REAGAN-UDALL FOUNDATION FOR THE FDA

Improving Access to Publicly Available FDA Information

THIS PROJECT IS FUNDED BY ARNOLD VENTURES
AND LYDA HILL PHILANTHROPIES

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SECTION 1.
Overview

From breaking news to up-to-the-minute weather forecasts, Americans are used to having easy-to-understand information at their fingertips. The same is true when it comes to reliable healthcare information: consumers, patients, and healthcare providers want to find credible information quickly and easily.

In its collection of approved medical product labeling, tracking of ongoing postmarketing commitments, and policy adjudications of relevant topics, the U.S. Food and Drug Administration (FDA) holds some of the most valuable data in human health, which has tremendous potential for improving understanding of medical products and enabling advancements that benefit all Americans. Making the wealth of information more accessible through other communication mechanisms could improve medical product use, as well as research.[1]

Clear, consistent communication is critical to the FDA's mission to promote and protect public health. As noted in the recently published report from the Reagan-Udall Foundation for the FDA (the Foundation), *Strategies for Improving Public Understanding of FDA-Regulated Products*[2], "a strong and continuous communications approach should be viewed as a fundamental aspect of the Agency's work."

The FDA provides information to the public in many ways, including through its website (https://www.fda.gov) and through the openFDA resource (https://open.fda.gov). End users of the FDA's publicly available information, and intermediaries who integrate that information into their digital content and products, both need accurate, accessible, and up-to-date information from the FDA. Better understanding the needs of these information stakeholders and identifying opportunities to improve how the FDA presents and disseminates this information can help support clear communication.

In the *FDA Information Technology Strategy for Fiscal Years 2024 to 2027*, the Agency outlines a vision to remove barriers and "unleash" the potential of its data to advance the public health mission. To best support the FDA in making publicly available data more accessible, we must understand the current online health information-seeking behavior of patients, healthcare professionals, and researchers as it pertains to FDA-regulated medical products, as well as key elements and needs of the digital intermediaries that often provide such information. The end goal of this effort is to facilitate the integration of FDA information into modern digital applications—creating an opportunity to improve access to highly technical information and present it in a way that can be easily understood by the intended audience.

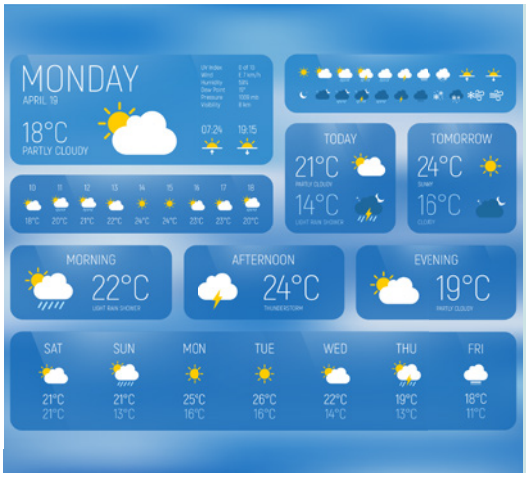
1.1 WHAT'S IN THIS REPORT

1.1.1 Objective

In this *Improving Access to Publicly Available FDA Information* project, the Foundation set out to characterize the information-seeking behavior of various FDA information stakeholders to specifically identify the types of information they seek, their sources of information, and opportunities for improving access to and use of the FDA's publicly available information. This report covers publicly available information related to the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

In the previously mentioned *FDA Information Technology Strategy for Fiscal Years 2024 to 2027*, the Agency outlines a vision to remove barriers and address "outdated data exchange practices, unstructured data

submissions, and undue limitations on data sharing," by making the highest impact data assets widely available in a format that supports modern data science practices and uses a customer-centric approach.



Before the National Oceanic and Atmospheric Agency (NOAA) modernized its technology structure in the 1990s, weather forecasting was limited. NOAA's modernization and associated restructuring (MAR) activity fundamentally changed the National Weather Service structure to ensure that rapid detection and timely forecasts and warnings could be delivered to the public. This data infrastructure is available to feed a communications network that packages and disseminates the information to the public and other outside users. Improved data outputs from NOAA led to the development of numerous smartphone weather apps. There are now more than 10,000 weather apps available. **Can we achieve the same results with FDA information?**

This report aspires to share (a) what information patients, caregivers, health professionals, researchers, and software or website companies seek about FDA-regulated medical products; (b) where these groups look for such drug and biologics information; (c) what type of data is publicly accessible; and (d) which data is currently available on the FDA website for external users to utilize in generating unique search query responses. The overarching goal is to improve publicly available FDA data access and facilitate integration of data to digital applications to help the public get accurate, science-based information they need to use medical products to maintain and improve their health.

1.1.2 Structure

Several types of research informed the findings presented in this report:

- A landscape analysis of available research and discussions regarding the current online health information-seeking behavior of patients, healthcare professionals, and professional researchers, related to FDA-regulated medical products
- A quantitative consumer survey
- A Catalog of FDA Data/Information Sources (included in Appendix) related to the work of FDA's Center for Drug Evaluation and Research, which provided Google Analytics on how consumers search for FDA-regulated products and how consumers land on the FDA.gov website
- In-depth interviews with stakeholders
- Roundtable discussions with experts, patients, and consumers

For this project, the Foundation defined two groups of key FDA information stakeholders (Box 1). The first were **end users** of publicly available FDA information, comprising three subgroups: patients and consumers, healthcare professionals, and professional researchers. Professional researchers included those associated with academic institutions, FDA-regulated medical product companies, consulting/professional services organizations, payors, and other entities in healthcare.

BOX 1. KEY FDA INFORMATION STAKEHOLDERS

End Users:

- Patients and consumers
- Healthcare professionals
- Professional researchers

Intermediary Partners:

- Health information websites and publishers
- App developers

The second group were **intermediary partners**, those that use—or could use—publicly available FDA information to develop digital content and products for end users. These included health information websites and publishers, patient advocacy and disease-specific websites, and app developers.

In this report, the Foundation presents its findings on information-seeking behavior of these key FDA information stakeholders and opportunities to make the FDA's publicly available information more accessible and useful. This report also details what information the FDA makes publicly available.

SECTION 2.

How Stakeholders Seek FDA Information

FDA information stakeholders use, gather, and/or disseminate the FDA's publicly available information. This report describes the information-seeking behavior of two groups of FDA information stakeholders: end users and intermediary partners.

Subgroups of **end users** access and use different types of publicly available FDA information and information from other sources for three distinct reasons:

- **Patients and consumers** learn about health conditions and drugs for themselves, family members, and friends.
- **Healthcare professionals** primarily use information about prescription and over-the-counter drug information to make clinical decisions at the point of care.
- **Professional researchers** generally seek greater amounts of data (including historical information) to explore trends and identify risks and opportunities.

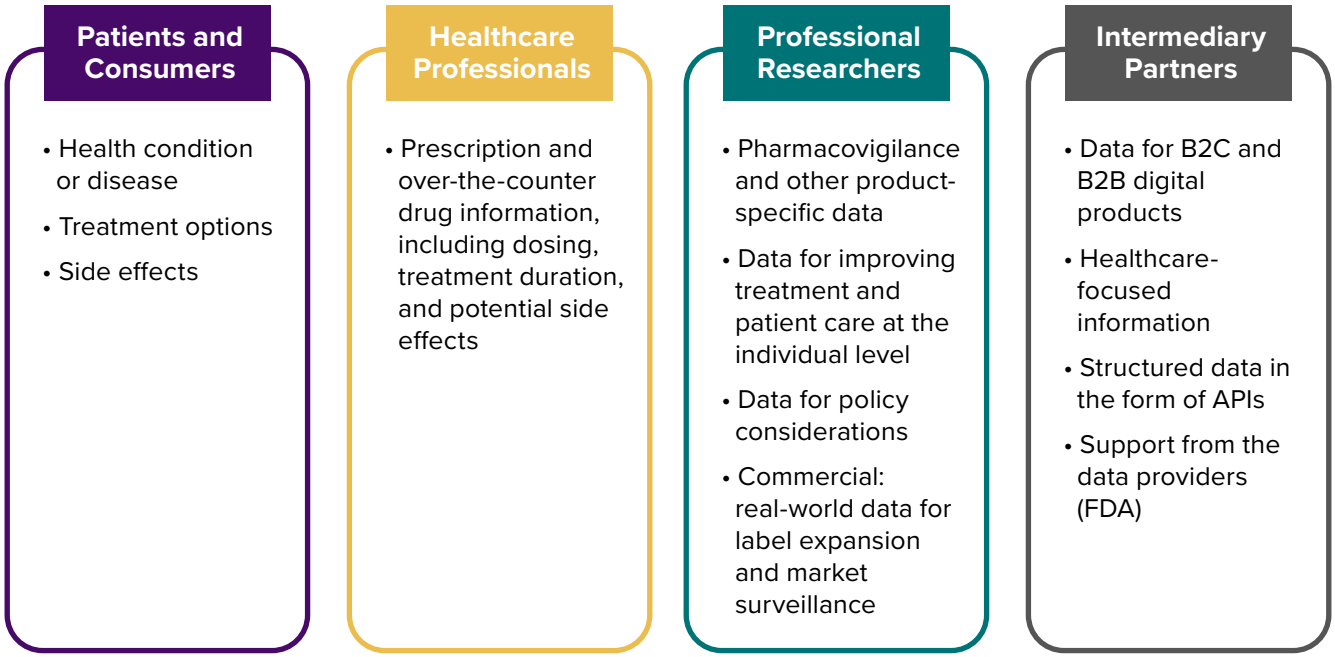
Intermediary partners use publicly available FDA information to develop digital content and products for the above subgroups of end users. Content and products include websites, mobile apps, and Software as a Service (SaaS) and artificial intelligence (AI) tools. This project focused primarily on intermediary partners that are health information websites, publishers, and software developers. Their digital products can be oriented toward consumers (B2C) or businesses (B2B). In addition, FDA's publicly available data can be used to create add-ons to current electronic health record (EHR) systems.

Information-seeking behavior by FDA information stakeholders—end users and intermediary partners—in this report refers to:

- **Common queries** (how they searched for health information) **and requests** (for data)
- **Sources of information** and data, including whether they used FDA information and data or other sources
- **Challenges encountered** that prevented them from fully accessing and using publicly available FDA information

The type of information sought varied by the FDA information stakeholder group and subgroup (Figure 1). Intermediary partners that develop digital products function best with structured data. Unstructured data, which is also extremely important, needs additional processing tools such as AI to gather information. End users look for the data to be distilled into information that is easy to access and understand.

FIGURE 1. Types of Information That End Users and Intermediary Partners Seek Online



2.1. END USERS

2.1.1 Patients and Consumers

The Foundation identified important differences in the information-seeking behaviors among FDA information stakeholders in terms of the types and sources of information sought and the challenges encountered. The project also revealed several opportunities for the FDA to make it easier for these groups to access and use its publicly available data and information. Public data from the FDA includes general information about FDA policies, guidelines, and regulations. It is typically non-sensitive and is intended to inform the public and stakeholders.

Since Internet access became mainstream at the turn of the century, patients and consumers have exhibited online health information-seeking behavior—and this global trend has continued to increase over time. Patients, caregivers, and consumers tend to seek information online directly from health information websites, social media platforms, and search engines. "From 2008 to 2017, the Internet was the most frequently used source of health information, with physician or healthcare provider consistently emerging as the second most frequent source."[3] Additionally, evidence shows that online health-seeking behavior continued to rise across all categories from 2017 to 2019, with the study concluding prior to the onset of the COVID-19 pandemic.[4]

For end users, online health information-seeking behavior often starts with an interest in a particular health or wellness condition, such as searching for potential causes of a symptom or treatment options for a provider-diagnosed condition. Individuals most often seek information for themselves, but also frequently conduct online research on behalf of a family member, a behavior referred to as "surrogate seeking."[5] Additionally, online information-seeking behavior tends to be common, with one study showing 19% of respondents reported seeking health information online as often as daily or weekly and 58% reported seeking health information at least monthly.[6] Some consumers and patients choose to engage with online health information as a precursor or alternative to a healthcare provider visit, citing lack of time, fear of communicable diseases associated with provider facilities, and no-cost access to useful information. In this same study, 67% of respondents reported seeking online information prior to visiting a physician "sometimes," "often," or "very often."

According to a 2021 survey of 1,000 U.S. adults, "Three in four Americans leave the doctor confused and dissatisfied for reasons that include disappointment in the level of Q&A they have with their doctor, confusion about their health, and a need to do more research," leading to online health information-seeking behavior.[7] Multiple studies show that consumers often engage in online health research to support information received by their provider. Another study showed that 94% of pregnant women searched online to verify information previously received from a healthcare professional, which increased their level of confidence in believing/adhering to this information.

In a broad scoping review of 118 sources, Wollmann et al. found that[8]:

- 58% of patients consult online sources before a consultative visit with a provider
- 62% consult online sources *after* a visit with a provider
- 74% search for general information regarding health risks
- 50% look for information regarding a specific condition or acute problem

Their evaluation concluded that patients and consumers want the following from online health information sources[8]:

- Clear demonstration of the authors' qualifications and experience
- Interactive tools and resources for caretakers
- Ability to connect with others
- Easy to access information
- Increased readability and understandability of information

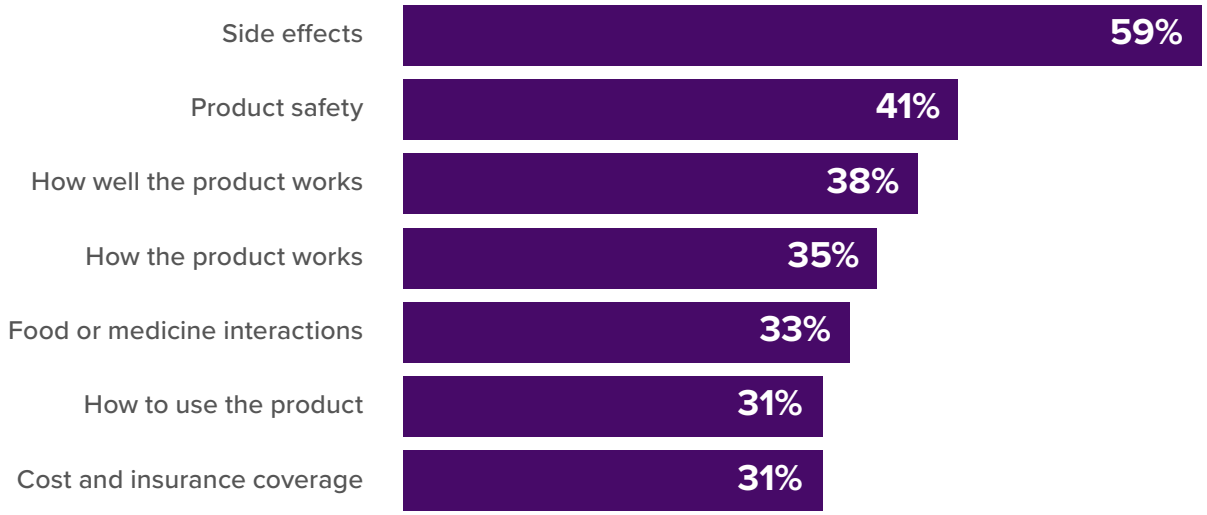
Despite the popularity of online health information-seeking behavior, many individuals still struggle to access, understand, and assess the quality of information available to them via the Internet. This presents a meaningful opportunity for FDA to participate in developing and promoting an ecosystem of accessible high-quality sources of online health information to advance the Agency's public health mission.

COMMON QUERIES AND REQUESTS

Patients and consumers usually searched online for information about a health condition (or disease), followed by possible treatments and side effects of treatments (Figure 2). Users of Drugs.com searched primarily for a specific drug and then its side effects.

FIGURE 2. Progression of Online Searches for Health Information by Patients and Consumers[7]

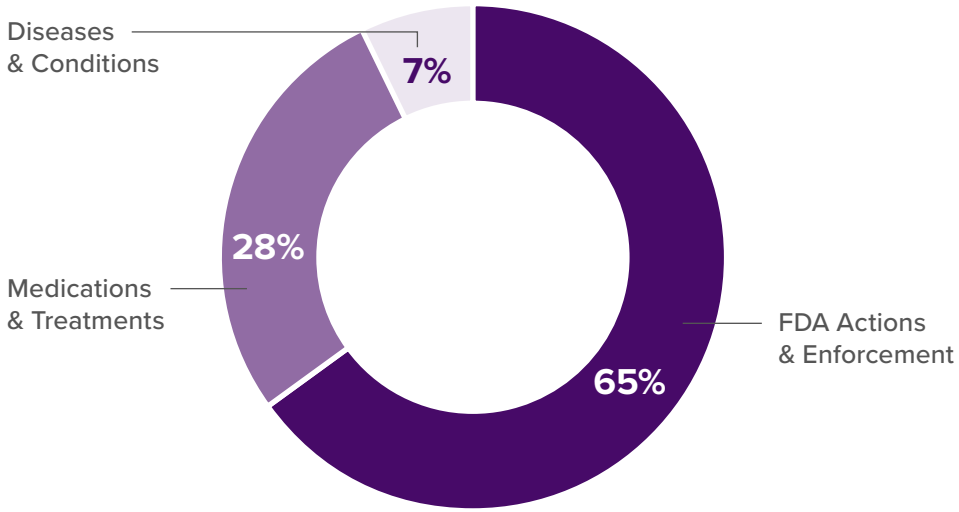
FIGURE 3. Common Queries by Patients and Consumers



Data located in Appendix, Table A.

Once patients and consumers found information online about the health condition, they searched for more specific information. For example, in a survey of 2,017 consumers conducted by the Foundation, 42% searched for health information on a specific medication, vaccine, or medical device in the last six months. Figure 3 shows common queries when exploring a specific product.

FIGURE 4. Searches of Information on the FDA's Website



Data located in Appendix, Table B.

In roundtable discussions, some patients and consumers shared that they prefer searching online using keywords, while others prefer formatting their searches as questions.

When patients and consumers visited the FDA's website, they were most interested in safety information, especially drug safety. FDA Actions & Enforcement was the most frequently searched category, according to the Foundation's report on FDA user search behavior and intent (Figure 4). This category contains keywords directly related to announcements, safety guidelines, health advisories, regulatory information, or compliance matters.

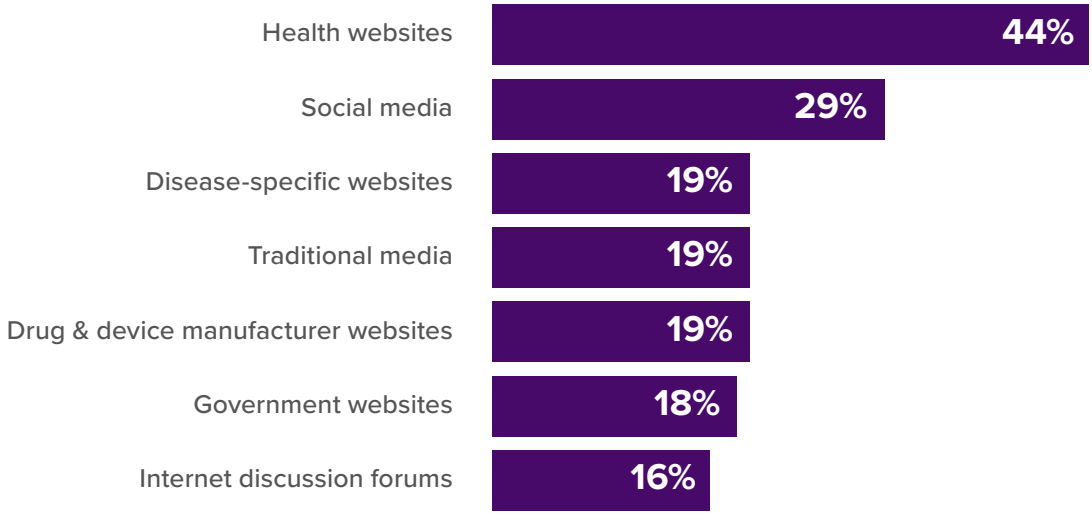
SOURCES OF INFORMATION

In terms of where patients and consumers go for information, they first sought health information via Google. The most common health websites they visited based on search results were WebMD, Mayo Clinic, Cleveland Clinic, and CDC. They did not typically search for "FDA." The most common way patients and consumers visited the FDA website was by Google organic search (meaning not paid for placement advertising). A less common way they arrived at FDA's website was via direct access, where they might type the FDA's URL or have it bookmarked.

> **"People usually already have their prescription form or their pharmacy bottle when they go to Google. There's a reasonable chance they end up on the FDA's website."**
>
> **— Website publisher**

Health information websites were the most common source of health information (Figure 5). Social media was the second most common source; however, patients and consumers reported trusting it the least (Figure 7).[9]

FIGURE 5. Common Sources of Health Information for Consumers and Patients



Data located in Appendix, Table C.

Most patients and consumers surveyed (72%) said that they often or always find what they are looking for during online health information searches. The graphic below illustrates how users find popular government, clinical, and retail health websites.

Organic searches (meaning not paid for placement advertising) drive the majority of traffic for all of the top five health websites and MedlinePlus.gov, while social media and referrals from other websites (included in the "other" category) drive a relatively small amount of traffic for all top sites. Furthermore, direct traffic is a measure of users going directly to a source (e.g., typing the website address into the browser or going to a bookmarked site) and suggests familiarity and/or trust by the user. The sites that contain significantly more healthcare reference content (e.g., Healthline.com, MayoClinic.org, WebMD.com, and MedlinePlus.gov), all receive a similarly high percentage of traffic from organic searches. Interestingly, while NIH.gov and MedlinePlus.gov are both government sources, users reach these websites in different ways, likely because they target different audiences (e.g., patients vs. researchers). As a retail pharmacy site, CVS.com is a bit of an anomaly among this

list of top health websites; it is expected that the traffic pattern would differ from information-oriented sites. Further, it is likely that CVS.com was receiving increased traffic at the time of this data snapshot due to the then-recent approval of an updated COVID-19 vaccine.

