The Alliance for a Stronger FDA

Overview; FDA's Missions, Responsibilities and Workloads

February 18, 2025

About the Alliance

- The Alliance for a Stronger FDA, created in 2007, is a multi-stakeholder organization with 150+ members
- The Alliance's unique coalition of patient and consumer groups and industry mirrors FDA's unique role in public health, safety, and commerce
- Members of the Alliance are devoted to ensuring the FDA has the resources it needs to protect the public and ensure timely access to innovative products that improve food safety and nutrition, cosmetics safety, animal health and human health
- The Alliance is committed to serve as a resource for policymakers and the public about the FDA's mission and responsibilities

The Mission of the FDA

The U.S. Food and Drug Administration (FDA) promotes and protects the public by ensuring that consumers have access to **safe foods and cosmetics** and **safe and effective medical products**. It is widely respected for its global leadership in science-based regulation.

The Mission of the FDA

- FDA oversees the safety of more than **$3.9 trillion** worth of food, tobacco and medical products produced in the U.S. and abroad
- FDA regulated products account for more than **21 cents of every consumer dollar spent** in the United States
- FDA regulates **100% of medical products** (drugs, biologics, medical devices, vaccines and veterinary products)
- FDA regulates about **77% of U.S. food supply** (except meat, poultry, and some egg products)
- FDA regulated products account for **18% of U.S. imports** (>$2,631B) and **18% of exports** (>$1,863B)

FDA at a Glance 2024

The Mission of the FDA

- There are over **23,000 prescription drugs approved** for marketing
- There are over **750 FDA licensed biologics**
- FDA oversees about **7,000 different types of medical devices (248,400 regulated devices)**
- There are approximately **1,600 approved animal products**
- FDA regulated products are manufactured or handled at nearly **300,000 registered facilities** (over half are ex-U.S.)

FDA at a Glance 2024; CDRH Annual Report 2024

FDA: Key Centers and Offices

The Center for **Drug** Evaluation and Research (CDER)

- Office of **Nonprescription** Drugs (ONPD)
- Office of **Generic** Drugs (OGD)
- Office of Therapeutic Biologics and **Biosimilars** (OTBB)
- Office of Surveillance and Epidemiology (OSE)

The Center for **Biologic** Evaluation and Research (CBER)

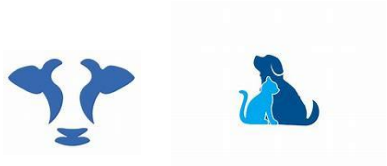
- Office of Compliance and Biologics Quality (OCBQ)

The Center for **Devices** and Radiological Health (CDRH)

FDA: Key Centers and Offices

The Center for **Devices** and Radiological Health (CDRH)

Office of Product Evaluation and Quality (OPEQ)



The Center for **Veterinary Medicine** (CVM)

Office of Surveillance and Compliance (OSC)

The Center for **Tobacco Products**

FDA: Key Centers and Offices

Deputy Commissioner of **Human Food**

The Human Foods Program (HFP, formerly CFSAN)

Office of the Chief Scientist

Office of **Cosmetics and Colors**

SAFE Office of **Inspectorates** (OII)

Biologics (OBI), Bioresearch Monitoring (OBMI), Drugs (OHADI), Food Products - Animal (OAFA) and Human (OHFI), Medical Device (OMDRHI) and Import (OIO)

Center for Drug Evaluation and Research

The Center for Drug Evaluation and Research (CDER) is charged with making sure that safe and effective medicines are available to improve the lives of patients and their families.

This includes prescription and over-the-counter medicines (novel drugs and biologics, generic drugs, biosimilars and over-the-counter medicines).

CDER also has regulatory oversight of things such as toothpaste, antiperspirants, shampoos and sunscreens.

