July 2025

Unified Intake Tool

Food & Drug Administration Service Blueprint

- UAT Federalist
- Safety Reporting Tool (SRP)
- MedWatch
- Vaccine Adverse Event Reporting System (VAERS)

Overview

The Food & Drug Administration currently receives over 250,000 product complaints and inquires per year. Complaints are received via MedWatch Online, Safety Reporting Portal (SRP), Email, Mail or Fax. These complaints can result in important actions including product recalls, warning letters, and license suspensions and other enforcement actions. Complaints are a critical source of data for the FDA oversight functionality in ensuring consumer safety.

Users and Scenarios

Streamline the complaint and inquiry process for public external users, as well as simplifying the communication of data to the Centers.

Goal

Provide a central public-facing point of entry for voluntary complaints on FDA.gov that will not only be seamless for the public to use but also result in more accurate and timely receipt of data to FDA Centers to be better equipped to act upon them.

Insights & Opportunities

- Today, the FDA has multiple intake points for consumer complaints and inquiries across various channels.
- Users are left to attempt to navigate these multiple channels on their own, with no or very little assurance on whether their message has made it to the right place.
- There is an estimated drop off rate of 70-90%, meaning a lot of potential valuable data is lost before it can be submitted.
- Since complaints and inquiries may need to go through internal triaging and routing which means either complaints are can be delayed in reaching the right destination or dropped entirely.

Scope

- Creation of a central intake form for voluntary complaints for the following centers:
  a. Center for Drug Evaluation & Research (CDER)
  b. Human Foods Program (HFP)
  c. Center for Devices & Radiological Health (CDRH)
  d. Center for Biologics Evaluation & Research (CBER)
  e. Center for Tobacco Products (CTP)
  f. Center for Veterinary Medicine (CVM)
  g. Office of Cosmetics & Colors (OCAC)
- Re-direction of complaints that fall outside of above Centers to appropriate federal agencies
- Acknowledgement of complaint submission and how the FDA will utilize the information from the complaint
- Reduce or sunset redundant web pages or subdomains
- Create a data set of complaint submissions capable of supporting AI/ML integration in the future

Time and key moments
Phase
Process step
User
Touchpoints
Additional information
Federalist screenshots
Report a problem to the FDA
What was the product?
Tell us what happened
Upload product photos
Product name
UPC number
Describe what happened step by step and timing
When did this happen?
Did hospitalization/death happen?
Upload any additional information
Did you already report this problem?
Tell us about who was harmed
How to reach you
Review your submission
Report successfully submitted
Safety Reporting Tool Screenshots
New guest report
Report type
Contact information
Problem summary
Product details
Vet visits
Attachments
Submission
Vaccine Adverse Event Reporting System (VAERS) Screenshots
Report an adverse event
Report online or Paper form
Patient information
Reporter information
Facility information
Vaccine information
MedWatch screenshots
Welcome / Type of report
Patient / What happened
Device information
Review and submit
Thank you / submission
Consumer/Patient paper form 3500B
Start of Health Professional flow
What happened
Product info
Concomitant product information
Paper form 3500 for professionals