SMG 2180.2

FDA Staff Manual Guides, Volume III – General Administration

Consumer Affairs

Review of High Risk/High Priority Voluntary Complaints Received by FDA

Effective Date: 01/08/2025

1. Purpose

FDA is committed to protecting public health, including promptly detecting and responding to signals of potential issues with the safety and effectiveness of FDA-regulated products. To that end, this Staff Manual Guide (SMG) outlines an Agency-wide policy for timeliness in the handling of voluntary high risk/high priority complaints received from sources outside of FDA.

2. Policy

A. Specific FDA Centers/Programs/Offices are responsible for the intake, evaluation, and closure of complaints. These are organized by product type and comprise the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Human Foods Program (HFP), Center for Tobacco Products (CTP), Center for Veterinary Medicine (CVM), and Office of the Chief Scientist (OCS) (hereafter called “evaluating groups”).

B. All FDA components[1] or individuals that receive complaints directly from a submitter and are not the appropriate recipient in the evaluating group will forward such complaints to the relevant evaluating group within two (2) business days of FDA receipt[2] using the Internal Agency forwarding model.

[1] Hereby defined as Centers, Programs, Super Offices, Offices, Divisions, Branches, Staffs, Teams, or other groups within FDA.

[2] Limited exceptions to this two-day forwarding time frame will be approved by the Inspections Oversight Board leadership and will not be read to extend the overall maximum timeframes outlined in this document.

C. Evaluating groups will determine whether a complaint meets the definition of high risk/high priority, and, if so, these complaints will be processed following an accelerated timeline, including, but not limited to, the below actions[3]:

1. **Initial Evaluation and Follow-up Activity Determination:** Within a maximum of twenty-four (24) business days from FDA receipt[4], the evaluating group will perform an initial evaluation and have designated management/authorized staff determine which, if any, follow-up activities are necessary, including if Office of Inspections and Investigations (OII) field follow-up activities are necessary.
2. **Field Activity Referral/Assignment Timeline:** If a high risk complaint requires acute field follow-up activities, the evaluating group will refer/assign these activities to OII within a maximum of 5 business days from the above follow-up activity determination.
3. **Field Activity Initiation and Execution Timeline:** When an evaluating group refers a high risk complaint for acute field follow up activities, OII will initiate these activities within 14 business days of referral/assignment receipt, and complete them on a timeline mutually agreed upon between the evaluating group and OII.

3. Definitions

The definitions for the terms below specified are for purposes of this policy and related internal policies of FDA Centers/Offices/Programs. All Centers/Offices/Programs will utilize process-related terms contained in the Agency complaints terminology guide.

Term	Definition
Complaint	Any voluntary submission to FDA alleging potential violation(s) of federal law, or an illicit or unsafe product or activity.
Life Threatening Injury/Illness	Injury or illness that requires hospitalization and/or life-saving medical intervention.
High Risk/High Priority Complaint	A Whistleblower/Confidential Source complaint, a complaint reporting a life-threatening injury/illness or death, or a complaint that requires prioritized follow-up determined by the evaluating group.

[3] Within the prescribed time frames, evaluating groups retain the flexibility to address high risk/high priority complaints as appropriate, based on the circumstances of each complaint.
[4] Limited exceptions to this 24-day evaluation period for specific situations or categories of complaints will be approved by the Inspections Oversight Board leadership.

Term	Definition
Whistleblower[5]	An individual who discloses information regarding an FDA-regulated entity/product that the individual acquired during their current or former employment with such an FDA-regulated 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 Devices and Radiological Health
- Director, Center for Drug Evaluation and Research
- Director, Center for Tobacco Products
- Director, Center for Veterinary Medicine
- Deputy Commissioner, Human Foods Program
- Chief Information Officer, Office of Digital Transformation
- Associate Commissioner, Office of External Affairs
- Associate Commissioner, Office of Inspections and Investigations
- Associate Commissioner, Office of Minority Health and Health Equity
- Deputy Commissioner and Chief Operating Officer, Office of Operations
- Deputy Commissioner, Office of Policy, Legislation, and International Affairs
- Chief Counsel, Office of the Chief Counsel
- Chief Medical Officer, Office of the Chief Medical Officer
- Chief Scientist, Office of the Chief Scientist
- Director, Office of the Executive Secretariat
- Associate Commissioner, Office of Women's Health
- Director, Oncology Center of Excellence

5. Procedures

All evaluating groups and the above-listed FDA components will implement and follow the general requirements and procedures set forth in this policy through

[5] The definitions are not intended to limit or broaden the rights of whistleblowers under applicable laws or policies of private or governmental entities.

issuance or revision of written standard operating procedures (SOPs) for high risk/high priority complaints by no later than June 30, 2025.

6. Effective Date

The guide is effective January 8, 2025.

7. Document History - SMG 2180.2, "Review of High Risk/High Priority Voluntary Complaints Received by FDA"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
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