CDER: Novel Prescription Medicines

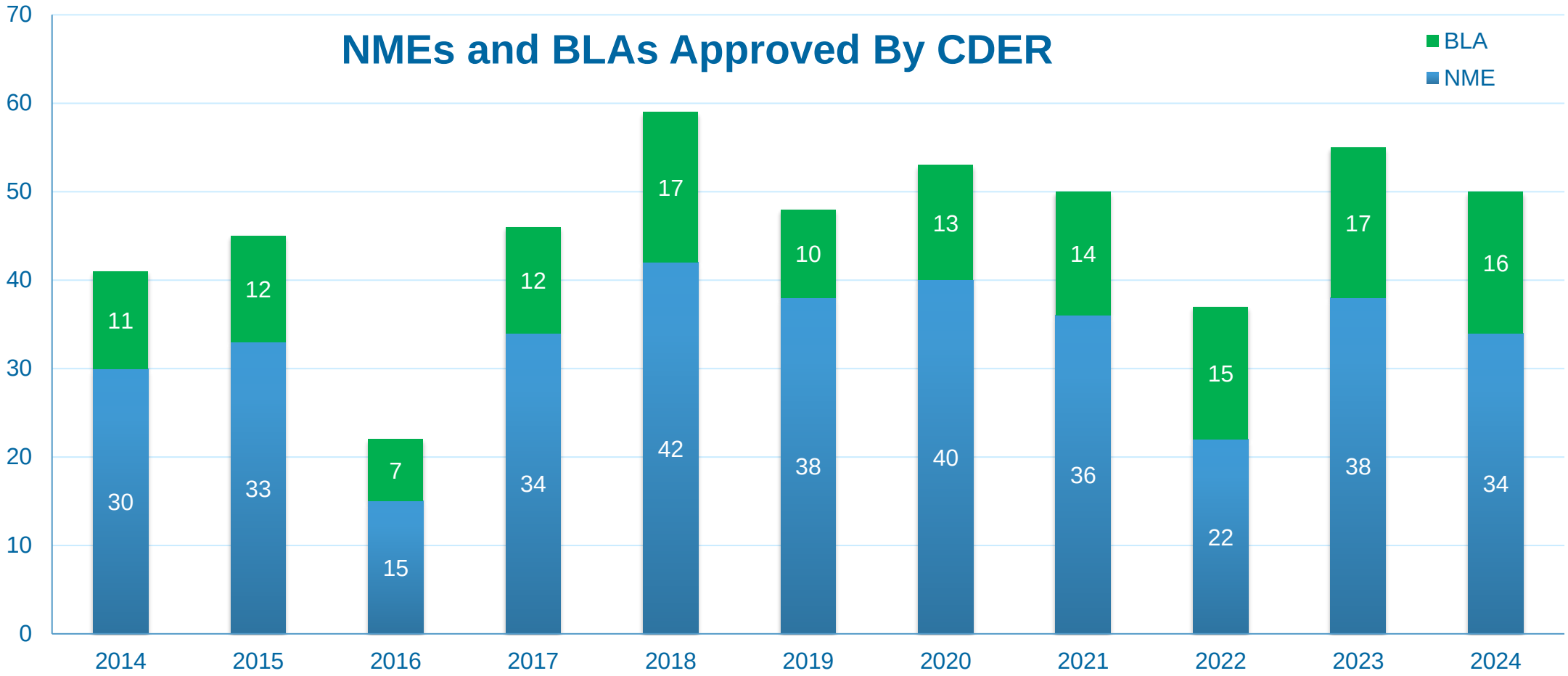
In 2024, the US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) approved **50 new molecular entities** (NMEs) and **biological therapeutics**

- **26** of these new drugs were approve to treat **rare diseases**
- **34** of the 50 (68%) novel drugs approved in 2024 were **approved in the U.S. first** (before any other country)

There were **14,870** of active commercial and research INDs being managed by CDER in 2024 (up from 10,702 in 2014)

