Case Study

FDA Consumer Complaint System

U.S. FOOD & DRUG ADMINISTRATION

Office of Operations | February 2026

Contents

Background

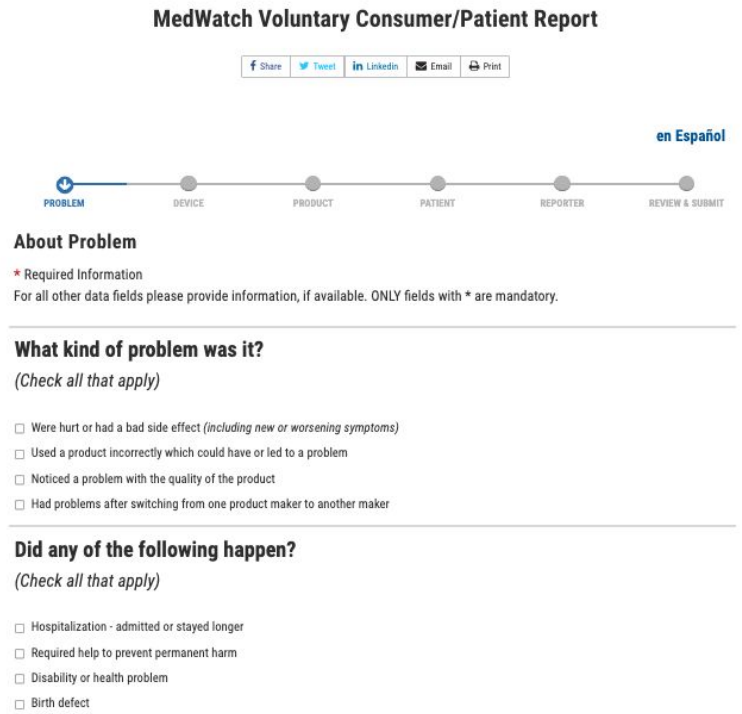
Currently the Food & Drug Administration **receives over 250,000 product complaints** on a yearly basis.

Currently the public and healthcare providers can **submit complaints and inquiries via multiple legacy systems** via MedWatch Online, Safety Reporting Portal (SRP), email, mail and fax.

Complaints can result in important actions including product recalls and license suspensions.

Current legacy systems

Safety reporting portal



MedWatch

Project history and pause

FDA engaged with the U.S. Digital Service (USDS) in 2024 to conduct a discovery sprint to modernize and streamline the complaint process as part of the modernization effort. This effort included user research with a diverse group of stakeholders.

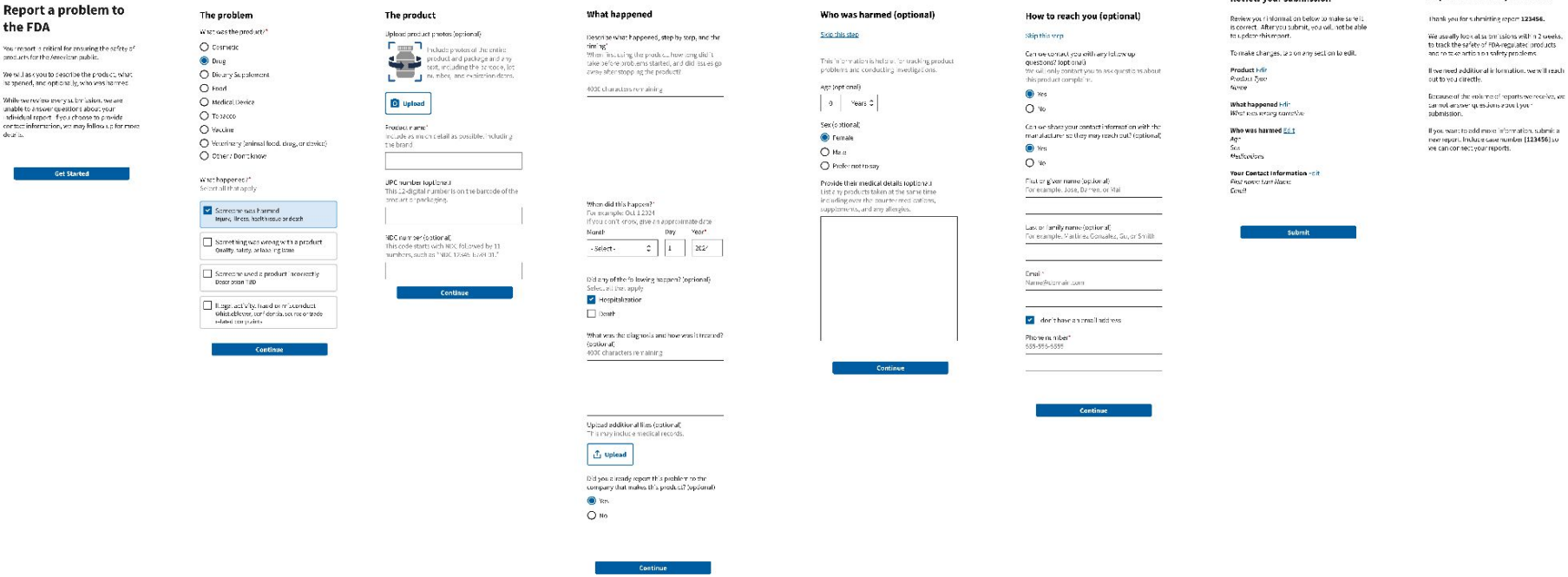
A central entry point was recommended hosted on FDA.gov to r**eplace the legacy systems** and **reduce the 70%-90% drop off rate** of submissions.

