

Case Study

FDA Consumer Complaint System



Contents



- Background
- Current legacy systems
- Service blueprint
- Project history and pause
- USDS designs
- Project resumes with challenges
- Project vision
- Project timeline
- Content review and recommendations
- Research highlights
- Who did we interview?
- Service blueprint
- Iterative prototypes
- Research recommendations
- Results and impact
- Launch and next steps

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

Name: Human Food Product Report
ID: 491063 (1)
Created: 02/17/2026

***=Required Field**

Introduction

Human Food Product Report

Contact Information

Your report is crucial to public health and can save lives! To assist with FDA's investigation, please provide:

- Clear product and package images (all sides) to include UPC, lot numbers, and best by date
- Location of purchase or website
- Your state or zipcode
- Your contact information for follow-up

Please contact SRPsupport@fda.hhs.gov if you are having any technical issues.

Report Identifying Information

Product Type Human Food

Please enter a title to help you identify this report.

Exit Submit Report Next >

[Safety reporting portal](#)

MedWatch Voluntary Consumer/Patient Report



[en Español](#)



About Problem

* Required Information

For all other data fields please provide information, if available. ONLY fields with * are mandatory.

What kind of problem was it?

(Check all that apply)

- Were hurt or had a bad side effect (including new or worsening symptoms)
- Used a product incorrectly which could have or led to a problem
- Noticed a problem with the quality of the product
- Had problems after switching from one product maker to another maker

Did any of the following happen?

(Check all that apply)

- Hospitalization - admitted or stayed longer
- Required help to prevent permanent harm
- Disability or health problem
- Birth defect

[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](https://www.fda.gov) to replace 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

Report a problem to the FDA

You must be 18 or older for ensuring the safety of someone for the reporter only.

The FDA asks you to describe the product, what happened, and options for how we'll meet.

While we review every submission, we are unable to answer questions about your individual report. If you choose to provide contact information, we may follow up for more details.

Get Started

The problem

What was the problem?

- Cosmetic
- Drug
- Biologics/implant
- Food
- Medical Device
- Toxics
- Vaccine
- Veterinary (animal food, drug, or device)
- Other (Don't know)

What happened?

Select all that apply:

- Someone was harmed (Injury, illness, health issue or death)
- Something went wrong with a product (Quality, safety, label, or dose)
- Someone used a product incorrectly (Dose, use, etc.)
- It got used in a way that it wasn't designed for (e.g., off-label use, use in a child, etc.)

Continue

< Back

The product

Upload product photos (optional)

Include photos of the actual product and packaging at any point, including the box, vial, syringe, and evidence/containers.

Upload

Product name*
Includes as much detail as possible, including the brand.

JPC number (optional)
This 12-digit number is on the barcode of the same or similar drug.

NDC number (optional)
This code starts with NDC, followed by 11 numbers, such as "488, 1234, 1234567."

Continue

< Back

What happened

Describe what happened, step by step, and the "how-to" for using the product, how long did it take for the problem to start, and did this happen after you started the product?

800 characters remaining

When did this happen?

(For example: Oct 1, 2024)

If you don't know, give us an approximate date.

Month Day Year

Did any of the following happen? (Optional)

Select all that apply:

- Hospitalization
- Death

What was the diagnosis and how was it treated?

800 characters remaining

Upload additional files (optional)

If you have medical records.

Upload

Did you already report this problem to the company that makes this product? (Optional)

- Yes
- No

Continue

< Back

Who was harmed (optional)

Select this step

This information is used in tracking product problems and conducting investigations.

Age (per cent)

0 Years

Select gender:

- Female
- Male
- Prefer not say

Provide the medical details (optional) List 2+ products taken at the same time including name, manufacturer, dosage, and any allergies.

Continue

< Back

How to reach you (optional)

Skip this step

Can we contact you if we need to follow up on this report? (Optional) We will only contact you to ask questions about this product complaint.

Yes

No

Can we share your contact information with the manufacturer so they may reach out? (Optional)

Yes

No

First or given name (optional)

(For example: Jose, Dr. etc. or title)

Last or family name (optional)

(For example: Smith, Gonzalez, Sr. or Sr.)

Email*

Name (optional)

Don't have a contact address

Phone number*

555-955-5555

Continue

< Back

Review your submission

Review your information before you make a final report. After you submit, you will not be able to update information.

To make changes, go to any section to edit.

Product title

Product type

Age

Gender

What happened first

Who was harmed last

Age*

Sex

Medical history

Your contact information (optional)

First or given name

Contact

Submit

Report successfully submitted

Thank you for submitting report 123456.

We usually process all submissions within 2 weeks, to track the safety of the medication and get you more information on a safety problem.

If we need additional information, we'll reach out to you directly.

Because of the volume of reports we receive, we can not answer questions about your submission.

