serves as the focal point within CBER to coordinate the response and immediately schedules an internal meeting with the Director and Deputy Director, OCBQ; the Director, Division of Case Management; and the Assistant to the Director for Policy, OCBQ, to discuss the available information.
 - a. During or immediately following this initial meeting, appropriate units within and outside the Center are notified via phone and/or electronic mail (e.g., product manufacturer, product Office, OBE, OCTMA, ORA, OCI, OC (EOC)).
 - b. OCBQ assembles the ad hoc internal response team.
2. OCBQ takes the lead, together with the ad hoc internal response team, in developing an immediate action plan for a potential counterfeit product event.

3. OCBQ communicates with the manufacturer regarding the event, as appropriate, to obtain information about the potential counterfeiting incident, the legitimate product that may have been counterfeited, complaints and adverse events reported for the subject product, and notice to the medical community, wholesalers, distributors, and consumers. Other members of the ad hoc internal response team may participate in communications with the manufacturer as appropriate.
4. OCBQ, OCTMA, and the press office coordinate with manufacturers to post on CBER's website the manufacturer's notice to the medical community, distributors, wholesalers, and the public. OCTMA develops a Question & Answer (Q&A) or other document, as appropriate, for consumers, for posting on CBER's website and/or FDA's website.
5. OCBQ consults with the manufacturer and the product office about the appropriate tests to assess the integrity and identity of the counterfeit product, and to discuss public health and safety issues relevant to the follow-up investigation. OCBQ communicates this information to OCI, the District Office(s) and/or the appropriate laboratory, as needed.
6. OCBQ analyzes information provided to CBER by consumers, and others, in conjunction with appropriate ad hoc response team focal points and:
 - a. Organizes reports and tracks information related to the counterfeit product provided to the agency, including the firm's adverse experience/event information, if appropriate;
 - b. Coordinates the interpretation of the data with the ad hoc response team focal points; and
 - c. Updates senior CBER management (Center Director, Deputy Center Directors, Associate Center Directors, or Office Directors), as necessary, on the progress of the investigation.

7. Effective Date

March 9, 2004

8. History

| Comment / Revision | Approved By | Approval Date | Version Number | Comment |
|---------------------------|-----------------------|----------------------|-----------------------|----------------|
| CBER OCBQ | Robert Yetter, PhD | 3/9/2004 | 1 | Original |

Updated: March 16, 2004