These efforts were paused in early 2025.

USDS designs

Report a Problem to the FDA (Draft) - Feb 2025

Drug > Someone was harmed



Project resumes with challenges

Work resumed in August 2025.

Key decisions had been made during the earlier phases, but **institutional knowledge had dispersed** creating gaps in rationale, research context, and design intent. **Re-establishing momentum required reconstructing artifacts** of what had been done, identifying what was still viable, and determining where assumptions needed to be re-validated.

With limited time and funding available, **each team member covered multiple roles and relied on scrappy, rapid research validation methods.**

Project vision

- Create single point of entry for complaints
- Consumer complaints submitted in 10 minutes or less
- Reduce cognitive load and drop-off rate
- Route complaints to the correct FDA center
- (WCAG) 2.1 Level AA compliance
- Utilizes FDA and USWDS component libraries

Project timeline

Mid 2025
Onboarding, discovery and ideation
Product strategy, roadmap and backlog created based on product vision.

- Gathering artifacts
- Service blueprint
- Research planning
- Design iterations

Fall 2025
Research and focus groups
- Recruiting and scheduling
- Research sessions conducted x2
- Synthesize findings
- Research share out

Fall 2025
Product design
Iterated on design prototypes and refined content for usability testing and stakeholder review.

- Clickable prototypes
- Content review
- Stakeholder and FDA center reviews

Late 2025
Final usability testing and iterations
- Research sessions conducted x2
- Focus group session
- Information architecture
- URL recommendations

Early 2026
Finalize iterations and development
Design/Dev handoff, documentation, specifications and product walkthroughs.

- Final design and content iterations
- Stakeholder and FDA center sign off
- Prep for go-live

Content review and recommendations

Research highlights

Who did we interview?

General public research

- 4 rounds of prototype testing - 40 total participants
- Age Ranges 19 - 64
- 50% high school education
- 50% higher education
- Backgrounds ranging from retail, retired, carpentry, writing and food licensing

Patient Engagement Collaborative (PEC) FDA focus group testing

- 16 total participants
- 12 in person, 4 virtual
- Ages ranging from college student to mid 50’s
- All have a background as a patient or medical advocate
- Majority of PEC members have high levels of education