FIGURE 6. Traffic Sources of Top 5 Health Websites

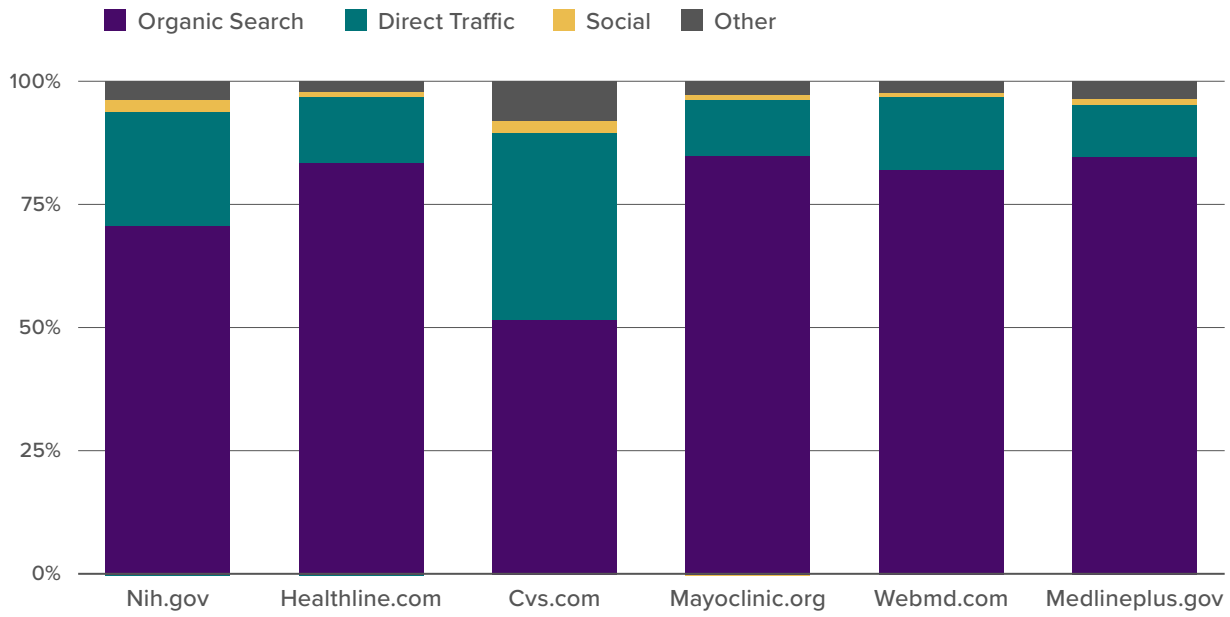
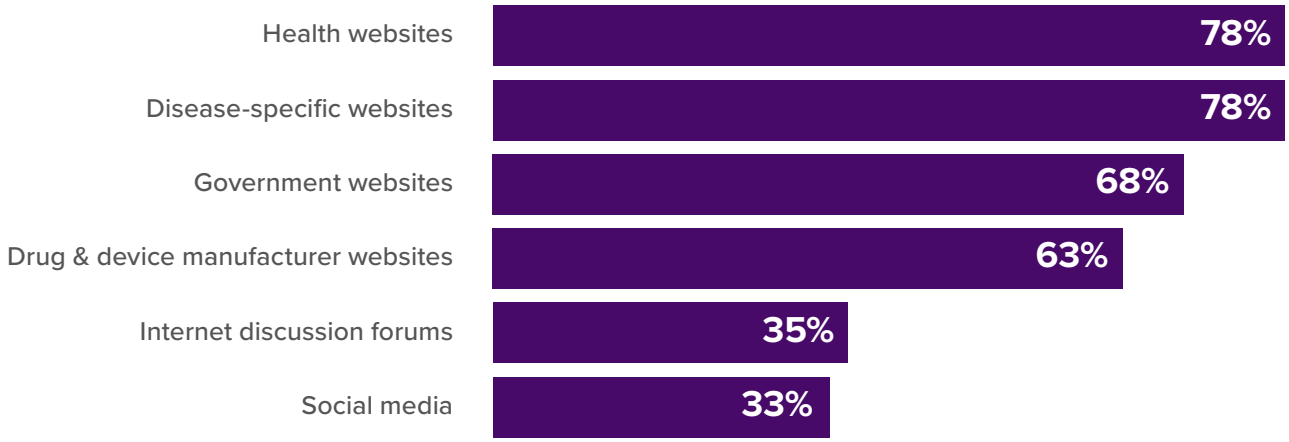


FIGURE 7. Levels of Trust in Sources of Online Health Information



Data located in Appendix, Table D.

More than two out of three patients and consumers said that they have at least some trust in health information from government websites, including the FDA's website. Yet only 20% of patients and consumers surveyed said they visited a government website for health information in the past six months.

Only half of patients and consumers said they validate the health information they find with simple steps such as checking the last updated date. Even fewer reported reviewing information about the website's funders or authors.

CHALLENGES ENCOUNTERED WHEN ACCESSING ONLINE HEALTH INFORMATION, INCLUDING FROM THE FDA

Understanding of health information seeking behavior via search engines by people in the U.S. is limited by a lack of available data and research. This makes it difficult to fully understand patients' and consumers' health information-seeking behavior regarding publicly available information from the FDA. The available research did show that:

- Government websites had less brand recognition than the top health information websites used by patients and consumers
- Patients and consumers want to find in-depth health information on the FDA's website faster
- Drugs.com and goodrx.com had more organic traffic than the FDA's website

In general, patients and consumers described challenges of using health information from all online sources, including:

- A struggle to access, understand, and assess the quality of online health information
- A lack of information that is easy to access and read
- Poor design (e.g., appearance, use of graphics) and usability (e.g., searching and navigating) of health information websites

2.1.2 Healthcare Professionals

The Foundation's research on the information-seeking behavior of healthcare professionals focused on digital resources for prescription drug and biologic information and over-the-counter drug information.

COMMON QUERIES AND REQUESTS

The explosion of Internet and mobile technology development since the turn of the century has led to a significant shift in the way healthcare professionals access and consume medical reference materials to assist in their clinical decision making. Printed content, such as academic journal articles and medical textbooks, is now readily available online. This has led to a change in how health professionals access and use medical reference materials. There is a vast and growing amount of digital reference material, software, and applications available to support clinical decision making, such as those associated with health risk screening, diagnosis, and disease management.

Healthcare professionals rely heavily on web and mobile application-based drug information databases to make clinical decisions at the point of care.10, 11 The professional's primary objective is to ensure both efficacy of treatment as well as patient safety, including prevention of injury from adverse drug reactions due to dosage, time course of a reaction and susceptibility factors (such as genetic predispositions), and drug-drug interactions.

One health information website reported that specific queries about drugs by healthcare professionals often focused on correct dosing and the length of treatment.

SOURCES OF INFORMATION

Healthcare professionals relied heavily on digital drug information databases (drug apps) from private companies (Table 1).

There are a large number of web-based mobile app drug information databases available to healthcare providers. Below, Table 1 provides an overview of 13 of the most commonly referenced resources.

TABLE 1. The 13 Most Common Drug Apps Used By Healthcare Providers Professionals[2]

SERVICE	PARENT COMPANY	PLATFORM	EST. APP INSTALLS*
Medscape®	WebMD, LLC	Web + Mobile App	5–10M
Lexicomp®	Wolters Kluwer N.V.	Web + Mobile App	1–5M
Epocrates®	athenahealth, Inc.	Web + Mobile App	1–5M
Drugs.com®	Drugsite Trust	Web + Mobile App	1–5M
UpToDate®	Wolters Kluwer N.V	Web + Mobile App + EMR	1–5M
Micromedex®	Merative	Web + Mobile App	100–500K
Skyscape Medical Library	Skyscape Medpresso, Inc.	Mobile App Only	100–500K
PEPID PDC	PEPID, LLC	Web + Mobile App	100–500K
Davis's Drug Guide	Unbound Medicine, Inc.	Web + Mobile App	100–500K
Hale's Medications & Mothers' Milk	Springer Publishing Company	Web + Mobile App	5–10K
RxList®	WebMD, LLC	Web Only	N/A
DrugBank	University of Alberta, managed by OMx Personal Health Analytics Inc	Web + License to Downloadable Database	N/A
Sequence2Script	University of Calgary	Web Only	N/A

* *Mobile application installs reflect global data from SensorTower for the Android platform and are not inclusive of iPhone users. This data is intended to be used for relative context only.*

The Epocrates® website claims that it was the top ranked medical app 10 years running[12] according to Clarivate's[13] Taking the Pulse® 2019 U.S. Physician Survey. A study by Apidi et al. found that out of eight mobile apps reviewed, the top four included Lexicomp®, Epocrates®, Drugs.com®, and Micromedex®. Some key differences noted include subscription fees, inclusion of drug images, and classification of drug interactions.[14] Notably absent from this list are the government-run resources Drugs@FDA Express, MedlinePlus (National Library of Medicine), and LactMed (U.S. Department of Health and Human Services). These resources are rarely, if ever, mentioned in available survey studies and tend to rank low relative to this list in both search engine results and mobile installations.

CHALLENGES ENCOUNTERED IN USING FDA INFORMATION AND DRUG APPS

Little data is available on how healthcare professionals use the FDA's information. Research did show that many government resources do not compete well against private sector drug apps, especially against free tools and subscription-based sources paid for by employers.

Multiple studies have shown that data and information offered by digital drug database applications is both incomplete and inconsistent, which can lead to critical errors and ultimately preventable adverse drug reactions.[14–16] One identifiable problem is that there is no current regulatory standard that exists for drug information databases, including web-based mobile apps, as they are generally considered low risk.[17] However, it is important to note that these resources often rely on teams of medical professionals (e.g., expert opinions which may be subjective) to develop, curate, and distill information from a variety of sources to build a product database,[12] which means the information presented is subject to interpretation and/or human error, along with obsolescence. Rambaran et al. claim that summarizing and compressing information carries an "inherent risk of misinformation and lack of completeness" which leads to "conflicting information and thus … room for errors and/or adverse drug events to occur."[16]

The majority of popular drug database applications target all healthcare professionals across multiple disciplines in a one-size-fits-all approach. This means, for example, that a pediatric intensive care unit nurse administering weight-based medication intravenously, an outpatient psychiatrist altering a patient's psychotropic treatment regimen, and a community pharmacist dispensing a prescription for an ACE inhibitor might all reference the same drug database application, despite having very different needs and levels of risk.

Ideally, the professionals in each of these examples should be able to quickly locate the information required to perform their job in a timeframe appropriate for the task at hand. In reality, however, there are on average roughly 500 adverse reactions associated with a single drug which can overwhelm providers while making it difficult to find the most critical warnings,[16] and frequent false alerts are leading to alarm fatigue, which can cause a significant negative impact in clinical decision making and ultimately patient safety.[15]

Resources targeting types of users, use settings, and disciplines or disease areas may better serve the needs of providers. This approach to fit-for-purpose application development requires a greater level of flexibility in the underlying datasets to create economic viability in the app development ecosystem. For example, data on weight-based dosing could be structured in a way for developers to easily incorporate the data into app-based calculators.

Similar to patient and consumer health information resources, design and usability both play a key role in providing healthcare professionals with the most important information, as fast as possible, and in the most user-friendly way possible.16 This includes search capabilities, ease of navigation, page layout, response times, as well as the frequency of data updates.[16,18] This may also help explain the relatively poor adoption of government resources, which tend to lag behind modern development trends.

Most available research on healthcare professionals revealed several hurdles to using private sector drug apps, which included:

- Incomplete and inconsistent information
- A one-size-fits-all approach that makes it difficult for healthcare professionals to find the information they need

- Design and usability issues, including inadequate search capabilities and insufficient frequency of data updates
- Often being limited to the one drug app their organizations subscribe to
- Quality and trustworthiness issues due to ads and the sale of data

> **"Healthcare professionals don't want to have to keep scrolling. They don't want to read through everything to find the information they need."**
>
> **— Website publisher**

2.1.3 Professional Researchers

COMMON QUERIES AND REQUESTS

When conducting research using information from the FDA and other sources, professional researchers were interested in datasets that they can use with AI and machine learning (ML) tools.

CHALLENGES ENCOUNTERED IN USING FDA INFORMATION

Professional researchers report experiencing a high degree of friction when mining publicly available data sources (e.g., FDA drug label data). Researchers are often "reinventing the wheel" when it comes to translating raw data into fit-for-purpose data models, which leads to costly inefficiencies that prevent the sharing of vital public health information. The process of collecting and cleaning, preprocessing for analysis, and transforming this information into analyzable data is both time-consuming and resource-intensive, which significantly delays or prevents reporting of research findings (or outcomes).

With individual researchers eager to publish findings and secure tenured positions at leading academic institutions, one of the primary motives of academic research is to promote scientific discovery in the field of medicine. Pharmaceutical, diagnostic, and medical device company research employees (and their consultants) have a financial responsibility to protect the interest of their investors and shareholders. These responsibilities translate into motivations that expand their market, namely drug discovery, label expansion, and risk management.

Professional researchers are increasingly turning to predictive modeling powered by large datasets that include publicly available information. In separate studies, researchers showed the ability to use natural language processing (NLP) and semantic web technology to simplify medical information.[19,20] Leroy et al. developed an algorithm to identify "difficult-to-understand" online health information and offer relatable alternatives for lay audiences.[20] Similarly, Martin-Hammond et al. demonstrated an ability to make OTC drug information more understandable for older adults.19 Both examples show an opportunity to improve patient comprehension and retention of their health information.

Several studies aimed to address the challenges of information overload for providers when making clinical decisions at the point of care. One approach leveraged AI to synthesize urological cancer information across hundreds of academic articles and clinical trial databases into digestible information about "specific combinations or sequences of therapeutic agents, including subdivisions according to drug, geography, investigator, and type of article/grade of evidence."[21] Others focused on building comprehensive drug indication databases to facilitate the development of integrated drug ontologies[22] and, by leveraging pharmacogenetic data, create a drug-gene pair database with associated clinical outcomes to assist in prescribing decisions.[23] Both teams relied heavily on publicly available FDA data, which demonstrates the importance of dataset accessibility and usability.

Professional researchers noted that transforming unstructured datasets such as FDA approvals and drug labeling into clean and structured data for use with AI/ML tools requires significant time and effort (Box 2).

Professional researchers in academic settings experienced hurdles related to the need to harmonize FDA information, make accessible information more timely and complete, add missing historical information, alleviate technology restrictions, and clarify the intended audience for specific information (Box 2).

> **"It's hard to know which FDA database to use. It would be great to just search in one place."**
>
> **— Payor**

BOX 2. CHALLENGES PROFESSIONAL RESEARCHERS FACE IN USING FDA INFORMATION

- Harmonization of data
  - Non-standardized database naming structure and unlinked databases
  - Inconsistencies between the NDC and the Orange Book
- Timely information
  - NDC outsourcing information updates are required in June and December only
  - Difficulty finding the information upload dates or data freshness
- Missing information
  - Accessing historical data is difficult; researchers often piece information together from other sources
  - Determining the status of postmarketing studies is challenging
  - NDC is missing data points such as the FDA Establishment Identifier (FEI) numbers and manufacturing sites, and is not included on all drug labels
  - ClinicalTrials.gov is missing analysis on placebo groups; researchers must submit a Freedom of Information Act (FOIA) request to access this information
  - Postmarket safety and efficacy information for products on expedited review pathways is not sufficient
  - FDA Form 483s inspectional observations
  - Warning letters
- Insufficient transparency
  - Supplemental and demographic information for clinical trial participants
  - Lack of access to information that is available to and shared with Congress
- Restrictions on new technology
  - Halting the downloading of public information with AI/ML tools and blocking access makes conducting research more difficult

In the commercial market, there are ML tools used to mine large datasets to assist in identifying potential molecular hits out of billions of compounds. The Open Drug Discovery Toolkit offers open-source, computer-aided drug discovery software licenses at no cost to academic and commercial users alike. Other examples include proprietary SaaS platforms that support computational mining and analysis of scientific datasets, such as Schrödinger and CDD Vault. Additionally, commercial researchers are leveraging real-world data to identify opportunities for label expansion. There are several for-profit companies offering data, software, and services in this space.

To protect the financial interests of an organization and minimize its risk, commercial researchers leverage business intelligence tools to conduct market surveillance using publicly available data. For example, Basil Systems, DrugPatentWatch, Elucidata, and Vivpro.ai use AI and ML insights from publicly available regulatory data. Additionally, leading healthcare consulting organizations, such as Axtria, Cognizant, IQVIA, and ZS Associates, develop proprietary analytical products that perform similar functions, as do quality management software (QMS) vendors, such as Greenlight Guru and Qualio. The value of QMS vendors is their ability to clean, structure, and transform disparate and disconnected datasets so that they can become fit-for-use within advanced data science and computing platforms.

Leveraging AI and ML for predictive modeling and direct access to clean, structured, and fit-for-purpose data is crucial for professional researchers, academic and commercial alike. Oftentimes, this means starting with messy unstructured data and transforming it, which is both time-intensive and costly. Data from publicly available datasets like FDA approvals and drug label databases are valuable but often require significant efforts to restructure the data for use by researchers.

Developing a fit-for-purpose database is the first and most critical step in data mining. Poluzzi et al. define this step as the "computer-assisted procedures, starting from processing of dataset by data 'cleaning' and culminating in the application of statistical techniques, often known as data mining algorithms."[24] Because so many studies, technologies, and approaches rely on data mining of publicly available sources, nearly every research team faces an identical challenge and solves it in similar ways, essentially "reinventing the wheel" time and time again.

In many of the studies referenced in this section, the authors openly discuss the challenges they face in mining publicly available data. Table 2 provides an overview of the studies and highlights authors' insights.

TABLE 2: Study Overview and Authors' Insights

AUTHOR	STUDY SUMMARY	QUOTE
Cheng et al.[23]	Cheng et al. mined drug labels and the FDA Table of Pharmacogenetic Associations[25] to first develop a list of drug-gene pairs in order to map to associated clinical outcomes so that it can be used by providers making prescribing decisions.	"To our knowledge, compilation and categorization of pharmacogenetic information from these two FDA resources has not yet been conducted."[23]
Wu et al.[26]	Wu et al. used BERT,[27] a natural language processing model, to mine the text of FDA drug labeling documents in order to extract the risk of drug-induced liver injury (DILI) for a given drug.	"There are over 130,000 drug labeling documents in the repository, of which 47,000 are labeling for prescription drugs and biologics. This represents large amounts of regulatory text data, making manually assessing all drug labeling documents prohibitory, if not impossible."[26]
Wu et al.[28]	Wu et al. also mined drug labels in order to classify ADRs by severity based on their labeling sections.	"Several reported studies have extracted ADRs from labeling documents, but most, if not all, did not discriminate the severity of the ADRs by the different labeling sections."[28]

AUTHOR	STUDY SUMMARY	QUOTE
Li et al.[29]	Li et al. manually extracted a list of drugs with corresponding indications from drug labels to build a prototype for automated monitoring and alerting of patient ADR risks.	"It would be optimal to extend the automated trigger-tool methodology to an all-inclusive set of drugs; however, current trigger-tool methodology requires manual database development for the triggers. In other words, a human user needs to enter ADR signs and symptoms into a database that serves as the underlying data set to scan the EHR content for ADR triggers."[29]
Jang et al.[30]	Jang et al. developed a model for quantitatively predicting DDIs based on pharmacokinetic data mined from drug labels.	"Many machine learning techniques provide a simple prediction for drug-drug interactions (DDIs). However, a systematically constructed database with pharmacokinetic (PK) DDI information does not exist, nor is there a machine learning model that numerically predicts PK fold change (FC) with it."[30]
Sharp et al.[22]	Sharp et al. mined multiple sources to develop a database mapping drugs to indications as a first step in creating a drug ontology.	"There is a wealth of available drug-indication information, but structuring and integrating it is challenging... The DID itself is not an ontology, but could be converted to one more easily than the contributing raw data."[22]
Sakeada et al.[31]	Sakaeda et al. mined the FAERS database to detect quantitative signals of association between a given drug and adverse event.	"All drug names were unified into generic names by a text-mining approach, because FAERS permits the registering of arbitrary drug names, including trade names and abbreviations. Spelling errors were detected by a spell checker software, GNU Aspell, and carefully confirmed by working pharmacists."[31]
Poluzzi et al.[24]	Poluzzi et al. mined Drugs@FDA to create a separate reference table of all generic and brand names of drugs in order to make use of FAERS data to study ADRs.	"In FDA_AERS, the drug(s) used by the patient are reported in the "DRUGNAME" field as free text: either brand name or generic name can be reported, but also a combination of both, and misspellings can be present because of the lack of drug codification. This issue represents an important limitation of FDA_AERS data mining, as recognized by various authors."[24]

Data mining algorithms are often unique and fine-tuned to a specific study or hypothesis; however, flexibility in the underlying data is needed, so it's not reasonable to focus on developing one-size-fits-all data models. Importantly, highly structured, relational, and interoperable datasets that accompany dense text-based regulatory documents have potential to significantly reduce the investment of time and resources required of researchers to make use of this uniquely valuable information.

2.1.4 End User Compilation

An in-depth look at the online health information needs of patients, providers, and researchers has revealed a number of challenges as well as opportunities to strengthen the information ecosystem with high quality data sources. As the regulator for all human health products in the U.S., the FDA is uniquely positioned to unleash valuable data assets for the benefit of public health. While the ultimate outputs and products may vary greatly, the underlying effort required to improve the structure and access to data is the same regardless of the user or use case.

2.2 INTERMEDIARY PARTNERS

This section presents findings on information-seeking behavior—common queries and requests, sources of information, and challenges encountered—for the second group of FDA information stakeholders: the intermediary partners. The Foundation also included technology companies in this group that are not typically intermediary partners to gather general insights. Altogether, the intermediary partners and technology companies involved in the research included:

- Health information websites and publishers
- App developers
- AI vendors
- Search engine platforms
- Other digital technology companies
- Industry
- Small software companies

In general, **intermediary partners** were the most likely to use the FDA as an information source because their role is to develop digital content and digital products for end users that are based on publicly available FDA information. Most used openFDA and the FDA website directly, according to the Foundation's interviews with representatives of a drug app, a health information publisher, and a biointelligence software platform, as well as a roundtable with representatives of the technology sector. A few reported using secondary drug information databases and apps that use the FDA's data in their products.