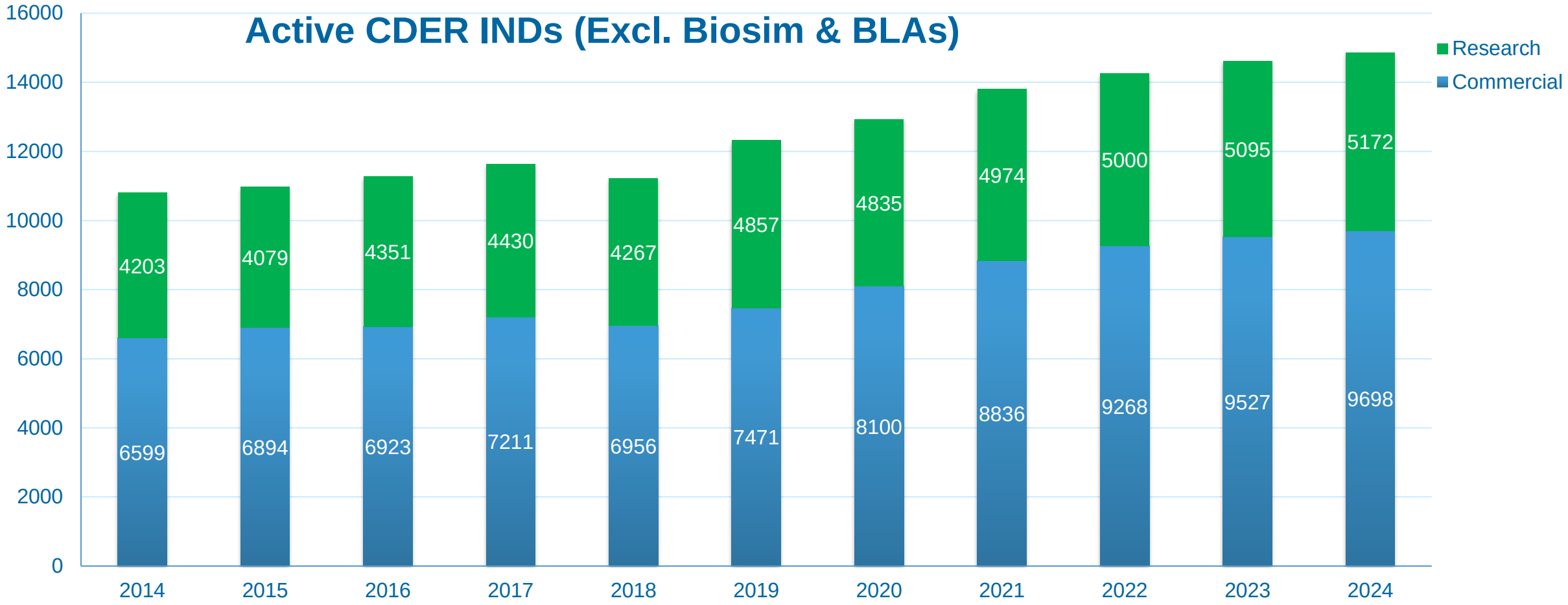
CDER: New Drug Therapy Approvals 2024

CDER Novel Drug and Biologic Approvals



2024 FDA Approvals Nature Reviews Vol.24.2025

CDER: Number of Active INDs



FDA INDs with Activity

CDER: Generic Prescription Medicines

Between 2020 - 2023, CDER approved **371 first time generics**

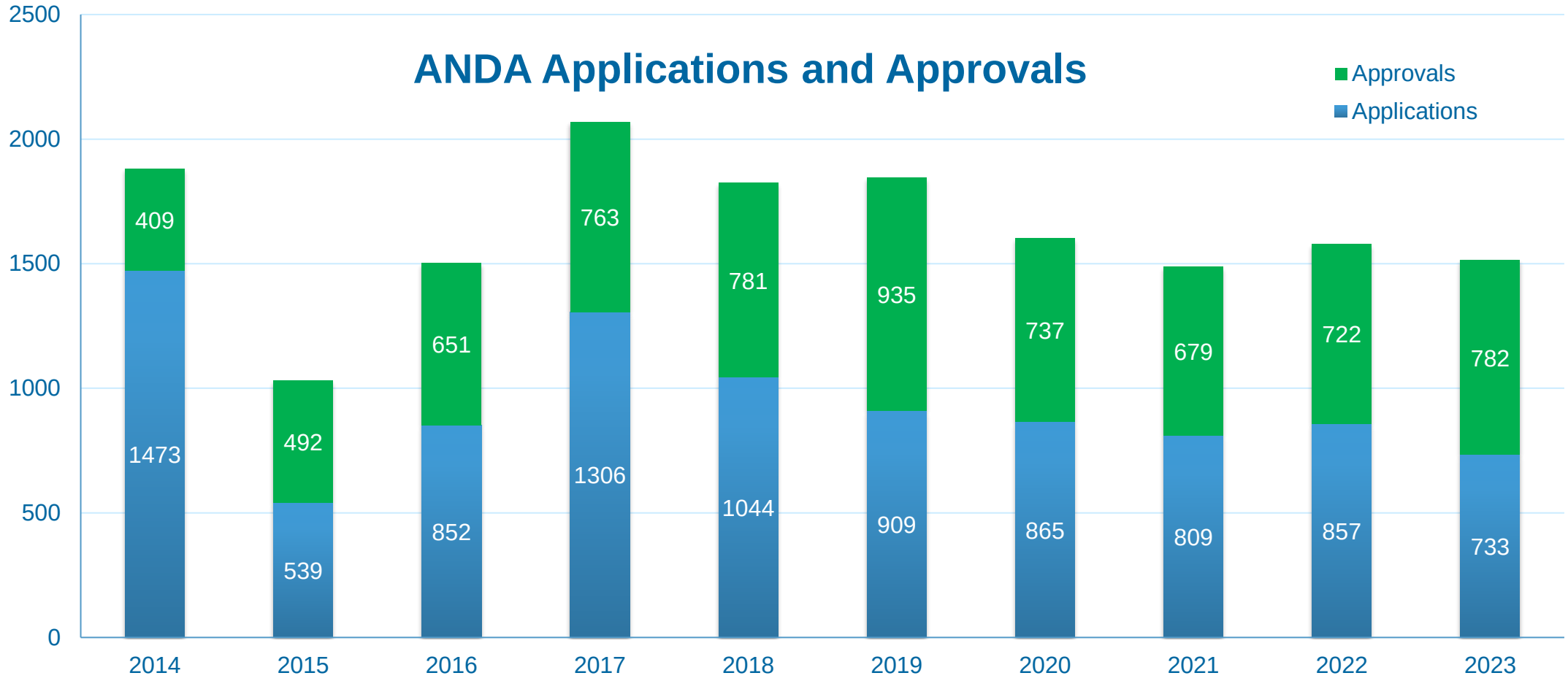
There were **733** Abbreviated New Drug Applications (ANDAs) and **782 approvals** in 2023

CDER: Generic Drugs Activities Report

18 biosimilars were approved in 2024 and the number of biosimilar INDS has increased from 31 in 2014 to 89 in 2024

CDER: New Drug Therapy Approvals 2024

CDER: Generic Applications & Approvals



CDER: Generic Drugs

CDER: Over the Counter Products (OTC)

OTC products can start as a prescription drug and be transitioned or get direct OTC approval based on data availability from foreign markets.