If you want to add more information, submit a new report. Include case number (123456) so we can connect your reports.

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



Fall 2025

Research and focus groups

- Recruiting and scheduling
- Research sessions conducted x2
- Synthesize findings
- Research share out

Late 2025

Final usability testing and iterations

- Research sessions conducted x2
- Focus group session
- Information architecture
- URL recommendations

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

Product design

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

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

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



Report a problem to the FDA

- Explain to users
 - why they should report; benefits of reporting
 - types of reports they can make
 - what they'll need to report
 - where to go for mandatory reporting

Choose report type

- What type of problem are you reporting?**
- A problem caused by a product or with a product
 - Illegal activity, misconduct, or fraud related to a product

- What was the product?**
- Cannabis
 - Cosmetic
 - Dietary Supplement
 - Drug
 - Food
 - Medical Device
 - Tobacco
 - Vaccine
 - Veterinary
 - Other/Don't know

I'm adding information to a report I already made.

Report number

Describe what happened

- Are you reporting something that happened to you or someone else?**
- This happened to me
 - This happened to someone else

- Did any of the following happen? Check all that apply.**
- Missed school/work
 - Treated at home
 - Physician visit
 - Hospitalization
 - Death
 - Other serious medical event

When did this happen? Estimate date is ok.

- Explain what happened in as much detail as possible Useful details include:**
- Information about the person(s) involved or affected
 - Timing of events: how long after using product did problem start; did it stop when you stopped using the product
 - Medical diagnosis and treatment, if any

Tell us about the product

What was the product? Include the name and brand, if you know it.

12-digit barcode/UPC number

I don't have the barcode.

NDC number (optional)

Only on drug reports

Upload a product photo (optional)

Share your information

- Are you a healthcare provider?**
- Yes
 - No

Would you like to provide contact information? Yes/No
The FDA may contact you only if we need more information.

If user selects "Yes," show following fields

First name

Last name

Email

Phone

Preferred contact method (select all that apply)

- Email
- Phone call

Can we share your info with manufacturer so they may reach out to you?

- Yes
- No

Review your report

Summary of user-submitted information, with links to edit

Thank you for reporting to the FDA

- Confirm receipt
- Include report #
- Explain FDA's next steps
- What to expect re: follow-up



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

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 inquiries 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 other 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:
 - Center for Drug Evaluation & Research (CDER)
 - Human Foods Program (HFP)
 - Center for Devices & Radiological Health (CDRH)
 - Center for Biologics Evaluation & Research (CBER)
 - Center for Tobacco Products (CTP)
 - Center for Veterinary Medicine (CVM)
 - Office of Cosmetics & Colors (OCCAC)
- 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

Process step	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	What did this happen?	Did you/your family/other support?
User									
Touchpoints									
Additional information	<ul style="list-style-type: none"> Be specific in your report Describe the problem Describe the product Describe the incident Describe the location Describe the date and time Describe the symptoms Describe the duration Describe the severity Describe the outcome Describe the action taken 		<ul style="list-style-type: none"> The duration of the incident The location of the incident The date and time of the incident The symptoms of the incident The duration of the incident The severity of the incident The outcome of the incident The action taken 	<ul style="list-style-type: none"> Be specific in your report Describe the problem Describe the product Describe the incident Describe the location Describe the date and time Describe the symptoms Describe the duration Describe the severity Describe the outcome Describe the action taken 	<ul style="list-style-type: none"> Be specific in your report Describe the problem Describe the product Describe the incident Describe the location Describe the date and time Describe the symptoms Describe the duration Describe the severity Describe the outcome Describe the action taken 	<ul style="list-style-type: none"> Be specific in your report Describe the problem Describe the product Describe the incident Describe the location Describe the date and time Describe the symptoms Describe the duration Describe the severity Describe the outcome Describe the action taken 	<ul style="list-style-type: none"> Be specific in your report Describe the problem Describe the product Describe the incident Describe the location Describe the date and time Describe the symptoms Describe the duration Describe the severity Describe the outcome Describe the action taken 	<ul style="list-style-type: none"> Be specific in your report Describe the problem Describe the product Describe the incident Describe the location Describe the date and time Describe the symptoms Describe the duration Describe the severity Describe the outcome Describe the action taken 	
Particular screenshots									

Report a problem to the FDA	What was the product?	How good report	Report type	Contact information	Product history	Product photo	Tell us what	Adverse events	Submission	Report a problem to the FDA	What was the product?

Report a problem to the FDA	Where is your report	Product/What happened	Device information	Process information	Regulatory information	Notice and action	Thank you/confirmation	Completed/Partial report from 2008	Product/What happened	What happened	Particulars



Iterative prototypes



An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

1 of 7 Getting started

Report a problem to the FDA

When submitting a report, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all. We receive reports from the public and when appropriate, publish safety alerts for FDA-regulated products.