2.2.1 Common Queries and Requests

Common queries and requests for FDA information and data from intermediary partners focused on:

- Approved drugs and new drug approvals
- Labeling information, including product labels and labeling changes
- Safety information, including adverse events, recalls, and new updates
- Postmarketing requirements and commitments

2.2.2 Challenges Encountered in Accessing and Using FDA Information

BOX 3. KEY OPPORTUNITIES FOR IMPROVING USE OF FDA INFORMATION BY INTERMEDIARY PARTNERS

- Make information searches easier and identify changes in information
- Information architecture (IA) can be improved for easier information discovery
- Use good flowcharts and other graphics to present data
- Harmonize data sources, so different structured datasets like APIs can be easily linked together by standardized and unique IDs
- Develop datasets that:
  - Include documentation about availability, timeliness, and updates
  - Are searchable
  - Have labeling that is consistent, updated, and downloadable
  - Provide a defined way to report typos or content errors to the FDA

Intermediary partners reported experiencing a number of hurdles in fully accessing FDA information and data (Box 3). Multiple intermediary partners shared several general challenges, revealing opportunities to improve access to and use of FDA information.

GENERAL CHALLENGES AND OPPORTUNITIES

Intermediary partners described searching through too much information to find what they need and would like it to be easier to access and use the information provided by the FDA. Specific examples of difficult-to-find information were:

- Drug indications by patient age (especially neonates)
- Specific drug indications by disease (e.g., oncology drugs are not searchable by type of cancer)
- Generic drugs

Other challenges included identifying changes to information, such as a drug indication, without reviewing source documents, and the need for more harmonized data sources so that different datasets like Application Programming Interfaces (API) can be easily linked together by standardized and unique IDs. Specifically, the intermediary partners said they would like to see the same identifiers (e.g., NDC Directory, index, or cross-reference numbers) across FDA datasets and also for external or third-party datasets. Intermediary partners added that they would like to see flowcharts and other graphic elements to present data.

Intermediary partners also would like to have access to searchable FDA datasets that include documentation about availability, timeliness, and updates on the data model and the metadata. For drug labels, they would like to see a consistent labeling structure for easier comparison of drugs with downloadable product labels and timely label updates, especially for older drugs where labeling is often vague.

Other opportunities included establishing a direct pathway or identifying a contact person for reporting typos or content errors to the FDA; creating an archive of old guidance documents so that intermediary partners can trace the evolution of the FDA's thinking on a topic; and providing an easy way to access information from public meetings and events or advisory meetings.

Intermediary partners would also like access to links to products by active ingredient (for generics and brand names of drugs), raw data on user fee performance metrics instead of compiled results, and a list of approved companion diagnostic tests for different drugs.

ADDITIONAL OPPORTUNITIES TO SERVE INTERMEDIARY PARTNERS

Specific opportunities voiced by intermediary partners included:

- Adding a feed of approved drugs, including the addition of new drugs upon approval
- Making information that is currently available in HTML tables available in a more useful format, such as an openFDA API
- Facilitating access to the history of a drug's review/approval status
- Providing regular updates of all datasets and including date of update
- Deleting conflicting information in datasets
- Developing an easier way to get information on biological products,[32] which is currently more difficult than finding information on drugs[33]
- Improving IA on the website to reduce the number of links needed to navigate to information

SECTION 3.

What Information the FDA Makes Publicly Available

This section of the report focuses on information and data that the FDA makes publicly available on its website (https://www.fda.gov) and on openFDA (https://open.fda.gov) related to drugs and biologics. The Foundation compiled FDA drug and biologics information currently available on CBER and CDER webpages and compiled the findings into a Catalog of FDA Data/Information Sources document (included in Appendix) that details how and what information and data the FDA makes publicly available. The Catalog of FDA Data/Information Sources was designed to make it easier for intermediary partners and professional researchers (Box 4) to access this highly fragmented information and data and integrate it into digital products.

BOX 4. KEY USERS OF THE CATALOG OF FDA DATA/INFORMATION SOURCES

- Software as a Service (SaaS) companies
- App developers
- AI companies
- Health information websites and publishers
- Professional researchers

In addition to organizing available FDA public data into one document that systematically categorizes and documents the FDA datasets, the Foundation aimed to provide a clear and reliable reference for intermediary partners and professional researchers seeking specific information. This structured approach facilitates easier discovery and understanding of FDA publicly available data and supports more efficient integration into various applications, such as research tools, healthcare websites, mobile apps, SaaS, AI tools, and more. The Catalog of FDA Data/Information Sources includes metadata descriptions, usage guidelines, and links to interactive tools and APIs, further enhancing the usability of FDA's data resources for intermediary partners.

3.1 CONTENTS OF THE CATALOG OF FDA DATA/INFORMATION SOURCES

The Catalog of FDA Data/Information Sources contains detailed information on dataset metadata for structured and unstructured data publicly available from the FDA (Box 5). Dataset metadata covers the structure, format, content, and other characteristics of the FDA's datasets and databases. Databases include Drugs@FDA, the FAERS, the Products Labeling Database, the NDC Directory, and more (Box 5).

Each data set includes a comprehensive description that provides an overview of its purpose and contents, helping users understand the scope and relevance of the information. The intended information stakeholders are clearly identified, highlighting which groups—such as healthcare professionals, researchers, and consumers—might benefit most from the dataset. Additionally, the usage volume for APIs is specified, giving users insight into how frequently the data is accessed and utilized, which can be a valuable indicator of its importance and business opportunity.

BOX 5. TYPES OF DATASETS IN THE CATALOG OF FDA DATA/INFORMATION SOURCES

- Datasets for end users (called **FDA customers**):
  - Patients and consumers
  - Healthcare professionals
  - Professional researchers
- Datasets for intermediary partners (called **FDA information partners**):
  - Health information websites and publishers
  - App developers
  - AI vendors
- Datasets on the FDA website and openFDA
- Datasets with data classification (data that is readily available to the public)

The Catalog provides crucial practical information, including links to the dataset's website, a mobile app link, API links, and if available, it provides a contact person for further inquiries. This guide helps users have direct access to the data and support resources, facilitating seamless integration into various applications. The inclusion of search fields and result set formats (HTML, PDF, CSV, Excel, etc.) along with the specific fields (columns) helps users quickly locate and retrieve the precise data they need. This level of detail is essential for enabling efficient data extraction and analysis, thereby supporting the development of innovative healthcare solutions and advancing research initiatives.

Each dataset includes:

- Description
- Intended information stakeholders
- Usage volume (for APIs)
- Links for the website, the dataset, a contact person, and if available, a mobile app
- Search field needed to retrieve data
- Result set format (HTML, PDF, CSV, Excel, etc.) and fields (columns)
- If applicable for the dataset: API website, dashboard, Data Entity Relationship Diagram (ERD), and Data Definition

BOX 6. PUBLIC DATASETS INCLUDED IN THE CATALOG OF FDA DATA/INFORMATION SOURCES

CENTER FOR DRUG EVALUATION AND RESEARCH

- Drugs@FDA Database
- FDA Adverse Event Reporting System
- Product Labels Database
- NDC Directory
- Recall Enforcement Report
- FDA Drug Alerts
- Drug Statements
- FDA Safety Information and Adverse Event Reporting Program (MedWatch)
- Drug Safety-related Labeling Changes (SrLC)
- FDA Drug Shortages
- Additions/Deletions for Prescription and OTC Drug Product Lists
- Dissolution Methods Database
- Inactive Ingredients in Approved Drug Products
- Medication Guides
- Postmarketing Requirements and Commitments
- Product-Specific Guidance for Generic Drug Development
- Risk Evaluation and Mitigation Strategies (REMS)
- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

- Blood Establishment Registration Database
- Human Cell and Tissue Establishment Registration Public Query
- Blood Grouping and Phenotyping Reagents
- Approved Cellular and Gene Therapy Products
- Biological Approvals
- Purple Book: Database of FDA-licensed (approved) Biological Products, including biosimilar and interchangeable products

3.2 DATA TYPES AND COMMUNICATION CHANNELS

3.2.1 Structured Data

Machine-readable and quantitative structured data uses a standardized format that is easy for people and computers to access, analyze, search, and store. Structured data is machine-readable and uses standard formats for systems to automate the exchange of information with each other. Structured data is preferred by intermediary partners for integrating publicly available FDA data into digital products. The FDA provides openFDA APIs with structured data in JSON/other formats (Figure 8).

FIGURE 8: Example of OpenFDA API Endpoint Return Data

For `count` queries (such as: https://api.fda.gov/drug/label.json?count=openfda.product_type.exact), the results section will look something like the following:


```
{
  "meta": {
    "disclaimer": "Do not rely on openFDA to make decisions regarding medical care. While we make every effort to ensure
that data is accurate, you should assume all results are unvalidated. We may limit or otherwise restrict your access to
the API in line with our Terms of Service.",
    "terms": "https://open.fda.gov/terms/",
    "license": "https://open.fda.gov/license/",
    "last_updated": "2017-12-02"
  },
  "results": [
    {
      "term": "HUMAN OTC DRUG",
      "count": 55849
    },
    {
      "term": "HUMAN PRESCRIPTION DRUG",
      "count": 33489
    }
  ]
}
```


The FDA website provides pages with embedded HTML tables of data that are best suited for human readability. These HTML tables can be exported to Excel or CSV formats but present challenges to intermediary partners and are not suited for automated data exchange between systems (Figure 9).

FIGURE 9: Example of HTML Table on Page Suitable for Human Readability

Search: Export Excel Show 10 entries

Brand Name (Drug Trials Snapshot)	Drug Name	Original Date of FDA Approval	FDA Approved Use on Original Approval Date*	Brand Name (Prescribing Information)
TEVIMBRA	tislelizumab-jsgr	March 14, 2024	To treat unresectable or metastatic esophageal squamous cell carcinoma	Tevimbra
LETYBO	letibotulinumtoxinA	February 29, 2024	To temporarily improve the appearance of moderate-to-severe glabellar lines	Letybo
AUGTYRO	repotrectinib	November 15, 2023	To treat ROS1-positive non-small cell lung cancer	Augtyro
FRUZAQLA	fruquintinib	November 8, 2023	To treat refractory, metastatic colorectal cancer	Fruzaqla

Showing 1 to 10 of 401 entries

Previous 1 2 3 4 5 ... 41 Next

Structured data is available on the FDA website (https://www.fda.gov) and openFDA (https://open.fda.gov).

On openFDA, users can access APIs and download raw data. According to the FDA, "openFDA provides APIs and raw download access to a number of high-value, high priority, and scalable structured datasets, including adverse events, drug product labeling, and recall enforcement reports."

APIs are software-to-software interfaces that allow different applications to talk to each other and exchange information or functionality. Information stakeholders send a request to the API to access data. The API then processes the request and sends a response. The most common ways to send a request to the API are:

- Manually, using a web browser (such as https://api.fda.gov/drug/label.json)
- Programmatically, by executing code that sends the request to the API

The structured data provided by openFDA APIs allows for seamless programmatic integration into various digital platforms and applications, enhancing the ability of developers to create innovative digital solutions that leverage the Catalog. This accessibility is crucial for developing healthcare tools, performing data analysis, and advancing research, as it ensures that high-quality, standardized data is readily available for automated processing and analysis. Furthermore, the use of APIs minimizes the need for manual data handling, reducing the risk of errors and increasing the efficiency of data-driven projects.

3.2.2 Unstructured Data

Unstructured data is qualitative content in HTML pages or PDF files on the FDA's website such as regulatory decisions, warnings, and labels. FDA Product Alert emails, a well-established FDA tool for communicating information, is an example of unstructured data.

This data is more difficult to analyze than structured data. Information stakeholders cannot directly integrate it into digital products and services, as they must first collect and process the data manually or use automation tools such as AI.

Despite the challenges, unstructured data holds significant value due to the depth and richness of the information it contains. Advanced technologies such as AI can be employed to extract meaningful insights from unstructured data. These tools can automate the extraction, transformation, and analysis processes, making it possible to derive actionable insights from large volumes of text-heavy content. By leveraging these technologies, stakeholders can unlock valuable information that can drive decision-making, enhance regulatory compliance, and improve public health outcomes.

Unstructured data is available throughout the FDA website (https://www.fda.gov).

3.2.3 Data Harmonization

Data harmonization refers to the process of standardizing data from various FDA sources to ensure consistency, accuracy, and usability relationships or links between data sources. The FDA collects and publishes vast amounts of data across different domains, including drug labeling, adverse events, and recall enforcement

reports. However, these datasets often originate from disparate systems and formats, making it challenging for users to integrate and analyze the information effectively. Through data harmonization, openFDA aligns these datasets into a common format, enabling seamless interoperability and enhancing the overall quality of the data (Table 8).

	Device	Drug			
Field	Drugs@FDA	Enforcement	Event	Label	NDC
manufacturer_name	✔	✔	✔	✔	✔
unii	✔	✔	✔	✔	✔
product_type	✔	✔	✔	✔	
spl_set_id	✔	✔	✔	✔	✔
route	✔	✔	✔	✔	
generic_name	✔	✔	✔	✔	
brand_name	✔	✔	✔	✔	
product_ndc	✔	✔	✔	✔	
substance_name	✔	✔	✔	✔	

One of the key benefits of data harmonization is the facilitation of automated data exchange and integration. By using standardized formats such as JSON for API responses, openFDA allows developers and researchers to easily incorporate FDA data into their applications and analyses. This harmonization process involves aligning data definitions, ensuring consistent use of terminology, and resolving discrepancies between datasets. As a result, users can trust that the data they are accessing is accurate, reliable, and compatible across different use cases and platforms.

Data harmonization supports advanced analytics and machine learning applications. Consistent and well-structured data is essential for training accurate predictive models and conducting meaningful trend analyses. With harmonized datasets, researchers can efficiently combine data from multiple sources to gain deeper insights into drug safety, efficacy, and public health trends. This unified approach not only enhances the value of the data but also accelerates the development of innovative healthcare solutions that rely on robust and integrated FDA information.

BOX 7. HARMONIZED FIELDS

- **Application Number:** Standardized format for New Drug Application (NDA), Abbreviated New Drug Application (ANDA), and Biologic License Application (BLA).
- **Brand Name:** Consistent naming conventions for drug brands across different datasets.
- **Generic Name:** Uniform generic names for drugs to ensure they are recognized across all data sources.
- **National Drug Code (NDC):** A standardized 10-digit, 11-digit, or 12-digit code that uniquely identifies drug products.

Limits of openFDA Harmonization

Not all records have harmonized fields. Because the harmonization process requires an exact match, some drug products cannot be harmonized in this fashion—for example, if the drug name is misspelled by the original data entry source or process outside of the FDA control. Some drug products will have openFDA sections, while others will not if there was no match during the harmonization process. Conversely, searching in these fields will only return a subset of records from a given endpoint.

3.3 Additional FDA Information and Communication Channels

While this report focuses on FDA information that is publicly available on the FDA website and openFDA, the Agency has many other information and communication channels that information stakeholders can access (Box 8). These additional channels ensure that the FDA's vast repository of data and information is disseminated widely and reaches diverse audiences. One such channel is the FDA MedWatch program, FDA's safety information and adverse event reporting program. MedWatch provides healthcare professionals and the public with access to timely safety alerts about drugs, medical devices, vaccines, and other FDA-regulated products. This program also allows users to report adverse events and product quality issues, facilitating real-time monitoring and response to potential health risks. MedWatch alerts are disseminated through email notifications, the FDA website, and social media platforms, ensuring broad and immediate access to critical safety information.

BOX 8. OTHER FDA INFORMATION AND COMMUNICATION CHANNELS

- FDA MedWatch
- Social media
- Email alerts
- RSS feeds
- Webinars and online seminars
- Federal Register
- Querying apps for multiple datasets
- Public meetings and workshops
- Industry notifications

In addition to MedWatch, the FDA engages with the public and stakeholders through various social media channels, including X (formerly Twitter), Facebook, and LinkedIn. These platforms are used to share important updates, safety information, and educational content. The FDA also conducts webinars, online seminars, and virtual meetings to provide in-depth information on specific topics, such as regulatory changes, new drug approvals, and public health initiatives. These interactive formats allow for real-time engagement and feedback from stakeholders, enhancing the FDA's ability to communicate effectively and transparently.

The FDA maintains a robust presence in the Federal Register, where it is required by law to publish proposed regulations, rule changes, and other official notices. The Federal Register is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations. It is a key resource for regulatory professionals and industry stakeholders, providing detailed information on the FDA's regulatory activities and inviting public comments on proposed actions. By leveraging these various channels, the FDA ensures that its information is accessible, transparent, and actionable for all stakeholders, from healthcare professionals and researchers to consumers and industry representatives.

SECTION 4.
Conclusion

Regardless of the group or subgroup, all FDA information stakeholders look for easier ways to find and use the information they seek, which presents an opportunity to facilitate better use of FDA information. Stakeholders identified specific challenges and opportunities for the FDA and other information sources to better serve stakeholder information needs (Figure 10).

FIGURE 10. Challenges and Opportunities in the Access and Use of Publicly Available Information

Patients and consumers

- Would like to be able to find in-depth health information on the FDA's website faster
- Need health information that is easier to access and read
- Struggle to access, understand, and assess the quality of health information

Healthcare professionals

- Experience hurdles in using private sector drug apps, especially:
  - Incomplete and inconsistent information
  - Limited search capabilities
  - Infrequent data updates

Professional researchers

- Need complete, harmonized, and updated information and data from the FDA
- Would like access to data that is currently difficult to access or not available, such as:
  - Historical data
  - Archived guidance documents to trace evolution of FDA's thinking on a specific topic
  - Status of postmarketing studies
  - Information on National Drug Code (NDC) on drug labels

Intermediary partners

- Need harmonized data sources
- Need the date that dataset was updated
- Would like searchable datasets that include documentation about availability, timeliness, and updates
- Want more datasets available in openFDA
- Prefer structured datasets, like APIs (unstructured information like PDFs, letters, or decisions require AI to extract machine-readable data)

In its collection of approved drug and biologic product labeling, tracking of ongoing postmarketing commitments, and policy adjudications of relevant topics, the FDA holds some of the most valuable data in human health, which has tremendous potential for improving understanding of medical products and enabling advancements that benefit all Americans. In this position, there is a remarkable opportunity for the Agency to ensure that its publicly available information is both accessible and presented in ways that best serve its information stakeholders. This holds true regardless of whether the end users of publicly available FDA information (patients, consumers, healthcare professionals, and professional researchers) go directly to the FDA for their health information or obtain it from intermediary partners that use publicly available FDA information to develop digital content and products for end users.

FDA information stakeholders need information that is easier to access and use. Patients and consumers often struggle to find and understand online health information. Professional researchers and intermediary partners need access to more complete and consistent information that is updated frequently and easy to search.

Most end users and intermediary partners would also like information to be easier to find and more visual (e.g., flowcharts). Providing additional apps that query multiple data sources simultaneously, as well as expanding openFDA and simplifying the process of creating queries and apps, would bring tremendous benefit to information seekers.

Having a better understanding of the needs of end users and intermediary partners will enable the FDA in the short term to ensure that patients, consumers, healthcare professionals, and researchers can easily find accurate and up-to-date information, and that intermediary partners can easily integrate FDA information into their digital content and products. In the long term, doing so would allow the Agency to improve its communication strategy and extend the functionality of its publicly available information.

SECTION 5.
Methods

The findings outlined in this report are based on several sources of information (Box 9). The Foundation engaged Damiano Group Scientific Communications to assist in developing the report, Copotential to provide the technical assessment, and Workforce Elevated to conduct survey analysis and roundtable moderator guide preparation.

Consumer Survey: The Foundation added several questions related to health information-seeking behavior to Echelon Insights' monthly national consumer omnibus survey (Box 10. Questions asked about the types of health information respondents search for, which sources they use to find health information online, how often they were able to find the health information they were looking for, their trust in various sources of health information, and actions they take to validate health information, such as checking the date of the information, checking the original source of information, and searching for other sources to verify the information.

Echelon Insights distributed this survey online on December 12–14, 2023, and 2,017 Americans responded. The margin of sampling error was +/- 2.5 percentage points. The sample was weighted using population benchmarks based on gender, age, race/ethnicity, education, income, employment, marital status, children, community, religion, and insurance. Key findings from the consumer survey were analyzed by Workforce Elevated. The survey results helped inform the findings about the patient and consumer end user subgroup for FDA information stakeholders presented in this report.

Catalog of FDA Data/Information Sources: The Foundation engaged Copotential to create a comprehensive catalog of publicly available FDA data related to the work of the CDER and the CBER. The Catalog includes detailed information on dataset metadata (not the data itself) of various FDA databases found on the FDA website (https://www.fda.gov) and the openFDA website (https://open.fda.gov), including Drugs@FDA, the FAERS, the Product Labels Database, the NDC Directory, and more. The Catalog of FDA Data/Information Sources is included as an appendix.

BOX 9. SOURCES OF INFORMATION FOR IMPROVING ACCESS TO PUBLICLY AVAILABLE FDA DATA

- Consumer survey (quantitative)
- Catalog of FDA Data/Information Sources
- FDA User Search Behavior and Intent Analysis
- Interviews with stakeholders (in-depth)
- Landscape analysis
- Roundtables with experts
- Roundtables with patients and consumers

BOX 10. HEALTH INFORMATION-SEEKING BEHAVIOR SURVEYED

- Types of health information consumers search for
- Sources used to find health information online
- How often consumers can find the health information they were looking for
- Consumers' trust in various sources of health information
- Actions consumers take to validate health information, such as:
  - Checking the date of the information
  - Checking the original source of information
  - Searching for other sources to verify the information

FDA User Search Behavior and Intent Analysis: The Foundation engaged Copotential to analyze FDA website traffic behavior (FDA, CDER, and CBER websites) and users' organic search keywords to better understand users' intent when searching. The data included in the analysis came from trusted data providers, ML algorithms, and Google trends. Copotential gathered FDA website traffic analytics, organic search data (worldwide or U.S. only), and keyword data. They integrated keyword data with Google trends to further understand users' search behavior and intent. Next, they analyzed and classified results to find common patterns and develop a data narrative.

The data reflects the entire month of December 2023 and a single day, February 4, 2024. The social and historical context of the timeframe selected for data analysis may introduce bias.

Interviews with Stakeholders: The Foundation recruited more than 15 experts from relevant fields, including government agencies, search platforms, health information websites, researchers, regulatory-focused nonprofit organizations, drug and biological manufacturers, AI vendors, and payors for 30- to 60-minute interviews. The team asked interviewees to share their experiences finding and using the FDA's publicly available information, including the types of information they seek, how they search for information, and the challenges they encounter in finding or using the information. They also asked some experts for general insights.