Most OTC products are marketed through the OTC drug monograph system which provides information on what kind of ingredients may be used to treat certain symptoms or conditions without a prescription, and the appropriate dose and instructions for use. OTC products that meet a monograph's requirements may be marketed without FDA review.

OTC products include, but are not limited to, pain relievers, eye drops, cold medicines, toothpaste and sunscreen.

Note: In 2020 the Over-the-Counter Monograph Safety, Innovation, and Reform Act was enacted. This act is intended to modernize the process by which FDA regulates over-the-counter monograph drugs. The FDA continues to implement the changes required under this law.

Office of Cosmetics and Colors

The Office of Cosmetics and Colors is charged with ensuring consumers have access to **safe cosmetics and color additives.**

Only cosmetic products and ingredients with color additives are regulated by the FDA. Products regulated by the FDA include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. It does not include soap.

However, there are laws and regulations that apply to cosmetics on the market in interstate commerce (Fair Packaging and Labeling Act). Specifically, **adulterated or misbranded cosmetics are prohibited from interstate commerce.**

Office of Cosmetics and Colors

The Modernization of Cosmetics regulation Act (MoCRA) was enacted in 2022.

The MoCRA Good Manufacturing Practices (GMPs), originally scheduled to begin implementation in December 2024, has been postponed until October 2025. The other modernization efforts are underway or on schedule for future implementation.

Center for Biologics Evaluation and Research

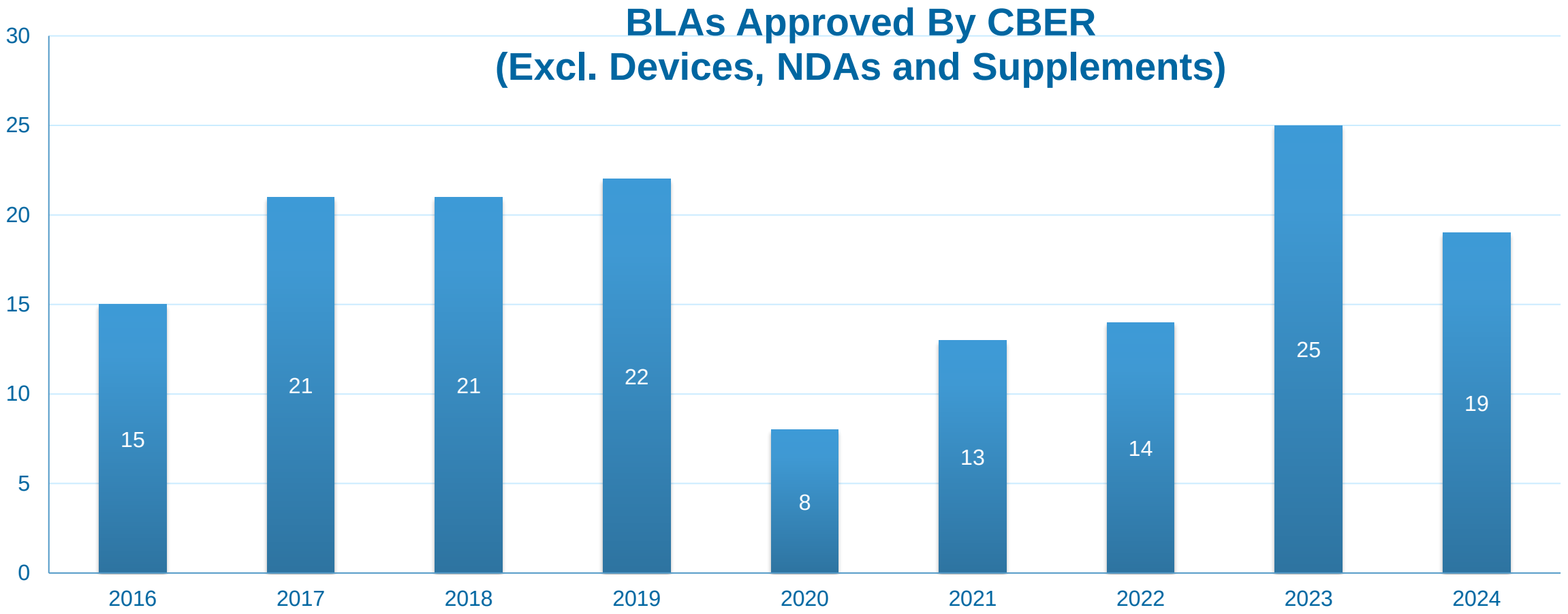
The Center for Biologic Evaluation and Research (CBER) is charged with ensuring that biological products (**blood, vaccines, gene therapies, and tissue products**) are safe and effective and available to the patients and families who need them. CBER also provides the public with information about how to safely utilize biological products.