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

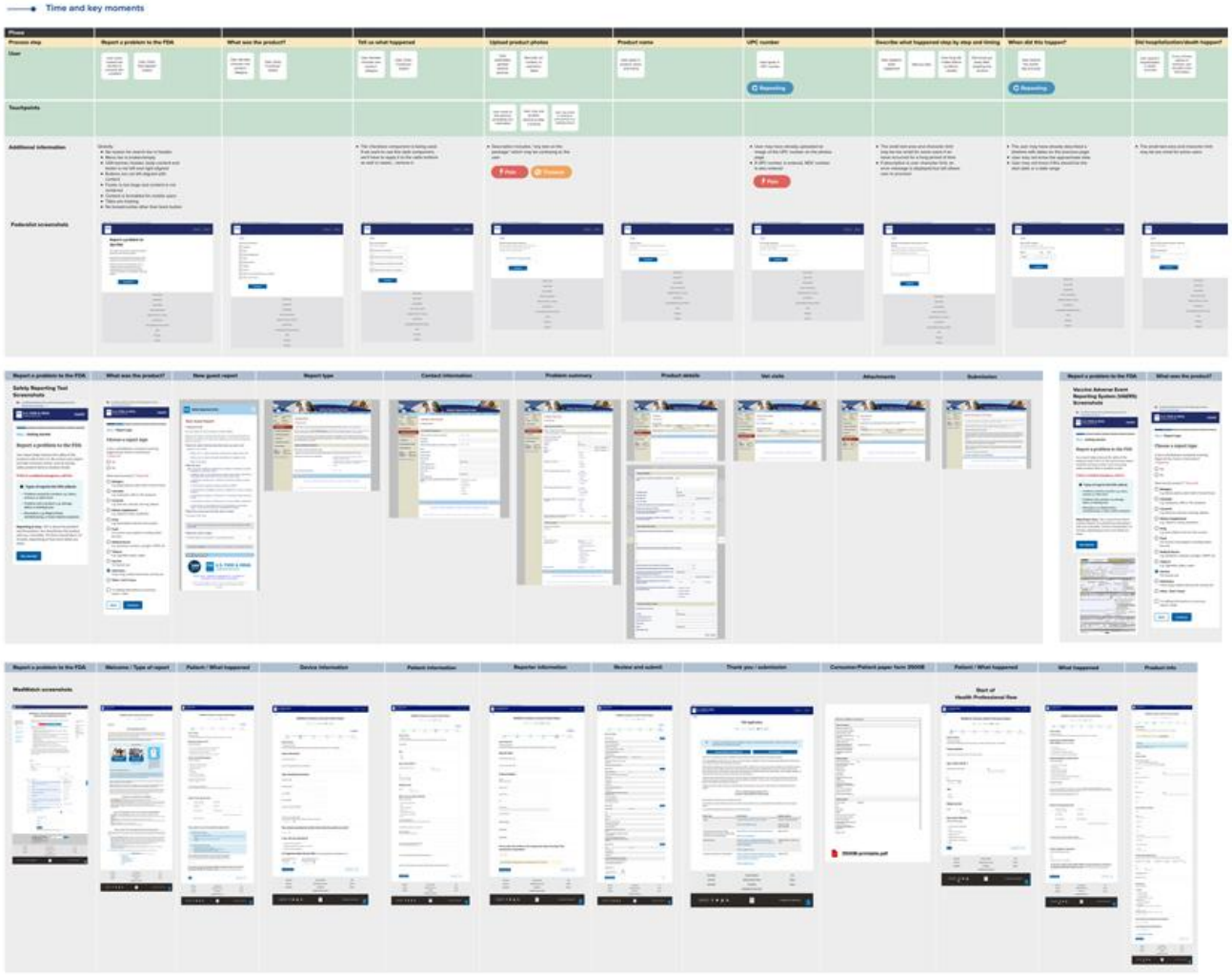
Provide a central public-facing point of entry for voluntary complaints on FDA.gov that will not only be seamless for the public to use but also result in more accurate and timely receipt of data to FDA Centers to be better equipped to act upon them.