Landscape Analysis: The Foundation conducted a literature review of nearly 70 sources, including health information websites and peer-reviewed research articles, to better understand the current online health information-seeking behavior of patients and consumers, healthcare professionals, and researchers as it pertains to FDA-regulated medical products. The landscape analysis helped inform the research in support of this project and report.

Roundtables with Experts: The Foundation convened two expert roundtables to learn more about stakeholder information needs and experiences accessing information on the FDA website or through various Agency information streams. The first roundtable consisted of academic researchers who use publicly available FDA data for research and policy work. The second roundtable consisted of experts from the technology sector, including individual developers, small software companies, product managers, data scientists, and AI practitioners. The Foundation team recruited participants for these roundtables, and Foundation staff moderated the discussions.

In the academic researcher roundtable, the Foundation gathered participant feedback on hurdles to using publicly available FDA data and information in their research, as well as their suggestions to make this data and information easier to use. In the technology expert roundtable, the Foundation gathered participant feedback on how these intermediary partners would leverage the FDA's publicly available drug information to create end user products including mobile apps, websites/SaaS, chatbots, and AI models.

Roundtables with Patients and Consumers: Echelon Insights, a research and polling company, was engaged to recruit participants for three patient and consumer roundtables:

- **Session 1**–U.S. adults who have sought health information online in the past 12 months. Participants were demographically diverse, though the group was weighted toward those who self-identify as non-white.
- **Session 2**–U.S. adults who have sought health information online in the past 12 months and have at least one chronic health condition (e.g., heart disease, diabetes, lung disease). Participants were demographically diverse, though the group was weighted toward those who self-identify as non-white.
- **Session 3**–U.S. adults diagnosed with a rare disease or serious health condition, or caregivers of patients diagnosed with a rare disease or serious health condition, who have looked for health information at least three times monthly. Participants were demographically diverse, though the group was weighted toward those who self-identify as non-white.

The Foundation developed moderator guides for each of these sessions, asking participants to share where and how they search for health information, how they deem health information trustworthy or untrustworthy, their preferred format for consuming health information (e.g., text vs. video), and related questions. Each session lasted approximately 60 minutes and included 8–10 participants. From these sessions, the Foundation identified common response themes, which were included in the findings listed in this report.

SECTION 6.

Acknowledgements

We thank the following individuals and others for sharing their expertise and perspectives for this project:

Laura Caliguiri

Matt Crowson

Lea Drye

Gerrit Hamre

Pravin Jadhav

Ashley Jones-Mitchell

Cameron Kieffer

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Brendan O'Leary

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Andrew Robertson

Brian Scarpelli

Khushboo Sharma

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Mariana Socal

Philip Thornton

John Whyte

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SECTION 7.

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SECTION 8.

Appendix

Data from the graphs included in this report and Data Catalog.

TABLE A: COMMON QUERIES BY PATIENTS AND CONSUMERS	
SEARCH TOPIC	**QUERIES**
Side effects	59%
Product safety	41%
How well product works	38%
How the product works	35%
Food or medicine interactions	33%
How to use the product	31%
Cost and insurance coverage	31%

TABLE B: SEARCHES OF INFORMATION ON THE FDA'S WEBSITE BY CATEGORY	
CATEGORY	**SEARCH VOLUME**
FDA actions and information	**65%**
Medication	**28%**
Treatments	**7%**

TABLE C: COMMON SOURCES OF HEALTH INFORMATION FOR CONSUMERS AND PATIENTS	
SOURCE	**USERS**
Health information websites	**44%**
Social media	**29%**
Disease-specific websites (e.g., American Cancer Society)	**19%**
Traditional media	**19%**
Drug and device manufacturer websites	**19%**
Government websites	**18%**
Internet discussion forums (e.g., Reddit and Quora)	**16%**

TABLE D: LEVELS OF TRUST IN SOURCES OF ONLINE HEALTH INFORMATION	
SOURCE	**USERS**
Health information websites	**78%**
Disease-specific websites	**78%**
Government websites	**68%**
Drug and device manufacturer websites	**62%**
Internet forums	**35%**
Social media	**33%**

SECTION 9.
Catalog of FDA Data/Information Sources Focused on the Center for Drug Evaluation and Research (CDER) and Center for Biologic Evaluation and Research (CBER)

A Supplement to Improving Access to Publicly Available FDA Information, from the Reagan-Udall Foundation for the FDA

DATA CATALOG TABLE OF CONTENTS

A. INTRODUCTION

The Catalog of FDA Data/Information Sources document, created by the Reagan-Udall Foundation for the FDA, serves as a comprehensive catalog of publicly available FDA data related to the work of the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).[1] The document is part of the discovery phase of a multi-phased initiative to make FDA's publicly available information easier to access.

This document aims to provide a single source for the publicly available FDA data that otherwise is highly fragmented and challenging to find and understand across the FDA website. The document hopes to facilitate the private sector development of applications, systems, and websites that advance and amplify FDA publicly available data in exciting new ways in the B2C (Business-to-Consumer) and B2B (Business-to-Business) business models, new digital channels and new ways to reach consumer segments, the healthcare industry, and the research and scientific community.

Overview

The document includes detailed information on dataset metadata, which refers to data about the data, such as the structure, format, content, and other characteristics of these datasets, of various FDA databases, including Drugs@FDA, the FDA Adverse Event Reporting System (FAERS), the Product Labels Database, and the National Drug Code (NDC) Directory, and more.

The FDA data can be categorized into structured and unstructured data.

Structured Data: Accessible through openFDA APIs and the FDA website, this data includes HTML tables and can be exported into Excel or CSV formats. The private sector can integrate this machine-readable FDA information into their digital products.

Unstructured Data: This data includes content found on the FDA website in the form of HTML content or PDF documents that might include regulatory decisions, warnings, and labels. The private sector can harness this unstructured data in automated or manual means to integrate it into their digital products.

Audience

This document is primarily designed for private sector companies that aim to harness FDA's public data for developing innovative healthcare solutions, such as SaaS companies, mobile app companies, and artificial intelligence (AI) companies for B2C and B2B business models. These companies can use this document to find FDA publicly available data, and quickly understand the data metadata and the optimal ways to get access to the data. Potential use cases include product managers trying to create a new digital product with the FDA's publicly available data; data analysts trying to answer questions about the healthcare space; and engineers seeking detailed insights into the nature and composition of the data.

1 The scope of this phase of the project is limited to information from CBER and CDER.

Assumptions

This document focuses on:

- Data found on the FDA website (https://www.fda.gov) and the openFDA site (https://open.fda.gov).
- Metadata of the FDA publicly available data and not on the data itself.
- Information from CBER and CDER.

Users of the FDA data should consider standard data assessment processes.

B. FDA STAKEHOLDERS AND THEIR CUSTOMERS

The FDA has numerous stakeholders, listed below along with types of publicly available data sought by their customers. This document focuses on three types of customers: customers and patients; healthcare professionals; and researchers and scientists. Throughout the document, special attention will be paid to customers and patients, as this would represent the B2C sector.

1. **Consumers and Patients:** The FDA provides information directly to consumers and patients to promote safe and informed choices. This includes drug safety warnings, recalls, and health education materials.
2. **Healthcare Professionals:** This group comprises doctors, nurses, pharmacists, and other healthcare providers. They rely on FDA information for updates on drug approvals, safety alerts, and to develop guidelines for medical practice.
3. **Researchers and Scientists:** Researchers in medicine and pharmacology often refer to FDA data and research findings for their studies.
4. **Pharmaceutical and BioTech Companies:** Companies that develop and manufacture drugs, therapeutics, and diagnostics closely follow FDA regulations and guidance to ensure compliance and market approval.
5. **Regulatory Professionals:** Professionals who work in regulatory affairs and compliance within industries regulated by the FDA use FDA guidance and updates to ensure their products meet regulatory standards.
6. **Government Agencies:** Other government agencies, both in the United States and internationally, may collaborate with or refer to the FDA for regulatory guidance and safety standards.
7. **Legal Professionals:** Attorneys and legal experts use FDA information in cases related to product liability, intellectual property, and regulatory compliance.
8. **Media and Journalists:** News outlets and journalists often report on FDA announcements, such as drug approvals, safety recalls, and policy changes, making the general public aware of important developments.
9. **Content Creators and Influencers:** Social Media content creators and influencers in the healthcare space may use FDA data to create content that explains, teaches, argues, debunks, amplifies, and informs their audiences on social media platforms and channels like Facebook, Instagram, X (Twitter), TikTok, and others.

C. FDA INFORMATION CHANNELS

The list below includes digital channels that the FDA uses to share publicly available data. This includes structured data like the FDA Datasets and unstructured data like the FDA website.

1. **FDA Website:** The FDA maintains an official website (www.fda.gov) where it publishes a wide range of information, including regulations, guidelines, press releases, safety alerts, and reports. This is a central hub for FDA-related information.
2. **FDA MedWatch:** MedWatch is the FDA's safety information and adverse event reporting mechanism. Healthcare professionals and the public can report adverse events, product complaints, and safety concerns through the MedWatch program, and the FDA uses this channel to disseminate safety alerts and updates.
3. **FDA Press Releases:** The FDA issues press releases to announce important updates, such as new drug approvals, safety warnings, recalls, and regulatory changes. These press releases are distributed to media outlets and posted on the FDA website.
4. **FDA Social Media:** The FDA maintains official social media accounts on platforms like X (Twitter) and Facebook, where it shares important updates, safety information, and health-related content. These channels allow for real-time communication and engagement with the public.
5. **FDA Email Alerts:** The FDA offers email subscription services that enable individuals to receive updates on specific topics of interest, such as drug safety, food recalls, or regulatory guidance.
6. **FDA Datasets:** The FDA offers various datasets covering a range of topics, including drug approvals, recalls, inspections, adverse events, and more. These datasets are often available for download on the FDA's Open Data Portal (open.fda.gov) and can be used for research and analysis.
7. **FDA RSS Feeds:** The FDA provides RSS feeds for various categories of information, allowing users to receive updates relating to specific areas of interest.
8. **FDA Webinars and Online Seminars:** The FDA conducts webinars, online seminars, and virtual meetings to share information and engage with stakeholders on topics related to regulations, product approvals, and public health.
9. **Federal Register:** Proposed regulations, rule changes, and other official notices are published in the Federal Register, a legal journal where the FDA communicates changes to regulatory requirements and invites public comments.
10. **FDA Databases and Tools:** The FDA maintains various databases and online tools that provide access to specific types of data, such as the Drug Approval Database and the Facility Registration System.
11. **Public Meetings and Workshops:** The FDA holds public meetings, workshops, and advisory committee meetings to discuss important regulatory matters and to solicit input from stakeholders.
12. **Industry Notifications:** The FDA communicates with regulated industries, such as pharmaceutical and BioTech companies, through industry-specific notifications, guidance documents, and compliance programs.

D. FDA INFORMATION PARTNERS

The list below includes private sector companies that may be using FDA publicly available data. The companies obtain that data in different ways; from the openFDA APIs; by scraping the FDA website; or by processing the FDA Email Alerts. These processes to obtain that data might be automatic, semi-automatic, and manual. The data obtained by these companies might be further validated for quality purposes.

1. **Drugs.com (drugs.com):** Drugs.com is a resource for medication information, interactions, and dosages, along with health news.
2. **WebMD (webmd.com):** WebMD is a comprehensive health and medical information website providing articles, news, and resources on a wide range of health topics.
3. **Mayo Clinic (mayoclinic.org):** Mayo Clinic offers authoritative health information, articles, and tools, as well as clinical expertise.
4. **DailyMed (https://dailymed.nlm.nih.gov/dailymed/):** The National Library of Medicine (NLM)'s DailyMed searchable database provides the most recent labeling submitted to the Food and Drug Administration (FDA) by companies. This database is often used to supplement the FDA website information.
5. **Healthline (healthline.com):** Healthline is a popular health and wellness website with articles, expert advice, and health tools.
6. **MedlinePlus (medlineplus.gov):** MedlinePlus, a service of the U.S. National Library of Medicine, provides reliable health information, including articles and interactive tutorials.
7. **Cleveland Clinic (my.clevelandclinic.org):** The Cleveland Clinic offers health information, articles, and resources on various medical conditions and treatments.
8. **Everyday Health (everydayhealth.com):** Everyday Health offers a variety of health and wellness content, including articles, videos, and expert advice.
9. **FamilyDoctor.org (familydoctor.org):** Operated by the American Academy of Family Physicians, FamilyDoctor.org provides reliable health information for patients and families, with a focus on primary care and preventive health.

E. FDA DATA CLASSIFICATION

The list below identifies possible FDA data governance. Among these categories, this document focuses on publicly available data (information) found on the FDA website and openFDA for The Center for Drug Evaluation and Research (CDER) and The Center for Biologics Evaluation and Research (CBER).

1. **Public Data:** Public data from the FDA includes information that is readily accessible to the public. This might include general information about FDA policies, guidelines, and regulations. It is typically non-sensitive and meant to inform the public and stakeholders.
2. **Confidential Data:** Confidential data includes information that is not publicly disclosed and is typically considered sensitive. This category includes trade secrets, proprietary research data, and certain pre-market approval information for drugs and medical devices. Access to confidential data is restricted to authorized individuals and organizations.
3. **Proprietary Data:** Proprietary data is closely related to confidential data and refers to information that belongs to a specific company or entity. It can include data submitted by pharmaceutical and medical

device companies during the drug approval process, which is protected from public disclosure to encourage innovation. Access to proprietary data is typically limited to the FDA and authorized personnel.

4. **Clinical Trial Data:** Clinical trial data is a specific type of data that pertains to the results of clinical trials conducted during the development of drugs and medical devices. This data is used by the FDA to evaluate the safety and efficacy of these products. It is considered confidential and not publicly available.
5. **Post-Market Surveillance Data:** This type of data relates to the monitoring of products once they are on the market. It includes adverse event reports, product complaints, and other information that helps the FDA assess the ongoing safety and effectiveness of regulated products.
6. **Regulatory Data:** Regulatory data encompasses all information related to the regulatory processes of the FDA. This includes product applications, submissions, approvals, and other documentation related to the regulation of food, drugs, medical devices, and other products.

F. FDA DATASET SELECTION CRITERIA

The FDA has a vast amount of publicly available data. It was necessary to establish selection criteria to present the FDA data that would provide value to the private sector. The criteria are defined as follows:

- Datasets for these “FDA Customers”
  - Healthcare Professionals, Consumers and Patients, and Researchers and Scientists
- Datasets for these “FDA Information Partners”
  - Companies like Drugs.com, WebMD
- Datasets found in these “FDA Information Channels”
  - FDA openFDA, FDA website
- Datasets with “FDA Data Classification” as follows
  - Public Data

G. FDA DATASET LIST

The list of publicly available FDA datasets below was selected based on previous criteria. Each dataset contains the following:

- Dataset description
- Customers that might be interested in the dataset (customers and patients, healthcare professionals, researchers and scientists, and/or private sector)
- Usage volume (available for APIs)
- Website link
- Website contact (or data owner contact)
- Website dataset link
- Website search fields
- Website result set format (HTML, PDF, CSV, Excel, etc.)
- Website result set fields (columns)
- If there is a mobile app available for the dataset, links to the corresponding App Stores.

If the dataset is in openFDA:

- API website link
- API dashboard link
- API Search link
- Data Entity Relationship Diagram (ERD) if available
- Data definition.

Center for Drug Evaluation and Research

LIST OF FDA PUBLIC DATASETS FOR THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER):

- Drugs@FDA Database
- Adverse Event Reporting System (FAERS)
- Product Labels Database
- National Drug Code (NDC) Directory
- Recall Enforcement Report
- Drug Alerts
- Drug Statements
- FDA Safety Information and Adverse Event Reporting Program
- Drug Safety-related Labeling Changes (SrLC)
- FDA Drug Shortages
- Additions/Deletions for Prescription and OTC Drug Product Lists
- Dissolution Methods Database
- Inactive Ingredients in Approved Drug Products
- Medication Guides
- Postmarketing Requirements and Commitments
- Product-Specific Guidances for Generic Drug Development
- Risk Evaluation and Mitigation Strategies (REMS)
- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Center for Biologics Evaluation and Research

LIST OF FDA PUBLIC DATASETS FOR THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER):

- Blood Establishment Registration Database
- Human Cell and Tissue Establishment Registration Public Query
- Blood Grouping and Phenotyping Reagents
- Approved Cellular and Gene Therapy Products
- Biological Approvals
- Purple Book (database of FDA-licensed (approved) biological products, including biosimilar and interchangeable products)[2]

H. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Drugs@FDA Database

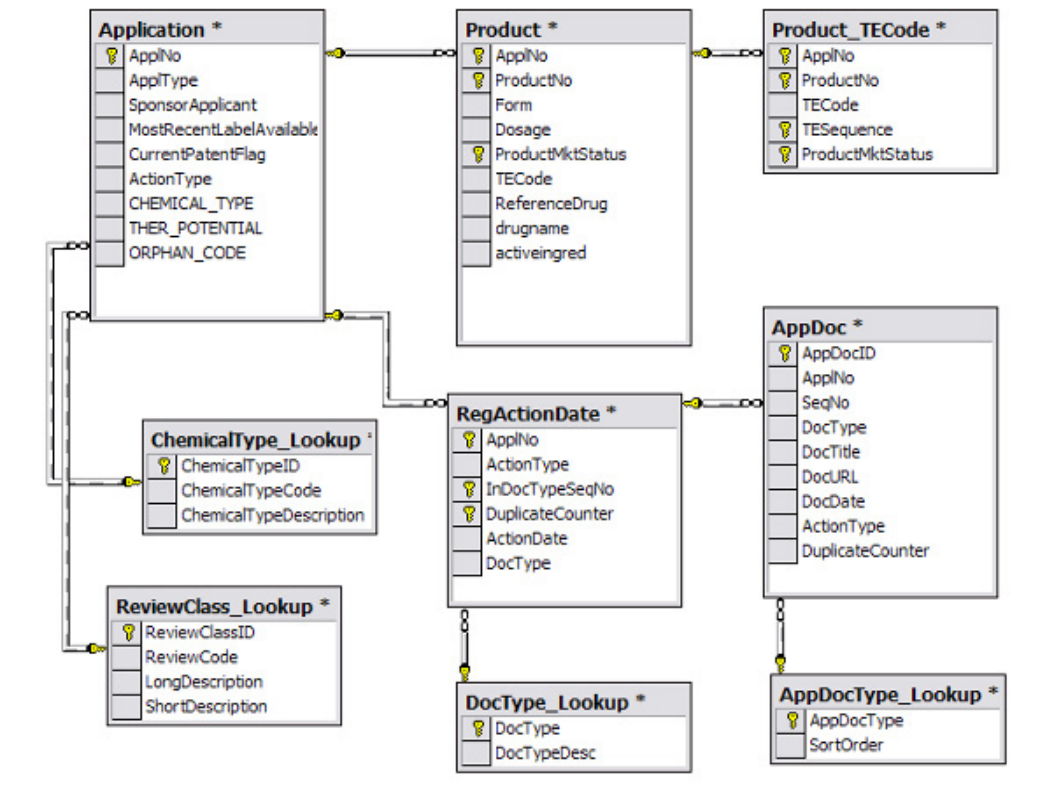
Description	The FDA Drugs@FDA Database is an online resource that provides comprehensive information about FDA-approved prescription and over-the-counter drugs, including their regulatory and approval history. This database allows users to search for specific drugs and view details such as product labeling, approval letters, reviews by FDA staff, and the history of changes to the drug's label. It's particularly useful for healthcare professionals, researchers, and consumers seeking detailed information about the regulatory background and evidence supporting the safety and efficacy of medications. By making this information publicly accessible, the FDA Drugs@FDA Database enhances transparency in the drug approval process and aids in informed decision-making about medication use. It reflects the FDA's commitment to providing accurate, up-to-date information on the medications available in the U.S. market. Information about FDA-approved brand names and generic prescription and over-the-counter human drugs and biological therapeutic products. Drugs@FDA includes most of the drug products approved since 1939. The majority of patient information, labels, approval letters, reviews, and other information are available for drug products approved since 1998.
Customers	• **Healthcare Professional**[3] • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ **Highly Usage**[4] — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

2 The Purple Book is a CDER database as CDER reviews BLAs. Both the CBER and CDER-regulated BLAs are in the Purple Book.

3 The bolded customers might benefit from the corresponding dataset.

4 Data usage is based on the openFDA API usage statistics https://open.fda.gov/about/statistics/, or correspondent website page traffic.