Mandatory reports can be submitted to the FDA via the [Safety Reporting Portal \(SRP\)](#).

Types of reports the FDA collects

- Someone was harmed by using a product including injury, illness or health issue
- A defect in the quality or safety of a product or a labeling issue
- Illegal activity, fraud, misconduct including confidential or trade-related complaints

When reporting a problem, the FDA will ask you to provide details on a the product, briefly describe what happened, and who was harmed.

If the FDA has follow up questions about your report and you choose to provide contact information, the FDA will contact you for more information

[Get started](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA
No FEAR Act

An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

2 of 7 Report type

Choose a report type

What type of problem are you reporting? (*Required)

Problem caused by a product or with a product

Illegal activity, fraud or misconduct

What was the product?*

Biologics
E.g. blood, plasma, stem cell or human tissue

Cannabis
E.g. marijuana, CBD or THC products

Cosmetic
E.g. skincare, haircare, tanning, tattoos

Dietary Supplement
E.g. vitamins, herbs, probiotics

Drug
E.g. prescription and over the counter

Food
For human consumption

Medical Device
E.g. band-aids, contacts, syringes, CPAPs, etc

Tobacco
E.g. cigarettes, pipes, vapes

Vaccine
For human use

Veterinary
(Food, drug, medical devices for animal use)

Other / Don't know

I'm adding information to a previous report I made

[Back](#) [Continue](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA
No FEAR Act

An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

3 of 7 What happened

Describe what happened

Are you reporting something that happened to you or someone else? (*Required)

This happened to me

This happened to someone else

Did any of the following happen? Check all that apply

Missed school/work

Treated at home

Physician visit

Hospitalization

Death

Other serious medical event

When did this happen?
Estimate date is ok

Month Day Year (*Required)

Explain what happened in as much detail as possible. (*Required)

- Information about the person(s) involved or affected
- Timing of events: how long after using the product did the problem start; did it stop when you stopped using the product
- Medical diagnosis and treatment, if any

4000 characters remaining

Are you a healthcare worker? (*Required)

Yes

No

[Back](#) [Continue](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA
No FEAR Act
Vulnerability Disclosure Policy
Website Policies / Privacy

An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

4 of 7 The product

Tell us about the product

What was the product? (*Required)
Include the name and brand if you know it.

12-digit product barcode/UPC number (*Required)

I don't have a product barcode

[Lookup UPC](#)

Upload a product photo
Include a photo of the product and any text on the package, including the barcode, lot number, and expiration dates.

Drag files here or choose from folder

[Back](#) [Continue](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA
No FEAR Act
Vulnerability Disclosure Policy
Website Policies / Privacy

An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

5 of 7 Contact information

Share your information

Skip this step

Would you like to provide contact information?
The FDA may contact you only if we need more information.

Yes

No

[Back](#) [Continue](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA
No FEAR Act
Vulnerability Disclosure Policy
Website Policies / Privacy
HHS.gov

Looking for U.S. government information and services? [Visit USA.gov](#)

An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

6 of 7 Review

Review your report

Review your information below to make sure it is correct. After you submit, you will not be able to update this report.

To make changes, tap on any section to edit.

Report type [Edit](#)

What type of problem are you reporting?
Someone was harmed

What was the product?
Food

What happened [Edit](#)

Are you reporting something that happened to you or someone else?
This happened to me

Did any of the following happen?
Missed school/work

When did this happen?
10/4/2025

Explain what happened in as much detail as possible.
I ate a can of Campbell's tomato soup and broke out in a rash an hour after consumption.

The product [Edit](#)

What was the product?
Campbell's tomato soup

12 digit product barcode/UPC number
949327432245

Upload a product photo
image_campbellssoup.png

Contact information [Edit](#)

Would you like to provide your contact information?
Yes

First or given name
Lisa

Last or family name
Johnson

Preferred method of contact
Email

Email
ljohnson@gmail.com

[Back](#) [Continue](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA

An official website of the United States government
Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

7 of 7 Thank you

Thank you for reporting to the FDA

This content is currently in review.

Thank you for submitting report **123456**. We usually look at submissions within 2 weeks, to track the safety of FDA-regulated products and to take action on safety problems.

If we need additional information, we will reach out to you directly. Because of the volume of reports we receive, we cannot answer questions about your submission.

If you want to add more information, submit a new report. Include report number **123456** so we can connect your reports.

If you'd like to keep a copy of your report you can [download it now](#).

I would like an email of my report

Email (*Required)
Name@domain.com

[Send report](#)

FDA Food & Drug Administration
Contact Center
1-888-INFO-FDA (1-888-463-6332) Contact FDA

FDA.gov
An official website of the Food & Drug Administration

FDA Archive
About FDA
Accessibility
Visitor Information
FOIA

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