In 2024, the US Food and Drug Administration's (FDA) Center for Biological Evaluation and Research (CBER) approved **19 biologic license applications.**

The clinical development pipeline for biologics is expected grow significantly over the next decade. In 2023 there were over **2,500 cell and gene therapy trials** underway and **more than 3,000 in pre-clinical development.**

BioSpace. 2023; Endpoints, 2023

CBER: Biologic Approvals



CBER. Biologic Approvals

FDA Adverse Event Reporting System (Drugs & Biologics)

The **FDA Adverse Event Reporting System (FAERS)** is a database of reports on adverse events, medication errors, and product quality complaints. The FDA uses FAERS to monitor the safety of drugs and biologics after they've been approved for marketing.

Cumulative Non-Serious FAERS Reports

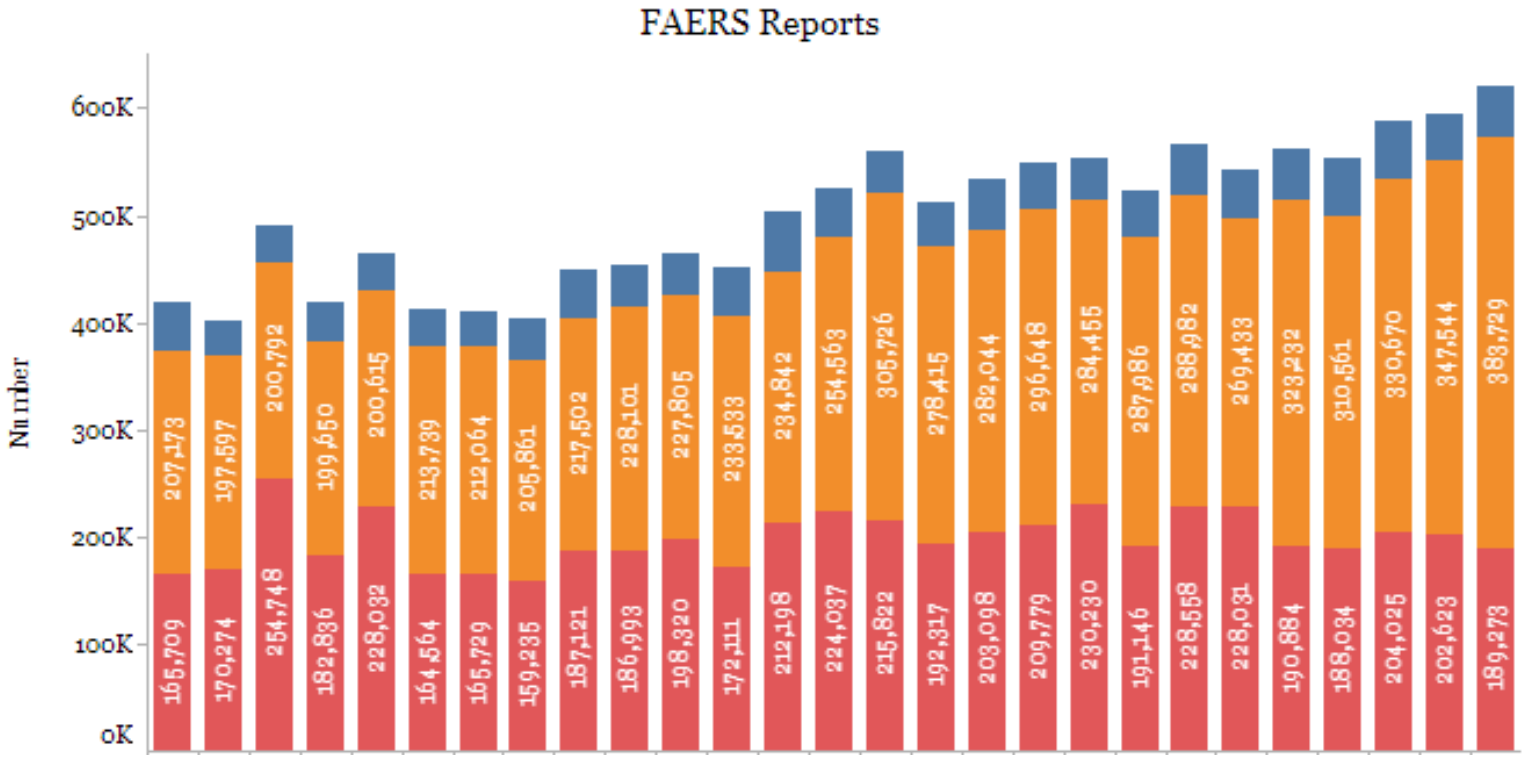
5,345,727

Cumulative Serious FAERS Reports

7,023,262

Cumulative FAERS Reports Related to Deaths

1,150,782



FDA-Tracts Post Approval Safety Monitory

Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) is charged with ensuring patients and providers have safe, effective, and high-quality medical devices and safe radiation-emitting products. They also work to ensure consumers, patients, their caregivers, and providers are informed about the products they regulate.