Website contact	
Website dataset	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Website search fields	Search by Drug Name, Active Ingredient, or Application Number
Website result set format	HTML page, CSV, Flat file, API available
Website result set fields	**Product** New Drug Application (NDA) Company Drug Name Active Ingredients Strength Dosage Form/Route (Tablet, Oral, Injectable, Capsule, Solutions, Cream, Injection, Vial, Single-Use, Solution, Subcutaneous) Marketing Status (None (Tentative Approval), Prescription, Over-the-counter, Discontinued) TE Code (None, AP) RLD (Yes, No) RS (Yes, No)
	Approval Date and History, Letters, Labels, Reviews Action Date Submission Action Type () Submission Classification Review Priority (Orphan Status) Letters, Reviews, Labels, Patient Package Insert Notes
	Labels Action Date Submission Supplement Categories or Approval Type Letters, Reviews, Labels, Patient Package Insert Note
	Other OTC Drugs with the same Active Ingredients, Strength and Dosage Form/Route Drug Name Active Ingredients Strength Dosage Form/Route Market Status RLD Application No. Company

Mobile app available?	**Apple** (https://itunes.apple.com/us/app/drugs-fda-express/id1318248918?mt=8) **Android** (https://play.google.com/store/apps/details?id=gov.fda.daf&hl=en)
API available?	**Yes** (see API section below for more info)
API website	https://open.fda.gov/apis/drug/drugsfda/
API dashboard, interactive, fields definitions	https://open.fda.gov/apis/drug/drugsfda/explore-the-api-with-an-interactive-chart/
API Search	https://open.fda.gov/apis/drug/drugsfda/searchable-fields/
Data Entity Relationship Diagram (ERD)	
	https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files
Data definition	**ActionTypes_Lookup** [ActionTypes_LookupID] [int] IDENTITY(1,1) NOT NULL [ActionTypes_LookupDescription] [varchar](100) NOT NULL [SupplCategoryLevel1Code] [varchar](100) NULL [SupplCategoryLevel2Code] [varchar](100) NULL

Data definition	
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	ApplicationsDocsType_Lookup [ApplicationDocsType_Lookup_ID] [int] IDENTITY(1,1) NOT NULL ApplicationDocsType_Lookup_Description] [varchar](200) NOT NULL
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Data definition	
	SubmissionPropertyType [ApplNo] [char](6) NOT NULL [SubmissionType] [char](10) NOT NULL [SubmissionNo] [int] NOT NULL [SubmissionPropertyTypeCode] [varchar](50) NOT NULL (Orphan or NULL) SubmissionPropertyTypeID [int] NOT NULL
	Submissions [ApplNo] [char](6) NOT NULL [SubmissionClassCodeID] [int] NULL [SubmissionType] [char](10) NOT NULL [SubmissionNo] [int] NOT NULL [SubmissionStatus] [char](2) NULL [SubmissionStatusDate] [datetime] NULL [SubmissionsPublicNotes] [text] NULL [ReviewPriority] [varchar](20) (Standard, Priority, NULL)
	TE [ApplNo] [char](6) NOT NULL [ProductNo] [char](3) NOT NULL [MarketingStatusID] [int] NOT NULL [TECode] [varchar](100) NOT NULL

Drugs@FDA from openFDA API

The openFDA Human Drug - Drugs@FDA, provides an API data dictionary found at:

- https://open.fda.gov/data/datadictionary
- https://open.fda.gov/fields/drugsfda_reference.pdf

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
application_ number	string	1	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the application number will be the CFR citation corresponding to the appropriate Monograph (e.g. “part 341”). For unapproved drugs, this field will be null.
openfda. application_ number	array of strings	1	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the application number will be the CFR citation corresponding to the appropriate Monograph (e.g. “part 341”). For unapproved drugs, this field will be null.

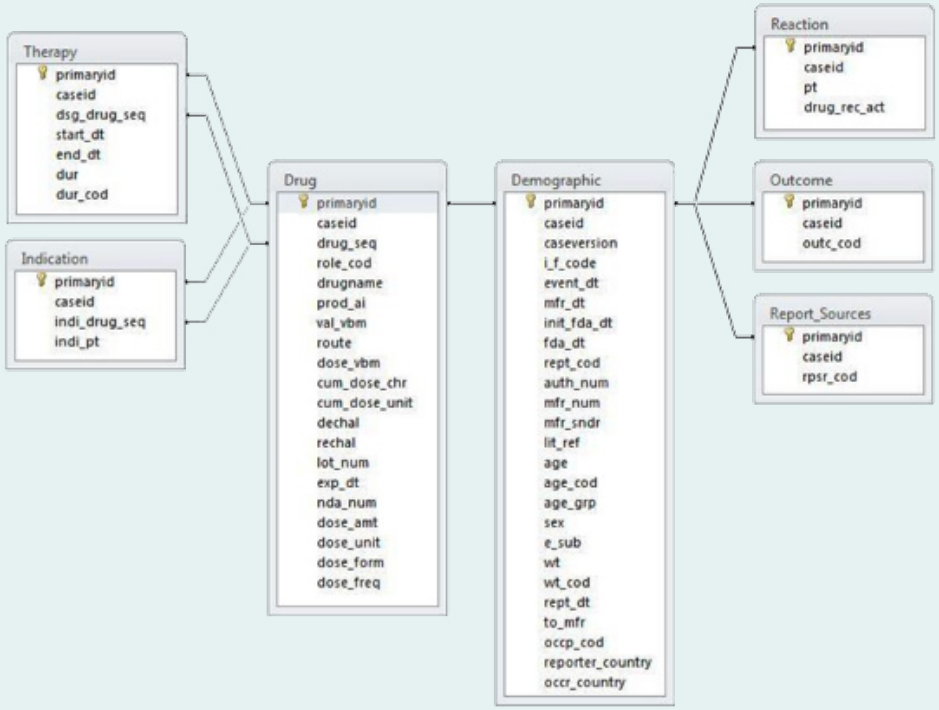
FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
openfda. brand_name	array of strings	1	Brand or trade name of the drug product.
openfda. generic_name	array of strings	1	Generic name(s) of the drug product.
openfda. manufacturer_ name	array of strings	1	Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.
openfda.nui	array of strings	1	Unique identifier applied to a drug concept within the National Drug File Reference Terminology (NDF-RT).
openfda. package_ndc	array of strings	1	This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug.
openfda. pharm_class_ cs	array of strings	1	Chemical structure classification of the drug product's pharmacologic class. Takes the form of the classification, followed by `[Chemical/Ingredient]` (such as `Thiazides [Chemical/Ingredient]` or `Antibodies, Monoclonal [Chemical/ Ingredient].
openfda. pharm_class_ epc	array of strings	1	Established pharmacologic class associated with an approved indication of an active moiety (generic drug) that the FDA has determined to be scientifically valid and clinically meaningful. Takes the form of the pharmacologic class, followed by `[EPC]` (such as `Thiazide Diuretic [EPC]` or `Tumor Necrosis Factor Blocker [EPC]`.
openfda. pharm_class_ moa	array of strings	1	Mechanism of action of the drug—molecular, subcellular, or cellular functional activity—of the drug's established pharmacologic class. Takes the form of the mechanism of action, followed by `[MoA]` (such as `Calcium Channel Antagonists [MoA]` or `Tumor Necrosis Factor Receptor Blocking Activity [MoA]`.
openfda. pharm_class_ pe	array of strings	1	Physiologic effect or pharmacodynamic effect—tissue, organ, or organ system level functional activity—of the drug's established pharmacologic class. Takes the form of the effect, followed by `[PE]` (such as `Increased Diuresis [PE]` or `Decreased Cytokine Activity [PE]`.
openfda. product_ndc	array of strings	1	The labeler manufacturer code and product code segments of the NDC number, separated by a hyphen.
openfda.route	array of strings	1	The route of administation of the drug product.
openfda.rxcui	array of strings	1	The RxNorm Concept Unique Identifier. RxCUI is a unique number that describes a semantic concept about the drug product, including its ingredients, strength, and dose forms.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
openfda.spl_id	array of strings	1	Unique identifier for a particular version of a Structured Product Label for a product. Also referred to as the document ID.
openfda. spl_set_id	array of strings	1	Unique identifier for the Structured Product Label for a product, which is stable across versions of the label. Also referred to as the set ID.
openfda. substance_ name	array of strings	1	The list of active ingredients of a drug product.
openfda.unii	array of strings	1	Unique Ingredient Identifier, which is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.
products. active_ ingredients	object	1	
products. brand_name	array of strings	1	Brand or trade name of the drug product.
products. dosage_form	string	1	The drug's dosage form. There is no standard, but values may include terms like `tablet` or `solution for injection`.
products. marketing_ status	string	1	Indicates how a drug product is sold in the United States.
products. product_ number	string	1	A product number is assigned to each drug product associated with an NDA (New Drug Application), ANDA (Abbreviated New Drug Application) and Biologic License Application (BLA). If a drug product is available in multiple strengths, there are multiple product numbers.
products. reference_drug	string	1	Indicates whether the drug product is a reference drug.
products. reference_ standard	string	1	Indicates whether the drug product is a reference standard.
products.route	string	1	The route of administation of the drug product.
products. te_code	string	1	The coding system for therapeutic equivalence evaluations allows users to determine whether FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter).
sponsor_name	string	1	The company that submitted an application to FDA for approval to market the drug product in the United States.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
submissions. application_ docs	array of [object Object]s	1	
submissions. review_priority	string	1	Pending.
submissions. submission_ class_code	string	1	The Submission Classification Code, previously known as the Chemistry Classification Code, is assigned as a “Type” code.
submissions. submission_ class_code_ description	string	1	The Submission Classification Code, previously known as the Chemistry Classification Code, is assigned as a “Type” code. This is a full description of the classification code.
submissions. submission_ number	string	1	A unique identifier for each submission under that application.
submissions. submission_ property_type	array of unde- fineds	1	
submissions. submission_ public_notes	string	1	Publicly available notes regarding the submission.
submissions. submission_ status	string	1	The current status of this submission.
submissions. submission_ status_date	string	1	The date the status was applied to the submission.
submissions. submission_ type	string	1	The type of the individual submission. Used in combination with submission_number.

Adverse Event Reporting System (FAERS)

Description	The FDA Adverse Event Reporting System (FAERS) is a database that collects reports of adverse events, medication errors, and product quality issues associated with the use of FDA-regulated drugs and therapeutic biologic products. This system is a vital tool for the FDA in monitoring the safety of pharmaceutical products postmarketing. Healthcare professionals, manufacturers, and consumers can submit reports to FAERS, which the FDA then analyzes to identify new safety information and potential trends in drug-related risks. Based on this analysis, the FDA may take regulatory actions, such as updating product labeling, issuing safety communications, or initiating product recalls. FAERS plays a crucial role in the FDA's ongoing efforts to ensure the safety and effectiveness of medications on the market, enhancing the protection of public health by facilitating early detection and response to potential drug-related issues. The FDA Adverse Event Reporting System (FAERS) is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA. The database is designed to support the FDA's postmarketing safety surveillance program for drug and therapeutic biologic products. Note: FAERS is a newer version of the Adverse Event Reporting System (AERS)
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ **Highly Usage** — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latest-quarterly-data-files
Website Contact	
Website dataset	https://fis.fda.gov/extensions/FPD-QDE-FAERS/FPD-QDE-FAERS.html
Website dashboard	https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis
Website result set	Downloadable ASCII or XML .ZIP file by year and quarter
Mobile app available?	No
Website search fields	N/A
API available?	Yes (see API section below for more info)
API website	https://open.fda.gov/apis/drug/event/
API dashboard, interactive, fields definitions	https://open.fda.gov/apis/drug/event/explore-the-api-with-an-interactive-chart/

API search	https://open.fda.gov/apis/drug/event/searchable-fields/
Data Entity Relationship Diagram (ERD)	
	https://fis.fda.gov/extensions/FPD-QDE-FAERS/FPD-QDE-FAERS.html
Data Definition	**File:when the file is unzipped, the fields information can be found in this path /faers_ascii_YYYYQN/ASCII/ASC_NTS.pdf** AGE N (numeric) 12 (including 2 decimal places) AGE_COD A (Alpha) 7 AGE_GRP AN (alphanumeric) 15 AUTH_NUM AN (alphanumeric) 50012 DATA ELEMENT DATA CONTENT MAX LENGTH CASEID N (numeric) 500 CASEVERSION N (numeric) 10 CUM_DOS_UNIT AN (alphanumeric) 50 CUM_DOSE_CHR AN (alphanumeric) 15 DECHAL A (Alpha) 20 DOSE_AMT AN (alphanumeric) 15 DOSE_FORM AN (alphanumeric) 50 DOSE_FREQ AN (alphanumeric) 50 DOSE_UNIT AN (alphanumeric) 50 DOSE_VBM AN (alphanumeric) 300 DRUG_REC_ACT AN (alphanumeric) 500 DRUG_SEQ N (numeric) 10 DRUGNAME AN (alphanumeric) 500

Data Definition	
	DSG_DRUG_SEQ N (numeric) 10 DUR N (numeric) 150 DUR_COD A (Alpha) 500
	E_SUB AN (alphanumeric) 1
	END_DT N (or D, date) 8
	EVENT_DT N (or D, date) 8
	EXP_DT N (or D, date) 1000
	FDA_DT N (or D) 8
	I_F_CODE AN (alphanumeric) 1
	INDI_DRUG_SEQ N (numeric) 10
	INDI_PT AN (alphanumeric) 1000
	INIT_FDA_DT N (or D) 8
	LIT_REF AN (alphanumeric) 1000
	LOT_NUM AN (alphanumeric) 1000
	MFR_DT N (or D) 8
	MFR_NUM AN (alphanumeric) 500
	MFR_SNDR AN (alphanumeric) 300
	NDA_NUM N (numeric) 100
	OCCP_COD A (Alpha) 300
	OCCR_COUNTRY A (Alpha) 2
	OUTC_COD A (Alpha) 4000
	PRIMARYID N (numeric) 1000
	PROD_AI AN (alphanumeric) 500
	PT AN (alphanumeric) 500
	RECHAL A (Alpha) 20
	REPORTER_COUNTRY A (Alpha) 50013
	REPT_COD A (Alpha) 9
	REPT_DT N (or D, date) 8
	ROLE_COD A (Alpha) 22
	ROUTE A (Alpha) 500
	RPSR_COD A (Alpha) 32
	SEX A (Alpha) 5
	START_DT N (or D, date) 8
	TO_MFR A (Alpha) 100
	VAL_VBM N (numeric) 22
	WT N (numeric) 14 (including 5 decimal places)
	WT_COD A (Alpha) 20

Data Dictionary for FAERS

PRIMARYID

Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

CASEVERSION

Safety Report Version Number. The Initial Case will be version 1; follow-ups to the case will have sequentially incremented version numbers (for example, 2, 3, 4, etc.).

I_F_COD

Code for initial or follow-up status of report, as reported by manufacturer.

CODE	MEANING_TEXT
I	Initial
F	Follow-up

EVENT_DT

Date the adverse event occurred or began. (YYYYMMDD format) – If a complete date is not available, a partial date is provided. See the NOTE on dates at the end of this section.

MFR_DT

Date manufacturer first received initial information. In subsequent versions of a case, the latest manufacturer received date will be provided (YYYYMMDD format). If a complete date is not available, a partial date will be provided. See the NOTE on dates at the end of this section.

INIT_FDA_DT Date FDA received first version (Initial) of Case (YYYYMMDD format)

FDA_DT

Date FDA received Case. In subsequent versions of a case, the latest manufacturer received date will be provided (YYYYMMDD format).4

1) DEMOGRAPHIC file (DEMOyyQq.TXT)

REPT_COD

Code for the type of report submitted (See table below) Also, see Section F, End Notes below.

CODE	MEANING_TEXT
EXP	Expedited (15-Day)
PER	Periodic (Non-Expedited)
DIR	Direct
5DAY	5-Day
30DAY	30-Day

AUTH_NUM

Regulatory Authority's case report number, when available.

+ New tag added in 2014Q3 extract.

MFR_NUM Manufacturer's unique report identifier.

MFR_SNDR Coded name of manufacturer sending report; if not found, then verbatim name of organization sending report.

Data Dictionary for FAERS

LIT_REF

Literature Reference information, when available; populated with last 500 characters if >500 characters are available.

+ New tag added in 2014Q3 extract.

AGE Numeric value of patient's age at event.

AGE_COD

Unit abbreviation for patient's age (See table below)

CODE	MEANING_TEXT
DEC	DECADE
YR	YEAR
MON	MONTH
WK	WEEK
DY	DAY
HR	HOUR

AGE_GRP

Patient Age Group code as follows, when available:

CODE	MEANING_TEXT
N	Neonate
I	Infant
C	Child
T	Adolescent
A	Adult
E	Elderly

+ New tag added in 2014Q3 extract.

SEX

Code for patient's sex (See table below)

CODE	MEANING_TEXT
UNK	Unknown
M	Male
F	Female5

E_ SUB Whether (Y/N) this report was submitted under the electronic submissions procedure for manufacturers.

1) DEMOGRAPHIC file (DEMOyyQq.TXT)

WT Numeric value of patient's weight.

Data Dictionary for FAERS

WT_COD

Unit abbreviation for patient's weight (See table below)

CODE	MEANING_TEXT
KG	Kilograms
LBS	Pounds
GMS	Grams

REPT_DT

Date report was sent (YYYYMMDD format). If a complete date is not available, a partial date is provided. See the NOTE on dates at the end of this section.

TO_MFR Whether (Y/N) voluntary reporter also notified manufacturer (blank for manufacturer reports).

OCCP_COD

Abbreviation for the reporter's type of occupation in the latest version of a case.

CODE	MEANING_TEXT
MD	Physician
PH	Pharmacist
OT	Other health-professional
LW	Lawyer
CN	Consumer

REPORTER_COUNTRY

The country of the reporter in the latest version of a case: NOTE: Country codes are available per the links below.

https://www.fda.gov/industry/structured-product-labeling-resources/geopolitical-entities-names-and-codes-genc

OCCR_COUNTRY The country where the event occurred.6

2) DRUG file (DRUGyyQq.TXT)

PRIMARYID Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

DRUG_SEQ Unique number for identifying a drug for a Case. To link to the THERyyQq.TXT data file, both the Case number (primary key) and the DRUG_SEQ number (secondary key) are needed. (For an explanation of the DRUG_SEQ number, including an example, please see Section F, End Notes 2, below.)

ROLE_COD Code for drug's reported role in event (See table below)

CODE	MEANING_TEXT
PS	Primary Suspect Drug
SS	Secondary Suspect Drug
C	Concomitant
I	Interacting

Data Dictionary for FAERS	**DRUGNAME** Name of medicinal product. If a “Valid Trade Name” is populated for this Case, then DRUGNAME = Valid Trade Name; if not, then DRUGNAME = “Verbatim” name, exactly as entered on the report.
	PROD_AI Product Active Ingredient, when available. + New tag added in 2014Q3 extract.
	VAL_VBM Code for source of DRUGNAME (See table below)
	CODE MEANING_TEXT 1 Validated trade name used 2 Verbatim name used
	ROUTE The route of drug administration
	DOSE_VBM Verbatim text for dose, frequency, and route, exactly as entered on report.
	CUM_DOSE_CHR Cumulative dose to first reaction7 2) DRUG file (DRUGyyQq.TXT)
Data Dictionary for FAERS	**CUM_DOSE_UNIT** Cumulative dose to first reaction unit CODE Meaning_Text ---- ---------- KG Kilogram(s) GM Gram(s) MG Milligram(s) UG Microgram(s) (µg) NG Nanogram(s) PG Picogram(s) MG/KG Milligram(s)/Kilogram UG/KG Microgram(s)/Kilogram (µG/KG) MG/M**2 Milligram(s)/Sq. Meter UG/M**2 Microgram(s)/Sq. Meter (µG/M**2) L Litre(s) ML Millilitre(s) UL Microlitre(s) (µL) BQ Becquerel(s) GBQ Gigabecquerel(s) MBQ Megabecquerel(s) KBQ Kilobecquerel(s) CI Curie(s) MCI Millicurie(s) UCI Microcurie(s) (µCI) NCI Nanocurie(s)

Data Dictionary for FAERS

MOL	Mole(s)
MMOL	Millimole(s)
UMOL	Micromole(s)
IU	International Unit(s)
KIU	International Unit*(1000s)
MIU	International Unit*(1,000,000s)
IU/KG	IU/Kilogram
MEQ	Milliequivalent(s)
PCT	Percent (%)
GTT	Drop(s)
DF	Dosage Form

NOTE: The list below provides Dose codes which are commonly reported; however, dose codes are not limited to this list and other code values may be present.

DECHAL Dechallenge code, indicating if reaction abated when drug therapy was stopped (See table below)

CODE	MEANING_TEXT
Y	Positive dechallenge
N	Negative dechallenge
U	Unknown
D	Does not apply8

2) DRUG file (DRUGyyQq.TXT)

RECHAL Rechallenge code, indicating if reaction recurred when drug therapy was restarted (See table below)

CODE	MEANING_TEXT
Y	Positive rechallenge
N	Negative rechallenge
U	Unknown
D	Does not apply

LOT_NUM Lot number of the drug (as reported).

EXP_DT Expiration date of the drug. (YYYYMMDD format) — If a complete date is not available, a partial date is provided, See the NOTE on dates at the end of this section.

NDA_NUM NDA number (numeric only)

DOSE_AMT Amount of drug reported

DOSE_UNIT Unit of drug dose

DOSE_FORM Form of dose reported

DOSE_FREQ

Code for Frequency

Data Dictionary for FAERS

CODE	Meaning_Text
1X	Once or one time
BID	Twice a day
BIW	Twice a week
HS	At bedtime
PRN	As needed
Q12H	Every 12 hours
Q2H	Every 2 hours
Q3H	Every 3 hours
Q3W	Every 3 weeks
Q4H	Every 4 hours
Q5H	Every 5 hours
Q6H	Every 6 hours
Q8H	Every 8 hours
QD	Daily
QH	Every hour
QID	4 times a day
QM	Monthly
QOD	Every other day
QOW	Every other week
QW	Every week
TID	3 times a day
TIW	3 times a week
UNK	Unknown

NOTE: The list below provides frequency codes which are commonly reported; however, dose frequency codes are not limited to this list and other code values may be present.9

3) REACTION file (REACyyQq.TXT)

PRIMARYID

Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

PT

"Preferred Term"-level medical terminology describing the event, using the Medical Dictionary for Regulatory Activities (MedDRA). The order of the terms for a given event does not imply priority. In other words, the first term listed is not necessarily considered more significant than the last one listed.

DRUG_REC_ACT

Drug Recur Action data - populated with reaction/event information (PT) if/when the event reappears upon readministration of the drug.

+ New tag added in 2014Q3 extract.

Data Dictionary for FAERS

4) OUTCOME file (OUTCyyQq.TXT)

PRIMARYID

Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

OUTC_COD

Code for a patient outcome (See table below)

CODE	MEANING_TEXT
DE	Death
LT	Life-Threatening
HO	Hospitalization - Initial or Prolonged
DS	Disability
CA	Congenital Anomaly
RI	Required Intervention to Prevent Permanent Impairment/Damage
OT	Other Serious (Important Medical Event)

NOTE: The outcome from the latest version of a case is provided. If there is more than one outcome, the codes will be line listed.10

5) REPORT SOURCE file (RPSRyyQq.TXT)

PRIMARYID

Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

RPSR_COD

Code for the source of the report (See table below)

CODE	MEANING_TEXT
FGN	Foreign
SDY	Study
LIT	Literature
CSM	Consumer
HP	Health Professional
UF	User Facility
CR	Company Representative
DT	Distributor
OTH	Other

NOTE: The source from the latest version of a case is provided. If there is more than one source, the codes will be line listed.

Data Dictionary for FAERS

6) THERAPY dates file (THERyyQq.TXT)

PRIMARYID

Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

DSG_DRUG_SEQ

Drug sequence number for identifying a drug for a Case. To link to the DRUGyyQq.TXT data file, both the Case number primary key) and the DRUG_SEQ number (secondary key) are needed. (For an explanation of the DRUG_SEQ number, including an example, see Section F, End Notes 2, below.)

