**SMG 2180.2**

**FDA Staff Manual Guides, Volume III – General Administration**

**Consumer Affairs**

# Review of Complaints to FDA Sourced from Whistleblowers and Confidential Sources

Effective Date: 05/03/2024



## 1. Purpose

FDA is committed to protecting the public health, including through its processes of intake and evaluation of information regarding the safety and effectiveness of FDA-regulated products. To that end, this Staff Manual Guide (SMG) outlines an agency-wide policy for initial review of complaints from industry whistleblowers and confidential sources, as defined below.

## 2. Policy

A. All Centers, Offices, and groups that investigate or decide on follow-up actions related to complaints (CDER, CBER, CTP, CFSAN, CVM, CDRH, Human Foods Program, as well as the Office of Regulatory Affairs and its suboffices) will, within a maximum of twenty-one (21) business days of initial FDA receipt, gather available information pertaining to complaints sourced from whistleblowers and confidential sources and will review the information with designated Center/Office management/authorized staff to enable management/authorized staff to determine whether follow-up action is necessary. Management/authorized staff will then have three (3) business days to determine next steps.

B. All Offices or groups that receive complaints but are not the appropriate investigative/deciding Office (inclusive of OC groups and Centers/Offices receiving incorrectly routed complaints), will forward such complaints to the appropriate investigative/deciding office within two (2) business days of receipt.

Any necessary exceptions to this 2-day forwarding time frame (e.g., for complaints received by mail) will not be read to extend the overall maximum 21-plus-3-day time frame for initial decision-making on whistleblower and confidential-source complaints.

C. The below-specified definition of "whistleblower" is for purposes of this policy and related internal policies of FDA Centers and Offices. The definition is not intended to limit or broaden the rights of whistleblowers under applicable laws or policies of private or governmental entities.

## 3. Definitions

**Whistleblower**: An individual who discloses information regarding an FDA-regulated entity/product that the individual acquired during their current or former employment with such an entity, alleging potential violation(s) of federal law, or an illicit or unsafe product or activity.

**Confidential Source**: An individual who provides non-public information about an FDA-regulated entity/product, alleging potential violation(s) of federal law, or an illicit or unsafe product or activity, and who requests anonymity.

## 4. Responsibilities

The following FDA officials are responsible for implementing this policy and procedures:

- Director, Center for Biologics Evaluation and Research
- Director, Center for Drug Evaluation and Research
- Director, Center for Food Safety and Applied Nutrition
- Director, Center for Devices and Radiological Health
- Director, Center for Tobacco Products
- Director, Center for Veterinary Medicine
- Associate Commissioner for Regulatory Affairs
- Deputy Commissioner for Human Foods
- Director, Office of Food Policy and Response
- Deputy Commissioner and Chief Operating Officer, Office of Operations
- Director, Office of the Executive Secretariat
- Chief Information Officer, Office of Digital Transformation

- Chief Scientist, Office of the Chief Scientist
- Chief Counsel, Office of the Chief Counsel
- Chief Medical Officer
- Associate Commissioner, Office of External Affairs
- Deputy Commissioner, Office of Policy, Legislation, and International Affairs
- Director, Oncology Center of Excellence
- Associate Commissioner, Office of Women's Health
- Associate Commissioner, Office of Minority Health and Health Equity

## 5. Procedures

All Centers and the above-listed Offices will implement and follow the general requirements and procedures set forth in this policy through issuance of written standard operating procedures (SOPs). Any necessary exceptions to the procedures set forth in this policy, and the reasons for such exceptions, will be included in the SOPs.

Within the maximum 21-plus-3-day time frame, Centers/Offices retain the flexibility to address whistleblower or confidential-source complaints as appropriate, based on the circumstances of each complaint.

## 6. Effective Date

The guide is effective 05/03/2024.

## 7. Document History - SMG 2180.2, "Review of Complaints to FDA Sourced from Whistleblowers and Confidential Sources"

| Status (I, R, C) | Date Approved | Location of Change History | Contact | Approving Official |
|---|---|---|---|---|
| Initial | 05/03/2024 | N/A | OC | Dr. Namandje Bumpus, Principal Deputy Commissioner |