There are over **7,000 different types of medical devices and** CDRH manages **248,400 regulated devices**. Some examples of devices that the CDRH reviews include pacemakers, hearing aids vascular stent systems, lasers, x-ray systems ultrasound equipment and in vitro diagnostics.

Center for Devices and Radiological Health

In 2024 CDRH authorized **120 novel devices**

In 2024 CDRH received over **24,400 submissions**

Since 2009 the number of innovative medical devices authorized annually by CDRH **has increased 5-fold**

CDRH has authorized more than **1,000 AI/ML enabled medical devices** (150 in 2024)

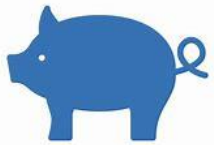
FDA at a Glance 2024; CDRH Annual Report 2024

Center for Veterinary Medicine

FDA's Center for Veterinary Medicine (CVM) is charged with protecting and promoting both human and animal health.

They work to make sure: **animal drugs** are safe, effective and properly labeled and packaged; that when **food-producing animals**, such as cattle and chickens, are treated with an animal drug, food made from those animals, such as meat, milk, and eggs, **are safe for people to eat**; that new **animal food additives are safe** and serve their intended function.

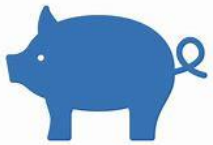
They monitor and investigate side effects and product quality problems that are reported for animal food, drugs, and devices (like thermometers and pacemakers).



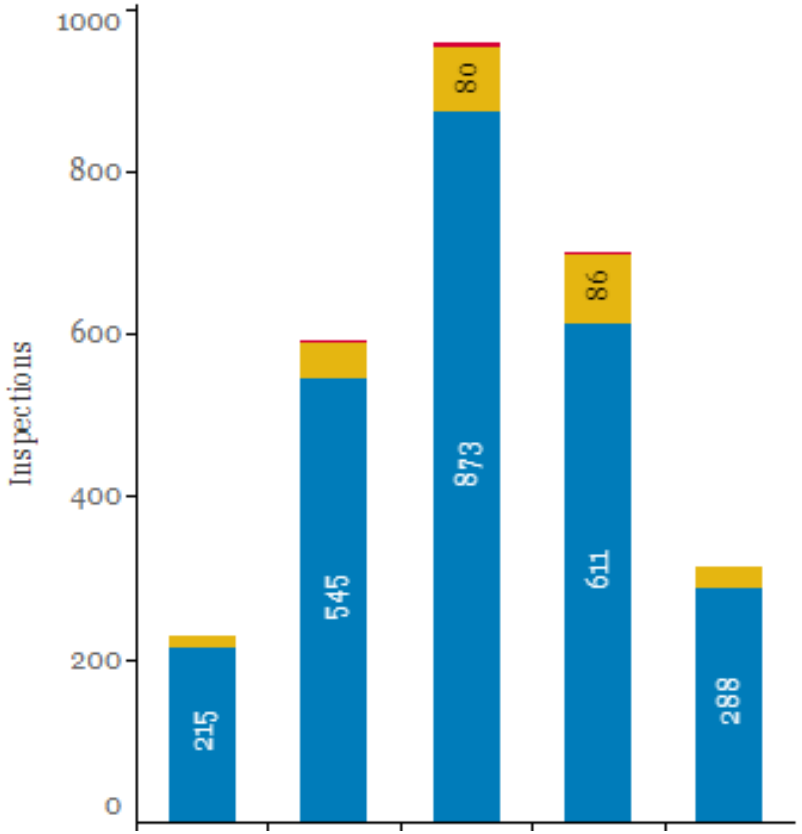
CVM has approved **157 animal drugs since 2018.**

Center for Veterinary Medicine

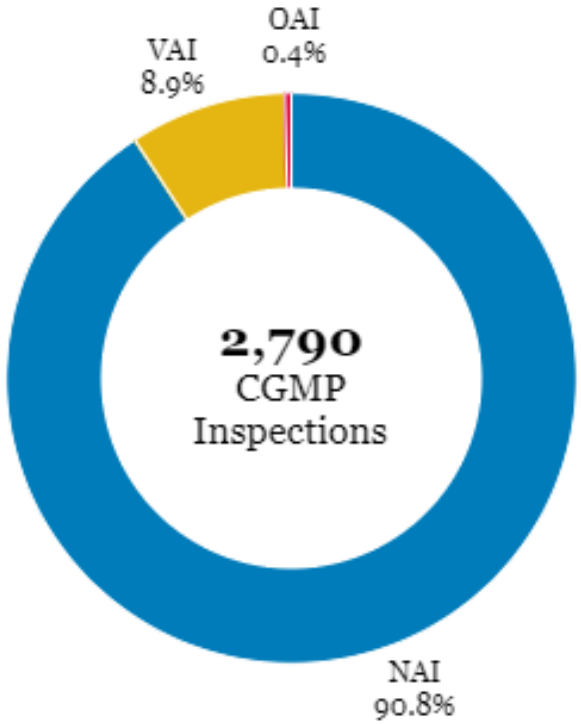
Ensuring the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs



Number of Inspections by Classification



Percent of Inspections by Classification

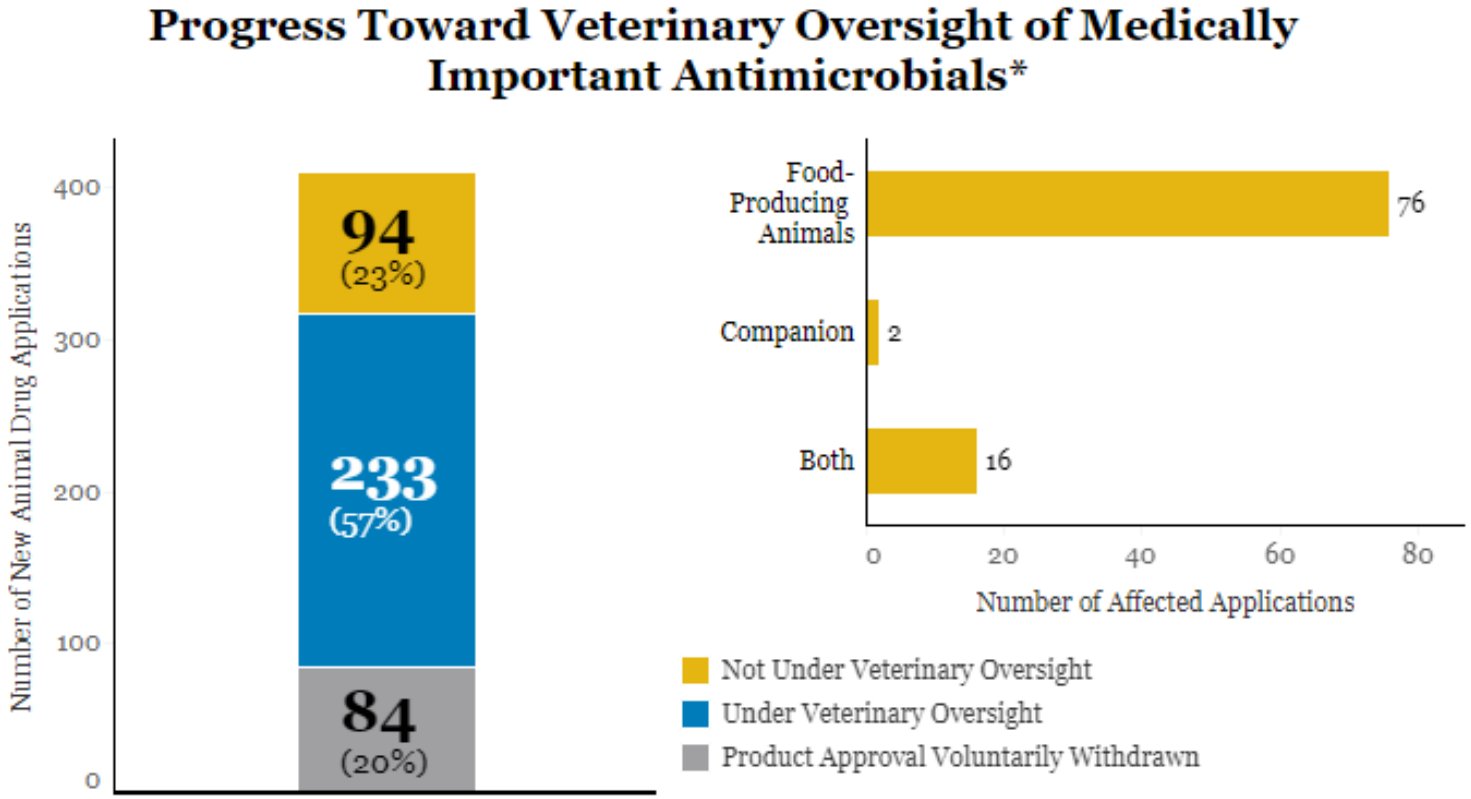


NAI = No Action Indicated
VAI = Voluntary Action Indicated
OAI = Official Action Indicated