START_DT

Date the therapy was started (or re-started) for this drug (YYYYMMDD) – If a complete date not available, a partial date is provided. See the NOTE on dates at the end of this section.

END_DT

A date therapy was stopped for this drug. (YYYYMMDD) — If a complete date not available, a partial date will be provided. See the NOTE on dates at the end of this section. DUR Numeric value of the duration (length) of therapy11

6) THERAPY dates file (THERyyQq.TXT)

DUR_COD

Unit abbreviation for duration of therapy (see table below)

CODE	MEANING TEXT
YR	Years
MON	Months
WK	Weeks
DAY	Days
HR	Hours
MIN	Minutes
SEC	Seconds

7) INDICATIONS for use file (INDIyyQq.TXT)

PRIMARYID

Unique number for identifying a FAERS report. This is the primary link field (primary key) between data files (example: 31234561). This is a concatenated key of Case ID and Case Version Number. It is the Identifier for the case sequence (version) number as reported by the manufacturer.

CASEID Number for identifying a FAERS case.

INDI_DRUG_SEQ

Drug sequence number for identifying a drug for a Case. To link to the DRUGyyQq.TXT data file, both the Case number (primary key) and the DRUG_SEQ number (secondary key) are needed. (For an explanation of the DRUG_SEQ number, including an example, see Section F, End Notes 2, below.)

	INDI_PT “Preferred Term”-level medical terminology describing the Indication for use, using the Medical Dictionary for Regulatory Activities MedDRA).

Adverse Event from openFDA API

The openFDA Human Drug – Event, provides an API data dictionary found at:

- https://open.fda.gov/data/datadictionary
- https://open.fda.gov/fields/drugevent_reference.pdf

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
authoritynumb	string	1	Populated with the Regulatory Authority’s case report number, when available.
companynumb	string	1	Identifier for the company providing the report. This is self-assigned.
duplicate	string	1	This value is `1` if earlier versions of this report were submitted to FDA. openFDA only shows the most recent version.
fulfillexpedite-criteria	string	1	Identifies expedited reports (those that were processed within 15 days).
occurcountry	string	1	The name of the country where the event occurred.
patient.drug	array of objects	1	
patient. patientage-group	string	1	Populated with Patient Age Group code.
patient. patientdeath	object	1	
patient. patientonse-tage	string	1	Age of the patient when the event first occured.
patient. patientonseta-geunit	string	1	The unit for the interval in the field `patientonsetage.
patient. patientsex	string	1	The sex of the patient.
patient. patientweight	string	1	The patient weight, in kg (kilograms).
patient. reaction	array of objects	1	

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
patient. summary	object	1	
primarysource. literaturerefer- ence	string	1	Populated with the Literature Reference information, when available.
primarysource. qualification	string	1	Category of individual who submitted the report.
primarysource. reportercoun- try	string	1	Country from which the report was submitted.
primarysource- country	string	1	Country of the reporter of the event.
receiptdate	string	1	Date that the _most recent_ information in the report was received by FDA.
receiptdatefor- mat	string	1	Encoding format of the `transmissiondate` field. Always set to 102 (YYYYMMDD).
receivedate	string	1	Date that the report was _first_ received by FDA. If this report has multiple versions, this will be the date the first version was received by FDA.
receivedatefor- mat	string	1	Encoding format of the `transmissiondate` field. Always set to 102 (YYYYMMDD).
receiver. receiverorgani- zation	string	1	Name of the organization receiving the report. Because FDA received the report, the value is always `FDA`.
receiver. receivertype	string	1	The type of organization receiving the report. The value,`6`, is only specified if it is `other`, otherwise it is left blank.
reportdupli- cate.duplica- tenumb	string	1	The case identifier for the duplicate.
reportdupli- cate.duplicate- source	string	1	The name of the organization providing the duplicate.
reporttype	string	1	Code indicating the circumstances under which the report was generated.
safetyreportid	string	1	The 8-digit Safety Report ID number, also known as the case report number or case ID. The first 7 digits (before the hyphen) identify an individual report and the last digit (after the hyphen) is a checksum. This field can be used to identify or find a specific adverse event report.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
safetyreport-version	string	1	The version number of the `safetyreportid`. Multiple versions of the same report may exist, it is generally best to only count the latest report and disregard others. openFDA will only return the latest version of a report.
sender.sender-organization	string	1	Name of the organization sending the report. Because FDA is providing these reports to you, the value is always `FDA-Public Use.`
sender.sender-type	string	1	The name of the organization sending the report. Because FDA is providing these reports to you, the value is always `2`.
serious	string	1	Seriousness of the adverse event.
seriousness-congenitala-nomali	string	1	This value is `1` if the adverse event resulted in a congenital anomaly, and absent otherwise.
seriousness-death	string	1	This value is `1` if the adverse event resulted in death, and absent otherwise.
seriousnessdis-abling	string	1	This value is `1` if the adverse event resulted in disability, and absent otherwise.
seriousness-hospitalization	string	1	This value is `1` if the adverse event resulted in a hospitalization, and absent otherwise.
seriousnesslife-threatening	string	1	This value is `1` if the adverse event resulted in a life threatening condition, and absent otherwise.
seriousnesso-ther	string	1	This value is `1` if the adverse event resulted in some other serious condition, and absent otherwise.
transmission-date	string	1	Date that the record was created. This may be earlier than the date the record was received by the FDA.
transmission-dateformat	string	1	Encoding format of the `transmissiondate` field. Always set to 102 (YYYYMMDD)

Product Labels Database

Description	The FDA Product Labels Database, also known as DailyMed, is a comprehensive repository of up-to-date labeling information for FDA-approved pharmaceutical products. It provides detailed and standardized information about drugs, including their uses, dosages, risks, ingredients, and directions for use. This database is a critical resource for healthcare providers, pharmacists, and patients, offering accessible and reliable information to guide the safe and effective use of medications. The labels include important details such as drug interactions, side effects, specific population usage (like children or pregnant women), and clinical pharmacology, ensuring that all stakeholders have the necessary knowledge to make informed decisions regarding drug therapies. Managed by the National Library of Medicine, this database reflects the FDA's commitment to transparency and public health by providing comprehensive and current drug information.

Description	FDA's labeling resources for human prescription drugs are primarily directed to industry staff who develop human prescription drug labeling. Human prescription drug labeling (1) contains a summary of the essential scientific information needed for the safe and effective use of the drug; and (2) includes the Prescribing Information, FDA-approved patient labeling (Medication Guides, Patient Package Inserts, and/or Instructions for Use), and/or carton and container labeling.
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ **Highly Usage** — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs
Website Contact	
Website dataset	https://nctr-crs.fda.gov/fdalabel/ui/search
Website result set	HTML table result, SPL Document, Link to DailyMed SPL, PDF, Link to Drugs@FDA, Link to Orange Book
Mobile app available?	Unknown
Website search fields	By Labeling Types Application Types or Marketing Categories & Product Name(s) Labeling Full Text Search Labeling Section(s) Route(s) of Administration Pharmacologic Class(es) Labeling, Product and Ingredient Identifiers
API available?	Yes (see API section below for more info)
API website	https://open.fda.gov/apis/drug/label/
API dashboard, interactive, fields definitions	https://open.fda.gov/apis/drug/label/explore-the-api-with-an-interactive-chart/
API search	https://open.fda.gov/apis/drug/label/searchable-fields/
Data Entity Relationship Diagram (ERD)	Unknown
Data Definition	Unknown

Product Labels from openFDA API

The openFDA Human Drug – Labels, provides an API data dictionary found at:

- https://open.fda.gov/data/datadictionary
- https://open.fda.gov/fields/druglabel_reference.pdf

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
abuse	array of strings	1	Information about the types of abuse that can occur with the drug and adverse reactions pertinent to those types of abuse, primarily based on human data. May include descriptions of particularly susceptible patient populations.
accessories	array of strings	1	Documentation forthcoming.
active_ ingredient	array of strings	1	A list of the active, medicinal ingredients in the drug product.
adverse_ reactions	array of strings	1	Information about undesirable effects, reasonably associated with use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. Adverse reactions include those that occur with the drug, and if applicable, with drugs in the same pharmacologically active and chemically related class. There is considerable variation in the listing of adverse reactions. They may be categorized by organ system, by severity of reaction, by frequency, by toxicological mechanism, or by a combination of these.
alarms	array of strings	1	Documentation forthcoming.
animal_ pharmacology_ and_or_ toxicology	array of strings	1	Information from studies of the drug in animals, if the data were not relevant to nor included in other parts of the labeling. Most labels do not contain this field.
ask_doctor	array of strings	1	Information about when a doctor should be consulted about existing conditions or sumptoms before using the drug product, including all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until a doctor is consulted.
ask_doctor_ or_pharmacist	array of strings	1	Information about when a doctor or pharmacist should be consulted about drug/drug or drug/food interactions before using a drug product.
assembly_or_ installation_ instructions	array of strings	1	Documentation forthcoming.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
boxed_warning	array of strings	1	Information about contraindications or serious warnings, particularly those that may lead to death or serious injury.
calibration_ instructions	array of strings	1	Documentation forthcoming.
carcinogene-sis_and_muta-genesis_and_ impairment_ of_fertility	array of strings	1	Information about carcinogenic, mutagenic, or fertility impairment potential revealed by studies in animals. Information from human data about such potential is part of the `warnings` field.
cleaning	array of strings	1	Documentation forthcoming.
clinical_ pharmacology	array of strings	1	Information about the clinical pharmacology and actions of the drug in humans.
clinical_studies	array of strings	1	This field may contain references to clinical studies in place of detailed discussion in other sections of the labeling.
compatible_ accessories	array of strings	1	Documentation forthcoming.
components	array of strings	1	Documentation forthcoming.
contraindica-tions	array of strings	1	Information about situations in which the drug product is contraindicated or should not be used because the risk of use clearly outweighs any possible benefit, including the type and nature of reactions that have been reported.
controlled_ substance	array of strings	1	Information about the schedule in which the drug is controlled by the Drug Enforcement Administration, if applicable.
dependence	array of strings	1	Information about characteristic effects resulting from both psychological and physical dependence that occur with the drug, the quantity of drug over a period of time that may lead to tolerance or dependence, details of adverse effects related to chronic abuse and the effects of abrupt withdrawl, procedures necessary to diagnose the dependent state, and principles of treating the effects of abrupt withdrawal.
description	array of strings	1	General information about the drug product, including the proprietary and established name of the drug, the type of dosage form and route of administration to which the label applies, qualitative and quantitative ingredient information, the pharmacologic or therapeutic class of the drug, and the chemical name and structural formula of the drug.
diagram_of_ device	array of strings	1	Documentation forthcoming.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
disposal_and_ waste_ handling	array of strings	1	
do_not_use	array of strings	1	Information about all contraindications for use. These contraindications are absolute and are intended for situations in which consumers should not use the product unless a prior diagnosis has been established by a doctor or for situations in which certain consumers should not use the product under any circumstances regardless of whether a doctor or health professional is consulted.
dosage_and_ administration	array of strings	1	Information about the drug product's dosage and administration recommendations, including starting dose, dose range, titration regimens, and any other clinically sigificant information that affects dosing recommendations.
dosage_forms_ and_strengths	array of strings	1	Information about all available dosage forms and strengths for the drug product to which the labeling applies. This field may contain descriptions of product appearance.
drug_abuse_ and_ dependence	array of strings	1	Information about whether the drug is a controlled substance, the types of abuse that can occur with the drug, and adverse reactions pertinent to those types of abuse.
drug_and_or_ laboratory_ test_ interactions	array of strings	1	Information about any known interference by the drug with laboratory tests.
drug_ interactions	array of strings	1	Information about and practical guidance on preventing clinically significant drug/drug and drug/food interactions that may occur in people taking the drug.
effective_time	string	1	Date reference to the particular version of the labeling document.
environmental_ warning	array of strings	1	
food_safety_ warning	array of strings	1	
general_ precautions	array of strings	1	Information about any special care to be exercised for safe and effective use of the drug.
geriatric_use	array of strings	1	Information about any limitations on any geriatric indications, needs for specific monitoring, hazards associated with use of the drug in the geriatric population.
guaranteed_ analysis_of_ feed	array of strings	1	Documentation forthcoming.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
health_care_ provider_letter	array of strings	1	Documentation forthcoming.
health_claim	array of strings	1	Documentation forthcoming.
how_supplied	array of strings	1	Information about the available dosage forms to which the labeling applies, and for which the manufacturer or distributor is responsible. This field ordinarily includes the strength of the dosage form (in metric units), the units in which the dosage form is available for prescribing, appropriate information to facilitate identification of the dosage forms (such as shape, color, coating, scoring, and National Drug Code), and special handling and storage condition information.
id	string	1	The document ID, A globally unique identifier (GUID) for the particular revision of a labeling document.
inactive_ ingredient	array of strings	1	A list of inactive, non-medicinal ingredients in a drug product.
indications_ and_usage	array of strings	1	A statement of each of the drug product's indications for use, such as for the treatment, prevention, mitigation, cure, or diagnosis of a disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition. This field may also describe any relevant limitations of use.
information_ for_owners_ or_caregivers	array of strings	1	Documentation forthcoming.
information_ for_patients	array of strings	1	Information necessary for patients to use the drug safely and effectively, such as precautions concerning driving or the concomitant use of other substances that may have harmful additive effects.
instructions_ for_use	array of strings	1	Information about safe handling and use of the drug product.
intended_use_ of_the_device	array of strings	1	Documentation forthcoming.
keep_out_of_ reach_of_ children	array of strings	1	Information pertaining to whether the product should be kept out of the reach of children, and instructions about what to do in the case of accidental contact or ingestion, if appropriate.
labor_and_ delivery	array of strings	1	Information about the drug's use during labor or delivery, whether or not the use is stated in the indications section of the labeling, including the effect of the drug on the mother and fetus, on the duration of labor or delivery, on the possibility of delivery-related interventions, and the effect of the drug on the later growth, development, and functional maturation of the child.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
laboratory_ tests	array of strings	1	Information on laboratory tests helpful in following the patient's response to the drug or in identifying possible adverse reactions. If appropriate, information may be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.
mechanism_ of_action	array of strings	1	Information about the established mechanism(s) of the drug's action in humans at various levels (for example receptor, membrane, tissue, organ, whole body). If the mechanism of action is not known, this field contains a statement about the lack of information.
meta.disclaimer	string	1	Important details notes about openFDA data and limitations of the dataset.
meta.last_ updated	string	1	The last date when this openFDA endpoint was updated. Note that this does not correspond to the most recent record for the endpoint or dataset. Rather, it is the last time the openFDA API was itself updated.
meta.license	string	1	Link to a web page with license terms that govern data within openFDA.
meta.results	object	1	
meta.type		1	
microbiology	array of strings	1	Documentation forthcoming.
nonclinical_ toxicology	array of strings	1	Information about toxicology in non-human subjects.
nonteratogen- ic_effects	array of strings	1	Other information about the drug's effects on reproduction and the drug's use during pregnancy, if the information is relevant to the safe and effective use of the drug.
nursing_ mothers	array of strings	1	Information about excretion of the drug in human milk and effects on the nursing infant, including pertinent adverse effects observed in animal offspring.
openfda. application_ number	array of strings	1	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the application number will be the CFR citation corresponding to the appropriate Monograph (e.g. "part 341"). For unapproved drugs, this field will be null.
openfda. brand_name	array of strings	1	Brand or trade name of the drug product.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
openfda. generic_name	array of strings	1	Generic name(s) of the drug product.
openfda. is_original_ packager	string	1	Whether or not the drug has been repackaged for distribution.
openfda. manufacturer_ name	array of strings	1	Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.
openfda.nui	array of strings	1	Unique identifier applied to a drug concept within the National Drug File Reference Terminology (NDF-RT).
openfda. original_ packager_ product_ndc	array of strings	1	This ndc identifies the original packager.
openfda. package_ndc	array of strings	1	This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug.
openfda. pharm_class_ cs	array of strings	1	Chemical structure classification of the drug product's pharmacologic class. Takes the form of the classification, followed by `[Chemical/Ingredient]` (such as `Thiazides [Chemical/Ingredient]` or `Antibodies, Monoclonal [Chemical/ Ingredient].
openfda. pharm_class_ epc	array of strings	1	Established pharmacologic class associated with an approved indication of an active moiety (generic drug) that the FDA has determined to be scientifically valid and clinically meaningful. Takes the form of the pharmacologic class, followed by `[EPC]` (such as `Thiazide Diuretic [EPC]` or `Tumor Necrosis Factor Blocker [EPC]`.
openfda. pharm_class_ moa	array of strings	1	Mechanism of action of the drug—molecular, subcellular, or cellular functional activity—of the drug's established pharmacologic class. Takes the form of the mechanism of action, followed by `[MoA]` (such as `Calcium Channel Antagonists [MoA]` or `Tumor Necrosis Factor Receptor Blocking Activity [MoA]`.
openfda. pharm_class_ pe	array of strings	1	Physiologic effect or pharmacodynamic effect—tissue, organ, or organ system level functional activity—of the drug's established pharmacologic class. Takes the form of the effect, followed by `[PE]` (such as `Increased Diuresis [PE]` or `Decreased Cytokine Activity [PE]`.
openfda. product_ndc	array of strings	1	The labeler manufacturer code and product code segments of the NDC number, separated by a hyphen.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
openfda. product_type	array of strings	1	
openfda.route	array of strings	1	The route of administation of the drug product.
openfda.rxcui	array of strings	1	The RxNorm Concept Unique Identifier. RxCUI is a unique number that describes a semantic concept about the drug product, including its ingredients, strength, and dose forms.
openfda.spl_id	array of strings	1	Unique identifier for a particular version of a Structured Product Label for a product. Also referred to as the document ID.
openfda. spl_set_id	array of strings	1	Unique identifier for the Structured Product Label for a product, which is stable across versions of the label. Also referred to as the set ID.
openfda. substance_ name	array of strings	1	The list of active ingredients of a drug product.
openfda.unii	array of strings	1	Unique Ingredient Identifier, which is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.
openfda.upc	array of strings	1	Universal Product Code
other_safety_ information	array of strings	1	Information about safe use and handling of the product that may not have been specified in another field.
overdosage	array of strings	1	Information about signs, symptoms, and laboratory findings of acute ovedosage and the general principles of overdose treatment.
package_ label_ principal_ display_panel	array of strings	1	The content of the principal display panel of the product package, usually including the product's name, dosage forms, and other key information about the drug product.
patient_ medication_ information	array of strings	1	Information or instructions to patients about safe use of the drug product, sometimes including a reference to a patient medication guide or counseling materials.
pediatric_use	array of strings	1	Information about any limitations on any pediatric indications, needs for specific monitoring, hazards associated with use of the drug in any subsets of the pediatric population (such as neonates, infants, children, or adolescents), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
pharmacody-namics	array of strings	1	Information about any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drug's clinical effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity.
pharmacog-enomics	array of strings	1	Documentation forthcoming.
pharmacokinet-ics	array of strings	1	Information about the clinically significant pharmacokinetics of a drug or active metabolites, for instance pertinent absorption, distribution, metabolism, and excretion parameters.
precautions	array of strings	1	Information about any special care to be exercised for safe and effective use of the drug.
pregnancy	array of strings	1	Information about effects the drug may have on pregnant women or on a fetus. This field may be ommitted if the drug is not absorbed systemically and the drug is not known to have a potential for indirect harm to the fetus. It may contain information about the established pregnancy category classification for the drug. (That information is nominally listed in the `teratogenic_effects` field, but may be listed here instead.)
pregnancy_or_ breast_feeding	array of strings	1	Documentation forthcoming.
purpose	array of strings	1	Information about the drug product's indications for use.
questions	array of strings	1	A telephone number of a source to answer questions about a drug product. Sometimes available days and times are also noted.
recent_major_ changes	array of strings	1	A list of the section(s) that contain substantive changes that have been approved by FDA in the product labeling. The headings and subheadings, if appropriate, affected by the change are listed together with each section's identifying number and the month and year on which the change was incorporated in the labeling.
references	array of strings	1	This field may contain references when prescription drug labeling must summarize or otherwise relay on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions.
residue_ warning	array of strings	1	Documentation forthcoming.
risks	array of strings	1	Documentation forthcoming.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
route	array of strings	1	Documentation forthcoming.
safe_handling_ warning	array of strings	1	Documentation forthcoming.
set_id	string	1	The Set ID, A globally unique identifier (GUID) for the labeling, stable across all versions or revisions.
spl_indexing_ data_elements	array of strings	1	Documentation forthcoming.
spl_medguide	array of strings	1	Information about the patient medication guide that accompanies the drug product. Certain drugs must be dispensed with an accompanying medication guide. This field may contain information about when to consult the medication guide and the contents of the medication guide.
spl_patient_ package_insert	array of strings	1	Information necessary for patients to use the drug safely and effectively.
spl_product_ data_elements	array of strings	1	Usually a list of ingredients in a drug product.
spl_ unclassified_ section	array of strings	1	Information not classified as belonging to one of the other fields. Approximately 40% of labeling with `effective_time` between June 2009 and August 2014 have information in this field.
statement_of_ identity	array of strings	1	Documentation forthcoming.
stop_use	array of strings	1	Information about when use of the drug product should be discontinued immediately and a doctor consulted. Includes information about any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.
storage_and_ handling	array of strings	1	Information about safe storage and handling of the drug product.
summary_of_ safety_and_ effectiveness	array of strings	1	Documentation forthcoming.
teratogenic_ effects	array of strings	1	_Pregnancy category A_: Adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy, and there is no evidence of a risk in later trimesters. _Pregnancy category B_: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
			Pregnancy category C: Animal reproduction studies have shown an adverse effect on the fetus, there are no adequate and well-controlled studies in humans, and the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. _Pregnancy category D_: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective). _Pregnancy category X_: Studies in animals or humans have demonstrated fetal abnormalities or there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).
troubleshoot-ing	array of strings	1	Documentation forthcoming.
use_in_ specific_ populations	array of strings	1	Information about use of the drug by patients in specific populations, including pregnant women and nursing mothers, pediatric patients, and geriatric patients.
user_safety_ warnings	array of strings	1	When a drug can pose a hazard to human health by contact, inhalation, ingestion, injection, or by any exposure, this field contains information which can prevent or decrease the possibility of harm.
version	string	1	A sequentially increasing number identifying the particular version of a document, starting with `1`.
warnings	array of strings	1	Information about serious adverse reactions and potential safety hazards, including limitations in use imposed by those hazards and steps that should be taken if they occur.
warnings_and_ cautions	array of strings	1	Documentation forthcoming.
when_using	array of strings	1	Information about side effects that people may experience, and the substances (e.g. alcohol) or activities (e.g. operating machinery, driving a car) to avoid while using the drug product.