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



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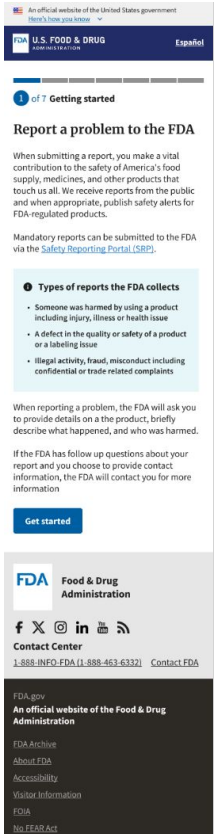
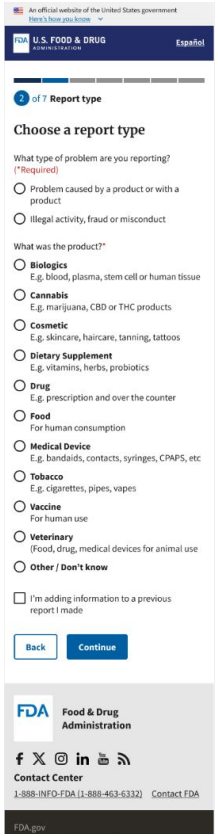
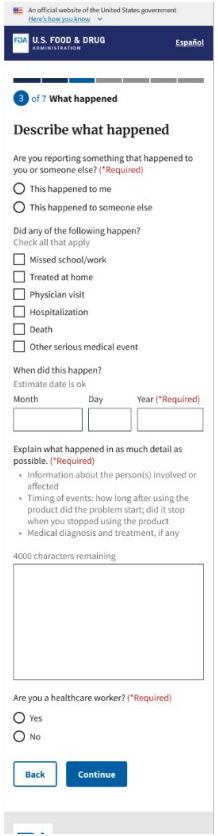
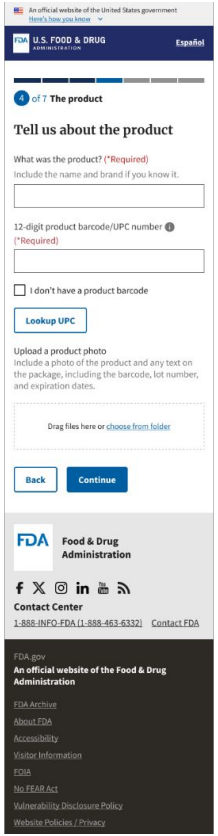
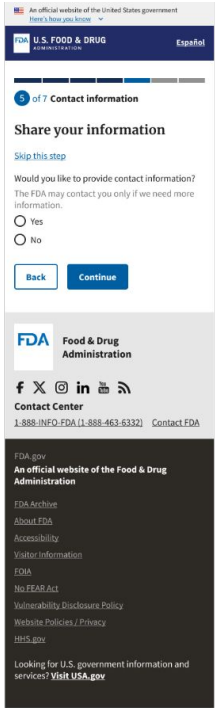
Iterative prototypes

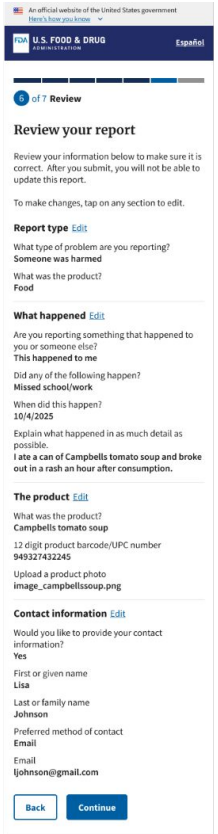


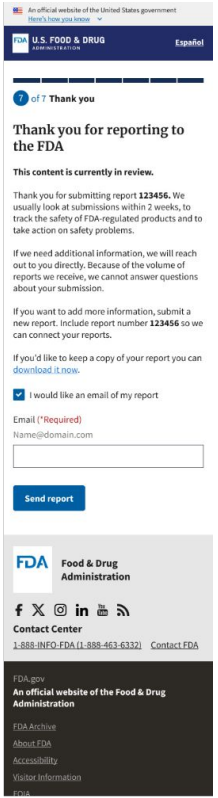












Research recommendations

Content focused revisions

- Suggest content improvements to include plain-language and consistent, approachable, professional voice and tone throughout
- Improve product category selection language and include examples
- Improve UPC/NDC descriptions and abbreviations
- Update landing and confirmation page language to include:
  - How submissions are used and why they matter
  - Materials needed to submit a complaint (product in hand)
  - Estimated time for completion
  - Expected follow-up from the FDA if applicable

Question revisions

- Add more severity options other than death and hospitalization
- Add option to specify whether report is for the user or someone else
- Remove the ability to upload medical records
- Limit NDC field to drug flow

Design revisions

- Improve help text and tool tips for UPC/NDC
- Ensure progress bar and steps completed is visible on all pages

Results and impact

The redesign resulted in measurable improvements such as

- Reduced cognitive load and anxiety
- Complaints submitted in an average of 5-10 minutes
- Significantly reduced drop off rate
- Higher quality of complaints submitted to the correct center

Launch and next steps

- New features are being tested and rolled out incrementally to ensure smooth adoption and to minimize disruption
- Launch is expected early 2026