National Drug Code (NDC) Directory

Description	The FDA National Drug Code (NDC) Directory is a comprehensive database that serves as a universal product identifier for human drugs in the United States. Each drug is assigned a unique 10-digit number, known as the National Drug Code, which identifies the labeler, product, and commercial package size. The NDC is used in various settings, including pharmacy billing and inventory management, and is essential for the tracking and monitoring of drugs. The FDA's NDC Directory lists both currently marketed drugs and those no longer in the market but previously submitted to the FDA, including prescription and over-the-counter pharmaceuticals, as well as insulin products and certain other biologic products. This directory provides vital information to healthcare providers, patients, and regulatory entities, facilitating the management, safety, and tracking of medications across the healthcare system. The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	↑ **Highly Usage** — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory
Website Contact	drugInfo@fda.hhs.gov
Website dataset	https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm
Website result set	HTML Table page, CSV
Mobile app available?	**Apple** (https://apps.apple.com/us/app/ndc-express/id1230454293?ls=1) **Android** (https://play.google.com/store/apps/details?id=gov.fda.ndc&pli=1)
Website search fields	**By Finished Products** Proprietary Name Application Number Nonproprietary Name NDC code Labeler

Website search fields	**By Unfinished Products** Nonproprietary Name NDC Code Labeler
	By Compounded Products Nonproprietary Name NDC Code Establishment Information
Website result set fields	**Proprietary Name** NDC Package Code Strength Dosage Form Route App. No. Labeler Name Product NDC Nonproprietary Name Substance Name Product Type Name Start Marketing Date End Marketing Date Market Category Package Description Pharm Class
API available?	Yes (see API section below for more info)
API website	https://open.fda.gov/apis/drug/ndc/
API dashboard, interactive, fields definitions	https://open.fda.gov/apis/drug/ndc/explore-the-api-with-an-interactive-chart/
API search	https://open.fda.gov/apis/drug/ndc/searchable-fields/
Data Entity Relationship Diagram (ERD)	Unknown
Data Definition	Unknown

NDC Directory from openFDA API

The openFDA Human Drug – NDC Directory, provides an API data dictionary found at:

- https://open.fda.gov/data/datadictionary
- https://open.fda.gov/fields/drugndc_reference.pdf

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
active_ ingredients. name	string	1	The names of the active, medicinal ingredients in the drug product.
active_ ingredients. strength	string	1	The strength of the active, medicinal ingredients in the drug product.
application_ number	string	1	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the application number will be the CFR citation corresponding to the appropriate Monograph (e.g. “part 341”). For unapproved drugs, this field will be null.
brand_name	string	1	Brand or trade name of the drug product.
brand_name_ base	string	1	The base of the brand name excluding its suffix.
brand_name_ suffix	string	1	A suffix to the proprietary name, a value here should be appended to the ProprietaryName field to obtain the complete name of the product. This suffix is often used to distinguish characteristics of a product such as extended release (“XR”) or sleep aid (“PM”).
dea_schedule	string	1	This is the assigned DEA Schedule number as reported by the labeler. Values are CI, CII, CIII, CIV, and CV.
dosage_form	string	1	The drug’s dosage form. There is no standard, but values may include terms like `tablet` or `solution for injection`.
finished	string	1	Details whether the product is finished or not. FDA does not review and approve unfinished products. Therefore, all products in this file are considered unapproved.
generic_name	string	1	Generic name(s) of the drug product.
listing_ expiration_date	string	1	This is the date when the listing record will expire if not updated or certified by the firm.
marketing_ category	string	1	Product types are broken down into several potential Marketing Categories, such as NDA/ANDA/BLA, OTC Monograph, or Unapproved Drug.
marketing_ end_date	string	1	This is the date the product will no longer be available on the market.
marketing_ start_date	type	1	This is the date that the labeler indicates was the start of its marketing of the drug product.
openfda. is_original_ packager	string	1	Whether or not the drug has been repackaged for distribution.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
openfda. manufacturer_ name	string	1	Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.
openfda.nui	string	1	Unique identifier applied to a drug concept within the National Drug File Reference Terminology (NDF-RT).
openfda. pharm_class_ cs	string	1	Chemical structure classification of the drug product's pharmacologic class. Takes the form of the classification, followed by `[Chemical/Ingredient]` (such as `Thiazides [Chemical/Ingredient]` or `Antibodies, Monoclonal [Chemical/ Ingredient].
openfda. pharm_class_ epc	string	1	Established pharmacologic class associated with an approved indication of an active moiety (generic drug) that the FDA has determined to be scientifically valid and clinically meaningful. Takes the form of the pharmacologic class, followed by `[EPC]` (such as `Thiazide Diuretic [EPC]` or `Tumor Necrosis Factor Blocker [EPC]`.
openfda. pharm_class_ moa	string	1	Mechanism of action of the drug—molecular, subcellular, or cellular functional activity—of the drug's established pharmacologic class. Takes the form of the mechanism of action, followed by `[MoA]` (such as `Calcium Channel Antagonists [MoA]` or `Tumor Necrosis Factor Receptor Blocking Activity [MoA]`.
openfda. pharm_class_ pe	string	1	Physiologic effect or pharmacodynamic effect—tissue, organ, or organ system level functional activity—of the drug's established pharmacologic class. Takes the form of the effect, followed by `[PE]` (such as `Increased Diuresis [PE]` or `Decreased Cytokine Activity [PE]`.
openfda.rxcui	string	1	The RxNorm Concept Unique Identifier. RxCUI is a unique number that describes a semantic concept about the drug product, including its ingredients, strength, and dose forms.
openfda. spl_set_id	string	1	Unique identifier for the Structured Product Label for a product, which is stable across versions of the label. Also referred to as the set ID.
openfda.unii	string	1	Unique Ingredient Identifier, which is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.
openfda.upc	string	1	Universal Product Code
packaging. description	string	1	A description of the size and type of packaging in sentence form. Multilevel packages will have the descriptions concatenated together.
packaging. marketing_ end_date	string	1	This is the date the product will no longer be available on the market.

FIELD_NAME	DATATYPE	DATASET_ NUMBER	DEFINITION
packaging. marketing_ start_date	string	1	This is the date that the labeler indicates was the start of its marketing of the drug product.
packaging. package_ndc	string	1	This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug.
packaging. sample	string	1	Indicates whether this is a sample packaging or not.
pharm_class	string	1	These are the reported pharmacological class categories corresponding to the SubstanceNames listed above.
product_id	string	1	ProductID is a concatenation of the NDC product code and SPL documentID.
product_ndc	string	1	The labeler manufacturer code and product code segments of the NDC number, separated by a hyphen.
product_type	string	1	Type of drug product
route	string	1	The route of administation of the drug product.
spl_id	string	1	Unique identifier for a particular version of a Structured Product Label for a product. Also referred to as the document ID.

Recall Enforcement Report

Description	The FDA Recall Enforcement Report is a comprehensive publication by the Food and Drug Administration that provides detailed information about all the recalls monitored by the FDA. This includes not just drugs, but also biologics, medical devices, food, and other products regulated by the FDA. The report categorizes recalls based on the severity of the risk involved, ranging from products that might cause serious health problems (Class I) to those that are unlikely to cause any adverse health reaction (Class III). Each entry in the report includes information about the product, the reason for the recall, the recalling firm, and the classification of the recall. This report is a key tool for the FDA in its mission to protect public health by ensuring that potentially harmful products are quickly and effectively removed from the market. It also serves as a transparent resource for consumers and healthcare professionals to stay informed about product safety concerns. All recalls monitored by FDA are included in the Enforcement Report once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Once FDA completes the hazard assessment, the Enforcement Report entry will be updated with the recall classification. Recall data in the Enforcement Report can be accessed through the weekly report publication, the quick and advanced search functionalities, and an Application Programming Interface (API).

Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
Website Contact	
Website dataset	https://www.accessdata.fda.gov/scripts/ires/index.cfm
Website result set	HTML Table page, CSV
Mobile app available?	N/A
Website search fields	**By Year, Month, Week** By Product Type (Drugs, Biologics) By Product Name By Event By Recall Firm
Website result set fields	**Product Type** Recently Update Record Product Description Classification Code Information Reason for Recall Recalling Firm
API available?	Yes (see API section below for more info)
API website	https://open.fda.gov/apis/drug/enforcement/
API dashboard, interactive, fields definitions	https://open.fda.gov/apis/drug/enforcement/explore-the-api-with-an-interactive-chart/
API search	https://open.fda.gov/apis/drug/enforcement/searchable-fields/
Data Entity Relationship Diagram (ERD)	Unknown
Data Definition	Unknown

Recall Enforcement Report from openFDA API

The openFDA Human Drug – Recall Enforcement Report, provides an API data dictionary found at:

- https://open.fda.gov/data/datadictionary
- https://open.fda.gov/fields/drugenforcement_reference.pdf

SECTION	FIELD NAME	TYPE	DESCRIPTION
Enforcement report	recalling_firm	string	The firm that initiates a recall or, in the case of an FDA requested recall or FDA mandated recall, the firm that has primary responsibility for the manufacture and (or) marketing of the product to be recalled.
Enforcement report	classification	string	Numerical designation (I, II, or III) that is assigned by FDA to a particular product recall that indicates the relative degree of health hazard.
Enforcement report	status	string	
Enforcement report	distribution_pattern	string	General area of initial distribution such as, “Distributors in 6 states: NY, VA, TX, GA, FL and MA; the Virgin Islands; Canada and Japan”. The term “nationwide” is defined to mean the fifty states or a significant portion. Note that subsequent distribution by the consignees to other parties may not be included.
Enforcement report	product_description	string	Brief description of the product being recalled.
Enforcement report	code_info	string	A list of all lot and/or serial numbers, product numbers, packer or manufacturer numbers, sell or use by dates, etc., which appear on the product or its labeling.
Enforcement report	reason_for_recall	string	Information describing how the product is defective and violates the FD&C Act or related statutes.
Enforcement report	product_quantity	string	The amount of defective product subject to recall.
Enforcement report	voluntary_mandated	string	Describes who initiated the recall. Recalls are almost always voluntary, meaning initiated by a firm. A recall is deemed voluntary when the firm voluntarily removes or corrects marketed products or the FDA requests the marketed products be removed or corrected. A recall is mandated when the firm was ordered by the FDA to remove or correct the marketed products, under section 518(e) of the FD&C Act, National Childhood Vaccine Injury Act of 1986, 21 CFR 1271.440, Infant Formula Act of 1980 and its 1986 amendments, or the Food Safety Modernization Act (FSMA).
Enforcement report	report_date	string	Date that the FDA issued the enforcement report for the product recall.

Enforcement report	recall_ initiation_ date	string	Date that the firm first began notifying the public or their consignees of the recall.
Enforcement report	initial_ firm_notifi- cation	string	The method(s) by which the firm initially notified the public or their consignees of a recall. A consignee is a person or firm named in a bill of lading to whom or to whose order the product has or will be delivered.
Enforcement report	recall_ number	string	A numerical designation assigned by FDA to a specific recall event used for tracking purposes.
Enforcement report	event_id	string	A numerical designation assigned by FDA to a specific recall event used for tracking purposes.
Enforcement report	product_ type	string	The type of product being recalled. For drug queries, this will always be `Drugs`.
Geographic data	city	string	The city in which the recalling firm is located.
Geographic data	state	string	The U.S. state in which the recalling firm is located.
Geographic data	country	string	The country in which the recalling firm is located.
openFDA	See the OpenFDA fields section on the API Reference page https:// open.fda.gov/api s/ openfda-fields/) for list of openFDA fields.		Different datasets use different drug identifiers—brand name, generic name, NDA, NDC, etc. It can be difficult to find the same drug in different datasets. And some identifiers, like pharmacologic class, are useful search filters but not available in all datasets.
			OpenFDA features harmonization of drug identifiers to make it easier to search enforcement report records by more identifiers, like product type (OTC versus prescription). Drug products that appear in enforcement reports are harmonized on NDC or UPC, if available. The linked data is listed as an openfda annotation in the patient.drug section of a result.
			Only a portion of enforcement reports have an openfda section. Because the harmonization process requires an exact match, some drug products cannot be harmonized in this fashion—for instance, if there is no NDC or UPC in the original enforcement report, there will be no openfda section.

Drug Alerts

Description	The FDA Drug Alerts are notifications issued by the Food and Drug Administration to inform healthcare professionals, patients, and the general public about critical drug-related information. These alerts can include warnings about potential side effects, recalls due to manufacturing issues, advisories about safe usage, or information about newly discovered drug interactions. The purpose of these alerts is to provide timely and essential information that can impact the safety and effectiveness of drug therapies. They play a vital role in the FDA's ongoing effort to monitor the safety of pharmaceutical products post-approval and ensure that any emerging risks or issues are promptly communicated and addressed to protect public health. The alerts are part of the FDA's broader strategy to maintain a safe pharmaceutical environment and to foster informed decision-making among healthcare providers and patients.
Customers	
	• Healthcare Professional • Customer and Patients • Researchers and Scientists • Private Sector
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/drugs/drug-safety-and-availability/drug-alerts-and-statements
Website Contact	
Website dataset	N/A
Website result set	HTML page, Excel
Mobile app available?	N/A
Website search fields	Text Search
Website result set fields	Date Description with link to the webpage with the alert
API available?	N/A

Drug Statements

Description	The FDA Drug Statements refer to official communications issued by the Food and Drug Administration regarding various aspects of pharmaceutical products. These statements can cover a wide range of topics, including announcements of new drug approvals, safety warnings, policy changes, regulatory updates, and guidance for industry and healthcare professionals. They are an essential means by which the FDA conveys critical information to the public, healthcare providers, and pharmaceutical companies, ensuring that stakeholders are informed about the latest developments in drug regulation, safety, and usage. These statements play a key role in the FDA's mission to protect public health by ensuring that drugs are safe, effective, and properly labeled, and they help maintain transparency and trust in the FDA's regulatory processes.
Customers	• Healthcare Professional • Customer and Patients • Researchers and Scientists • Private Sector
Usage	↑ **Highly Usage** — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/drug-safety-and-availability/drug-alerts-and-statements#statements
Website Contact	
Website dataset	N/A
Website result set	HTML page, Excel
Mobile app available?	N/A
Website search fields	Text Search
Website result set fields	Date Description with link to the webpage with the alert
API available?	N/A

FDA Safety Information and Adverse Event Reporting Program

Description	The FDA Safety Information and Adverse Event Reporting Program, also known as MedWatch, is an initiative designed to collect and monitor information about adverse events and safety issues related to drugs, medical devices, and other FDA-regulated products. Healthcare professionals and consumers can report adverse events, which are then analyzed by the FDA to identify safety trends and potential risks. If a significant risk is identified, the FDA may take action, such as updating product labels with new safety information, issuing safety alerts, or implementing regulatory changes. This program is a critical tool in the FDA's effort to ensure the safety and effectiveness of medical products post-market, facilitating early detection of potential health risks and enhancing patient protection. MedWatch, the FDA's medical product safety reporting program for health professionals, patients and consumers. MedWatch receives reports from the public and when appropriate, publishes safety alerts for FDA-regulated products such as: • Prescription and over-the-counter medicines • Biologics such as blood components, blood/plasma derivatives and gene therapies. • Medical devices such as hearing aids breast pumps, and pacemakers. • Combination products such as pre-filled drug syringe, metered-dose inhalers and nasal spray. • Special nutritional products such as dietary supplements, medical foods and infant formulas. • Cosmetics such as moisturizers, makeup, shampoos, hair dyes and tattoos. • Food such as beverages and ingredients added to foods.
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
Website Contact	
Website dataset	N/A
Website result set	HTML page, Excel
Mobile app available?	N/A
Website search fields	Text Search By Product Type (Biologic, Drugs, Medical Devices) By Year

Website result set fields	Date Safety Alert with link to the webpage with the alert Product Type
API available?	N/A

Drug Safety-related Labeling Changes (SrLC)

Description	The FDA's Drug Safety-related Labeling Changes program involves the continuous monitoring and updating of prescription drug labeling to reflect new safety information that emerges after a drug has been approved and marketed. This initiative is crucial for providing healthcare professionals and patients with the most current information regarding the risks, side effects, and safe use of medications. When new data indicate a significant health risk or a change in the understanding of a drug's safety profile, the FDA requires manufacturers to update their product labels accordingly. These changes can include new warnings, contraindications, dosage adjustments, or adverse reaction information. The goal of this program is to enhance patient safety by ensuring that drug labels accurately represent the latest scientific knowledge and clinical experience, thereby aiding healthcare professionals in making informed prescribing decisions and helping patients to use their medications safely and effectively. The Drug Safety-related Labeling Changes (SrLC) database provides approved safety-related labeling changes from January 2016 forward. Data prior to January 2016 will continue to be available on the MedWatch website.
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/
Website Contact	druginfo@fda.hhs.gov
Website dataset	N/A
Website result set	HTML page, PDF, Excel, CSV
Mobile app available?	N/A
Website search fields	By Drug Name By Date Search

Website result set fields	Drug Name Active Ingredient Application Number Application Type Supplement Date Database Updated
API available?	N/A

FDA Drug Shortages

Description	The FDA's Drug Shortages program addresses the issue of shortages in pharmaceutical drugs, a significant public health concern that can delay or even deny critical care for patients. The program's primary goal is to prevent and mitigate drug shortages in the United States. When a shortage occurs, the FDA works closely with pharmaceutical manufacturers, other federal agencies, and healthcare professionals to gather information about the shortage, its causes, and potential solutions. This can involve identifying alternative sources of the drug, expediting review processes for new and alternative manufacturers, or adjusting regulatory requirements temporarily. The FDA also communicates actively with the public and healthcare providers about the status of drug shortages and potential alternatives. This proactive approach aims to minimize the impact of shortages on patient care and ensure the continued availability of essential medications. Current and Resolved Drug Shortages and Discontinuations Reported to FDA
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
Website Contact	
Website dataset	N/A
Website result set	HTML page
Mobile app available?	N/A

Website search fields	Search by Generic Name or Active Ingredient text By Current/Resolved Shortage By Discontinuations By Therapeutic Categories By New and Updated
Website result set fields	**Current/Resolved Shortage** A drug receives Resolved status when the Drug Shortages Staff (DSS) determines that the market is covered, based on information from all manufacturers. The market is considered covered when supply is available from at least one manufacturer to cover total market demand. However, some manufacturers may not have all presentations available. DSS monitors the supply of products with Resolved status. For the most current supply information, contact the manufacturers. Generic Name or Active Ingredient Status **Discontinuations** Discontinuations Listed by Generic Name or Active Ingredient Companies are required under Section 506C of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (as amended by the Food and Drug Administration Safety and Innovation Act) to notify FDA of a permanent discontinuance of certain drug products, six months in advance, or if that is not possible, as soon as practicable. These drugs include those that are life-supporting, life-sustaining or for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery. The discontinuations listed on the site reflect information received from manufacturers and are for informational purposes only. Withdrawal notifications can be found here: https://www.federalregister.gov Generic Name or Active Ingredient **Therapeutic Categories** Company Name Company Contact Information (Phone Number) Presentation Posting Date Related Information **New and Updated** Company Name Company Contact Information (Phone Number) Presentation Availability and Estimated Shortage Duration Related Information Shortage Reason (per FDASIA)
API available?	N/A

Additions/Deletions for Prescription and OTC Drug Product Lists

Description	This document is not a cumulative list of approved Prescription and OTC Drug Products but a list of the new additions and new deletions to the Prescription and OTC Drug Product Lists for a specific month. This information must be used in conjunction with the most current Cumulative Supplement and Orange Book. Additions and deletions are identified in this document by the symbols >ADD> and >DLT>, respectively. Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the current Edition List will then be added to the "Discontinued Drug Product List" of the following Edition.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/drugs/drug-approvals-and-databases/additionsdeletions-prescription-and-otc-drug-product-lists
Website Contact	
Website dataset	N/A
Website result set	PDF
Mobile app available?	N/A
Website search fields	N/A
Website result set fields	By Year, Month Name Route Dose Addition/Deletion
API available?	N/A

Dissolution Methods Database

Description	For a drug product that does not have a dissolution test method in the United States Pharmacopeia (USP), the FDA Dissolution Methods Database provides information on dissolution methods presently recommended by the Division of Bioequivalence, Office of Generic Drugs.
Customers	• Healthcare Professional • Customer and Patients • Researchers and Scientists • Private Sector
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/drug-approvals-and-databases/dissolution-methods-database
Website Contact	
Website dataset	https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm
Website result set	HTML page, CSV, Excel
Mobile app available?	N/A
Website search fields	Search for a Dissolution Method text
Website result set fields	Drug Name Dosage Form USP Apparatus Speed (RPMs) Medium Volume (mL) Recommended Sampling Times (minutes) Date Updated
API available?	N/A

Inactive Ingredients in Approved Drug Products

Description	The Inactive Ingredient Database provides information on inactive ingredients present in FDA-approved drug products. This information can be used by industry as an aid in developing drug products. For new drug development purposes, once an inactive ingredient has appeared in an approved drug product for a particular route of administration, the inactive ingredient is not considered new and may require a less extensive review the next time it is included in a new drug product. For example, if a particular inactive ingredient has been approved in a certain dosage form at a certain potency, a sponsor could consider it safe for use in a similar manner for a similar type of product.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • Private Sector
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredients-approved-drug-products-search-frequently-asked-questions
Website Contact	IIDUpdate@fda.hhs.gov
Website dataset	https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm
Website result set	HTML page, CSV, Excel
Mobile app available?	N/A
Website search fields	Search for Inactive Ingredient Name text
Website result set fields	Inactive Ingredient Route Dosage Form CAS Number UNII Maximum Potency per unit dose Maximum Daily Exposure (MDE) Record Update
API available?	N/A

Medication Guides

Description	The FDA's regulation of medication, specifically human prescription drugs and therapeutic biological products, involves a comprehensive process to ensure that these products are safe, effective, and high-quality. This regulatory framework encompasses the entire lifecycle of these products, from preclinical research to post-market surveillance. For prescription drugs, this includes a rigorous evaluation of clinical trial data to assess the balance of benefits and risks, quality control in manufacturing processes, and monitoring for adverse effects once the product is on the market. The FDA's role in regulating these products is crucial in maintaining the integrity of the U.S. drug supply and ensuring that the medications available to patients are both effective for their intended use and safe for consumption. This database contains MGs for FDA-approved human prescription drugs and therapeutic biological products. Although this database does not include MGs for vaccines, allergenic products, blood products, plasma derivatives, and cellular and gene therapy products, such MGs can be found on FDA Label or DailyMed. For more information about MGs see "What are Medication Guides" on the Patient Labeling Resources webpage.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • Private Sector
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	
Website Contact	
Website dataset	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide.page
Website result set	HTML page, CSV
Mobile app available?	N/A
Website search fields	Search text
Website result set fields	Drug Name Active Ingredient Form;Route App. No. Company Date
API available?	N/A

Postmarketing Requirements and Commitments

Description	The FDA Postmarketing Requirements and Commitments refer to obligations that drug and biological product manufacturers undertake after receiving FDA approval. These requirements and commitments are designed to gather additional information about a product's safety, efficacy, and optimal use, often emerging from conditions of the product's initial approval or as part of the FDA's ongoing surveillance. They can include postmarketing studies and clinical trials to assess rare adverse events, long-term effects, and other aspects not fully captured before approval. The aim is to continuously monitor the performance and impact of these products in real-world settings, ensuring ongoing protection of public health. The FDA tracks these postmarketing activities to ensure compliance and publicly shares the status of these obligations to maintain transparency and inform healthcare professionals and the public. The phrase postmarketing requirements and commitments refers to studies and clinical trials that sponsors conduct after approval to gather additional information about a product's safety, efficacy, or optimal use. Some of the studies and clinical trials may be required; others may be studies or clinical trials a sponsor has committed to conduct.
Customers	• Healthcare Professional • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments
Website Contact	pmcweb@cder.fda.gov
Website dataset	https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm
Website result set	HTML page
Mobile app available?	N/A
Website search fields	By Applicant By Product By NDA/ANDA/BLA Number By Requirement/Commitment Status (Ongoing, Pending, Delayed, Terminated, Submitted, Fulfilled, Released, All Statuses By Required Under (Accelerated Approval, Animal Efficacy Rule, Pediatric Research Equity Act, FDAAA Section 505(o)(3) NDA/ANDA/BLA Approval Date From NDA/ANDA/BLA Approval Date To

Website result set fields	Applicant Product NDA/BLA Number NDA/BLA Approval Date Annual Report Due Date Annual Report Received Required Under Original Projected Completion Date Description Current Status Explanation of Status
API available?	N/A

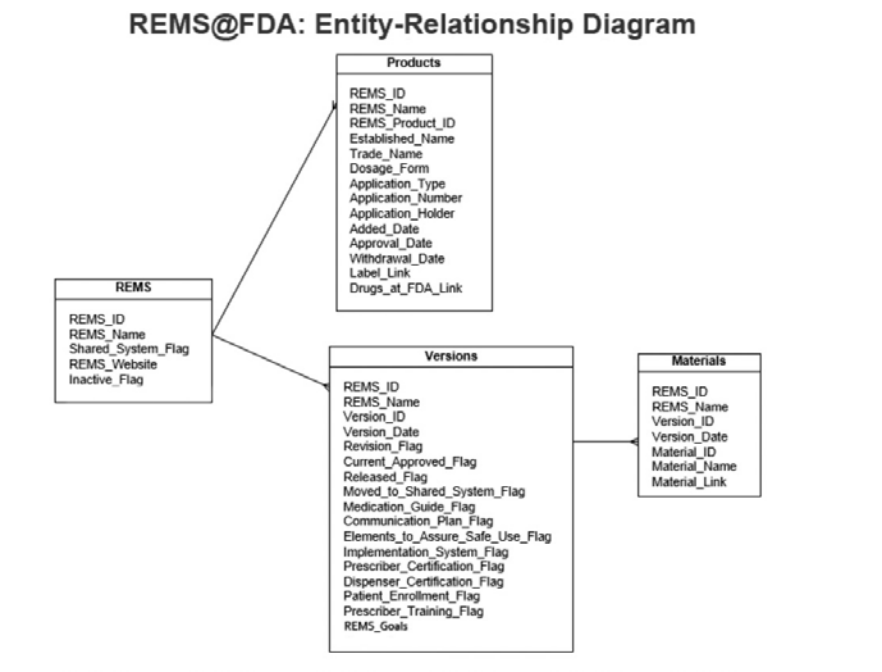
Product-Specific Guidances for Generic Drug Development

Description	The FDA's Product-Specific Guidances for Generic Drug Development are recommendations intended to assist the pharmaceutical industry in developing generic drugs. These guidances offer clear, detailed recommendations on the approach to be taken for developing and testing generic drugs, ensuring they meet the necessary quality, safety, and efficacy standards. They cover a range of issues, including bioequivalence testing, analytical methods, and formulation design, tailored to specific reference listed drugs. By providing these guidances, the FDA aims to streamline the generic drug approval process, encourage the development of generic medications, and thus increase their availability in the market. This initiative is part of the FDA's broader effort to promote public health by ensuring access to effective, affordable medications. To successfully develop and manufacture a generic drug product, an applicant should consider that their product is expected to be: pharmaceutically equivalent to its reference listed drug (RLD), i.e., to have the same active ingredient, dosage form, strength, and route of administration under the same conditions of use; bioequivalent to the RLD, i.e., to show no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient; and, consequently, therapeutically equivalent, i.e., to be substitutable for the RLD with the expectation that the generic product will have the same safety and efficacy as its RLD.
Customers	• Healthcare Professional • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm
Website Contact	edata@fda.hhs.gov

Website dataset	https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm
Website result set	HTML page, Excel, CSV, PDF
Mobile app available?	N/A
Website search fields	Search text
Website result set fields	Active Ingredient (link to Specific Guidance) Type Route Dosage Form RLD or RS Number
API available?	N/A

Risk Evaluation and Mitigation Strategies (REMS)

Description	The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. The FDA's Risk Evaluation and Mitigation Strategies (REMS) program is designed to manage known or potential risks associated with certain medications, ensuring their benefits outweigh the risks. The FDA can require REMS for specific drugs with serious safety concerns to help ensure safe use. These strategies can include various elements such as medication guides, patient package inserts, communication plans for healthcare professionals, and requirements for monitoring, patient selection, and patient education. The program aims to enhance patient safety while maintaining access to these medications for those who need them, effectively balancing the need for medication safety with the practicality of drug accessibility. The REMS program represents a critical aspect of the FDA's commitment to drug safety and public health.
Customers	• Healthcare Professional • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
Website Contact	
Website dataset	https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm

Website result set	HTML page, Excel, CSV
Mobile app available?	N/A
Website search fields	Keyword text
Website result set fields	Name REMS Approved Last Updated MedGuide (MG) Comm. Plan (CP) ETASU Imp. System (IS)
API available?	N/A
API website	N/A
API dashboard, interactive, fields definitions	https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/dfa2f0ce-4940-40ff-8d90-d01c19ca9c4d/state/analysis
API search	N/A
Data Entity Relationship Diagram (ERD)	 https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page
Data Definition	https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page

1. **REMS**

The **REMS** table includes one record for each REMS program, including REMS that are no longer in place. Detailed information about each REMS program is not included in this table, but can be found in the REMS Versions table.

This table includes the following fields:

- **REMSID:** A unique key used to identify each REMS.
- **REMS_Name:** The name used on the REMS website to refer to the REMS program. Generally, single-product REMS are referred to by the brand name of the product, while shared system REMS are referred to by the name of the molecule or class to which they apply.
- **Shared_System_Flag:** A flag that indicates whether a REMS is a shared system REMS.
- **REMS_Website:** A link to the application-holder's official website for the REMS.
- **Inactive_Flag:** A flag that indicates REMS programs that are no longer active. A REMS program may become inactive if the REMS requirement is released, if it is a single-product REMS that is incorporated into a shared system, or if all products under the REMS have been withdrawn and are published in the Federal Register (FR).

2. **Versions**

The REMS **Versions** table includes a record for each change to the REMS, including a record for each newly approved REMS, an additional record for each modification or revision to that REMS, and a record when the REMS requirement is released or the REMS is moved to a shared system. For more information about REMS revisions and modifications, please see FDA's Draft Guidance, Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry.

This table includes the following fields.

- **REMSID:** A unique key used to identify each REMS.
- **REMS_Name:** The name used on the REMS website to refer to the REMS program. Generally, single-product REMS are referred to by the brand name of the product, while shared system REMS are referred to by the name of the molecule or class to which they apply.
- **VersionID:** A unique key used to identify the version of the REMS.
- **Version_Date:** The date this version of the REMS was approved. The earliest version_date of the REMS is the date that the REMS was initially approved. For REMS that are no longer in place, the latest version_date indicates the date that the REMS was removed.
- **Revision_Flag:** A flag that indicates whether this version of the REMS is a revision as defined in FDA's Draft Guidance, Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry. REMS revisions are defined as being limited to editorial changes, corrections of typographical errors, and changes in the application holder name or address. If the flag is equal to 0, this indicates that this version of the REMS is a newly approved REMS or a modification to that REMS.
- **Current_Approved_Flag:** A flag that indicates whether this is the most recent version of a currently approved REMS (i.e., the version of the REMS that would appear on the REMS website homepage).
- **Released_Flag:** A flag that indicates whether the REMS was released as of that version_ date.
- **Moved_to_Shared_System_Flag:** A flag that indicates whether the REMS was moved to a shared system as of that version_date.

Data Definition

- **Medication_Guide_Flag: A** flag that indicates whether a REMS has a Medication Guide as one of its elements. Note that many REMS products have medication guides that are not part of the REMS program and are not captured here. For a full list of medication guides, click here.
- **Communication_Plan_Flag:** A flag that indicates whether this version of the REMS has a communication plan as one of its elements.
- **Elements_to_Assure_Safe_Use_Flag: A** flag that indicates whether this version of the REMS has elements to assure safe use.
- **Implementation_System_Flag:** A flag that indicates whether this version of the REMS has an implementation system as one of its elements. This applies only to REMS with elements to assure safe use.
- **Prescriber_Certification_Flag:** A flag that indicates whether this version of the REMS requires prescribers to become certified in order to be able to prescribe the drug. This applies only to REMS with elements to assure safe use.
- **Dispenser_Certification_Flag:** A flag that indicates whether this version of the REMS requires dispenser to become certified in order to be able to dispense the drug. This applies only to REMS with elements to assure safe use.
- **Patient_Enrollment_Flag:** A flag that indicates whether this version of the REMS requires patients to be enrolled in the REMS program. This applies only to REMS with elements to assure safe use.
- **Prescriber_Training_Flag:** A flag that indicates whether the REMS provides training to prescriber as part of its Elements to Assure Safe Use.
- **REMS_Goals:** The goals for each REMS Program, as specified in the REMS Document.

3. **Products**

The **Products** table includes a record for each application that has been subject to a REMS.

This table includes the following fields

- **REMSID:** A unique key used to identify each REMS.
- **REMS_Name:** The name used on the REMS website to refer to the REMS program. Generally, single-product REMS are referred to by the brand name of the product, while shared system REMS are referred to by the name of the molecule or class to which they apply.
- **ProductID:** A unique key used to identify the drug
- **Established_Name:** The official nonproprietary name assigned to the drug. Generally, this is the “generic” name of the drug.
- **Trade_Name:** The proprietary or brand name for the drug, where it exists. Many generic products do not have trade names.
- **Dosage_Form:** The dosage form of the drug.
- **Application_Type:** The type of marketing approval the drug received. A drug may be marketed under a New Drug Application (NDA), Biologics License Application (BLA), or as a generic drug under an Abbreviated New Drug Application (ANDA).
- **Application_Number:** The number assigned by FDA staff to each application. One drug can have more than one application number if it has different dosage forms or routes of administration.
- **Added_Date:** The date the drug was added to the REMS. For most drugs, this is the same as the date that the REMS was initially put into place, but the dates may be different, if, for instance, a new drug is added to an existing shared system.
- **Approval_Date:** The date the drug was initially approved for marketing.

Data Definition	• **Withdrawal_Date:** The date published in the Federal Register announcing the drug was withdrawn from the market. If the drug was not withdrawn or the withdrawal was not announced in the Federal Register then this date will be blank. • **Label_Link:** A link to the drug's label on DailyMed. DailyMed is a website hosted by the National Library of Medicine that provides information on the drug's current labeling. The current labeling shown on DailyMed may be different from the version that was initially approved by FDA and displayed at Drugs@FDA. • **Drugs_at_FDA_Link:** A link to regulatory information about a drug at Drugs@FDA. Drugs@FDA is a catalog that provides information about FDA-approved products, including the product's approval history, FDA-approved labeling, therapeutically equivalent products, and consumer information.
	4. **Materials** The **Materials** table includes a record for each material included as part of each version of the REMS. As used in this database, the term REMS materials refers to both the REMS document and the REMS' appended materials designed for stakeholders. Most information about REMS materials is available only for REMS versions that were current as of July 31, 2014 or later. This table includes the following fields: • **REMSID:** A unique key used to identify each REMS • **REMS_Name:** The name used on the REMS website to refer to the REMS program. Generally, single-product REMS are referred to by the brand name of the product, while shared system REMS are referred to by the name of the molecule or class to which they apply. • **MaterialID:** A unique key used to identify the REMS material • **Material_Name:** The name of the material, as specified in the REMS document • **Material_Link:** A link to download the material from the REMS website. • **VersionID:** A unique key used to identify the version of the REMS • **Version_Date:** The date this version of the REMS was approved. The earliest version_date of the REMS is the date that the REMS was initially approved. For REMS that are no longer in place, the latest version_date indicates the date that the REMS was removed.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Description	The FDA Orange Book, officially titled Approved Drug Products with Therapeutic Equivalence Evaluations, is a resource that identifies drug products approved by the FDA on the basis of safety and effectiveness. It provides information about generic equivalents to brand-name drugs, patent expiration dates, and exclusivity periods. This book is essential for healthcare professionals for selecting therapeutically equivalent drug products, and it plays a key role in the generic drug approval process, fostering competition and accessibility in the pharmaceutical market. The publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • **Private Sector**

Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book
Website Contact	orangebook@fda.hhs.gov
Website dataset	https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm
Website result set	HTML page, CSV, Excel The entire Orange Book can be downloaded here: https://www.fda.gov/media/76860/download?attachment
Mobile app available?	**Apple** (https://apps.apple.com/us/app/ob-express-2-0/id1229831803?ls=1) **Android** (https://play.google.com/store/apps/details?id=gov.fda.obook)
Website search fields	**Search by Proprietary Name, Active Ingredient or Application Number** Full text Search **Search by Applicant (Company)** Full text Search or Name Search **Search by Dosage Form (for example: *TABLET*)** Dosage Search **Search by Route of Administration (for example: *ORAL*)** Route Search **Search by Patent Number** Patent Number Search **View Newly Added Patents or Delisted Patents** Newly Added Patents Delisted Patents
Website result set fields	Mkt. Status Active Ingredient Proprietary Name Appl. No. Dosage Form Route Strength TE code RLD RS Applicant Holder
API available?	Yes, openFDA, see Drugs@FDA Database

I. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

Blood Establishment Registration Database

Description	The FDA Blood Establishment Registration is a legal requirement for all U.S. facilities involved in the collection, processing, and storage of human blood and blood products. This registration, overseen by the Food and Drug Administration, is essential for maintaining a comprehensive list of active blood establishments and ensuring their adherence to federal standards and regulations. The process involves submitting detailed information about the establishment, including operations and changes in facility status. This registration plays a pivotal role in the FDA's regulatory oversight, including regular inspections to verify compliance. Ultimately, it is a critical component in safeguarding public health by ensuring the safety and availability of the blood supply for medical uses.
Customers	• Healthcare Professional • Customer and Patients • Researchers and Scientists • Private Sector
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/find-blood-establishment
Website Contact	bloodregis@fda.hhs.gov
Website dataset	https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/
Website result set	HTML page
Mobile app available?	N/A
Website search fields	FDA Established ID (FEI) Application Name Establishment Name Other Names Establishment Type (Broker/Warehouse, Collection Facility, Community (Non-Hospital) blood bank, Component preparation facility, distribution center, hospital blood bank, hospital transfusion center, Manufacturer of licensed devices, Non-hospital Transfusion Service, Other, Plasmapheresis center, Product Testing Laboratory) Establishment Status (Active, Inactive, Pre-register) State City Zip code Country (United States, Non-US) Official name (Last, First)

Website result set fields	**First page** Establishment Name City, State/Zip FEI Establishment Status **Second page** Matrix
API available?	N/A

Human Cell and Tissue Establishment Registration (HCTERS) Public Query Application

Description	The FDA Human Cell and Tissue Establishment Registration (HCTERS) Public Query Application is a publicly accessible tool provided by the Food and Drug Administration for searching and viewing information about establishments registered to handle human cells, tissues, and cellular and tissue-based products (HCT/Ps). This application offers critical details such as the names, addresses, and contact information of these establishments, along with the types of HCT/Ps they manage. Its primary purpose is to promote transparency, facilitate informed decision-making among healthcare providers and patients, and support the FDA's regulatory efforts in ensuring the safety and compliance of facilities dealing with human cell and tissue products, thereby aiding in the prevention of communicable diseases and the assurance of product effectiveness and safety.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/human-cell-and-tissue-establishment-registration-hcters-public-query-application
Website Contact	tissuereg@fda.hhs.gov
Website dataset	https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm
Website result set	HTML page
Mobile app available?	N/A

Website search fields	Establishment Name Establishment Function (Distribute, Donor Testing, Label, Package, Process, Recover, Screen, Store) Product (Amniotic Membrane, Blood Vessel, Bone, Cardiac Tissue – non – valved, Cartilage, Cornea, Dura Mater, Embryo, Fascia, Heart Valve, HPC Apheresis, HPC Cord Blood, Ligament, Nerve Tissue, Oocyte, Ovarian Tissue, Pancreatic Islet Cells – autologous, Parathyroid, Pericardium, Peripheral Blood Mononuclear Cells, Peritoneal Mem brane, Sclera, Semen, Skin, Tendon, Testicular Tissue, Tooth Pulp, Umbilical Cord Tissue) Establishment Status (Active, Inactive, Pre-register) State City Zip code Country (United States, Non-US)
Website result set fields	**First page** Application Name/Establishment Name City, State/Zip FEI Establishment Status **Second page** Matrix
API available?	N/A

Blood Grouping and Phenotyping Reagents

Description	The FDA Blood Grouping and Phenotyping Reagents details regulated products for blood grouping, essential in transfusion medicine. It lists various manufacturers and their specific licensed reagents used to determine blood types and identify red blood cell antigens. These reagents ensure safe blood transfusions by confirming blood compatibility. This includes a range of reagents for different blood group systems, highlighting the FDA's regulatory oversight in ensuring the accuracy and safety of these critical medical products.
Customers	• **Healthcare Professional** • Customer and Patients • **Researchers and Scientists** • **Private Sector**
Usage	⬆ Highly Usage — Medium Usage ⬇ Low Usage
Website	https://www.fda.gov/vaccines-blood-biologics/blood-blood-products
Website Contact	
Website dataset	https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/blood-grouping-and-phenotyping-reagents

Website result set	HTML page
Mobile app available?	N/A
Website search fields	N/A
Website result set fields	Manufacturer STN Trade Name Product
API available?	N/A

Approved Cellular and Gene Therapy Products

Description	The FDA Cellular and Gene Therapy Products provides information about products that have been approved for therapeutic use in various medical conditions. These innovative treatments, developed through advanced biotechnological methods, include gene therapies for genetic disorders, cellular therapies for cancer and other diseases, and tissue-engineered products for regenerative medicine. The information highlights the FDA's role in ensuring the safety and effectiveness of these groundbreaking therapies.
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products
Website Contact	
Website dataset	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products
Website result set	HTML page
Mobile app available?	N/A
Website search fields	N/A

Website result set fields	Name Link to manufacture Description
API available?	N/A

Biological Approvals

Description	The FDA's 2023 Biological Approvals outlines the Center for Biologics Evaluation and Research's (CBER) regulatory activities for the year. It includes information on the approval of new Biologics License Applications (BLAs) and significant BLA supplements, which contribute to public health advancements. Approvals for medical devices associated with the collection, processing, testing, manufacture, and administration of licensed blood, blood components, and cellular products. This resource is part of the FDA's commitment to transparency in its approval processes and public health enhancements.
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2023-biological-approvals
Website Contact	
Website dataset	https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2023-biological-license-application-approvals
Website result set	HTML page
Mobile app available?	N/A
Website search fields	N/A
Website result set fields	Name Indication for Use STN Manufacturer/License Number Approval Date
API available?	N/A

Purple Book: Database of Licensed Biological Products

Description	The Purple Book is a database that contains information about all FDA-licensed biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products. The Purple Book also contains information on all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER). Some of the information you can find in the Purple Book includes: • The date on which a biological product was licensed under section 351(a) or 351(k) of the Public Health Service Act (PHS Act). • Whether a biological product licensed under section 351(k) of the PHS Act has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product). • The date of expiration of applicable exclusivity for a biological product if FDA has determined that the biological product is eligible for reference product exclusivity under section 351(k)(7) of the PHS Act or first interchangeable biological product exclusivity under section 351(k)(6) of the PHS Act, as appropriate. • Patent information for certain licensed biological products required by the Biological Product Patent Transparency section of the Consolidated Appropriations Act of 2021.
Customers	• **Healthcare Professional** • **Customer and Patients** • **Researchers and Scientists** • **Private Sector**
Usage	↑ Highly Usage — Medium Usage ↓ Low Usage
Website	https://purplebooksearch.fda.gov/about
Website Contact	
Website dataset	https://purplebooksearch.fda.gov
Website result set	HTML page
Mobile app available?	N/A
Website search fields	Full Text Search

Website result set fields	First Page Product Name Link to BLA Number Second Page Biosimilar(s) Interchangeable(s) Reference Product(s)
API available?	N/A

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