FDA-Track

Center for Veterinary Medicine

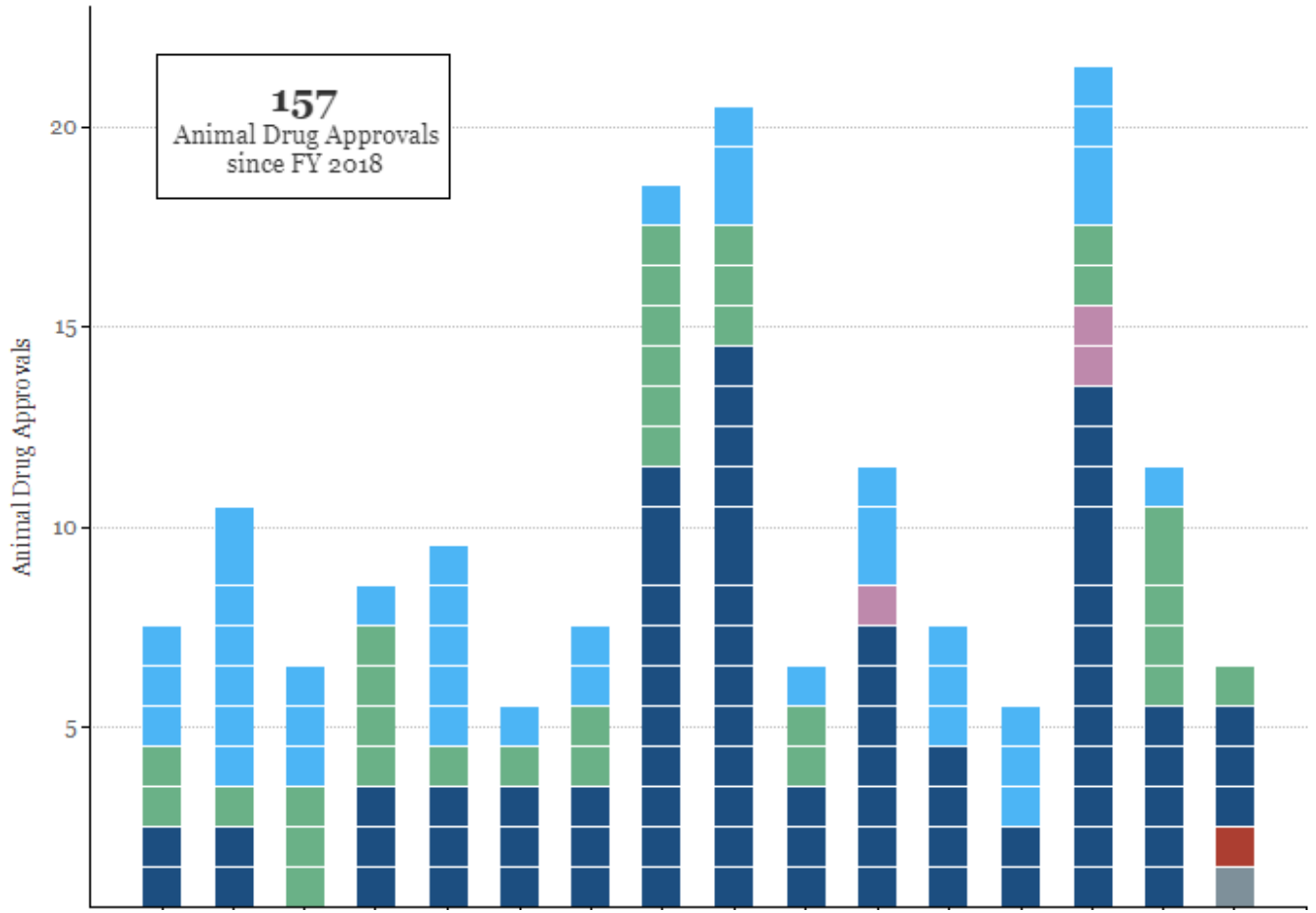
Foster Judicious Use of Medically Important Antimicrobials in Animals to Slow Development of Antimicrobial Resistance



FDA-Track

Center for Veterinary Medicine

Animal Drug Approvals



FDA-Track

The Human Food Program

The Human Foods Program (HFP) oversees all FDA activities related to food safety and nutrition, organized in a single group working under the Deputy Commissioner of Human Foods.

The HFP's stated vision is to ensure that food is a source of wellness for all U.S. consumers. To achieve that vision the HFP works to prevent foodborne illness, reduce diet related chronic disease, and ensure chemicals in food are safe.

The Human Food Program

The Human Foods Program has the following offices

- The Office of Microbiological Food Safety which works to **prevent pathogen-related foodborne illness**
- The Office of Food Chemical Safety, Dietary Supplements, and Innovation which focuses on **food chemical safety and dietary supplement policies**
- The Nutrition Center of Excellence which elevates and **empowers action on nutrition** initiatives to help reduce the burden of diet-related chronic diseases, improve health equity, and ensure the nutritional adequacy and safety of infant formula

The Human Food Program

The Human Foods Program approved a reorganization plan in May 2024 and implementation is underway.

The reorganization was undertaken after reviewing findings and recommendations from various sources, including a Reagan-Udall Foundation evaluation and internal reviews of the agency's infant formula response.

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State Food Safety Laboratories

The Food and Drug Administration (FDA) works with state food safety laboratories across the country to monitor and detect public health threats.

From 2019 – 2024, state food safety laboratories tested **71,541 human and animal food samples** for health risks and reduced illness from contaminated food across the country.

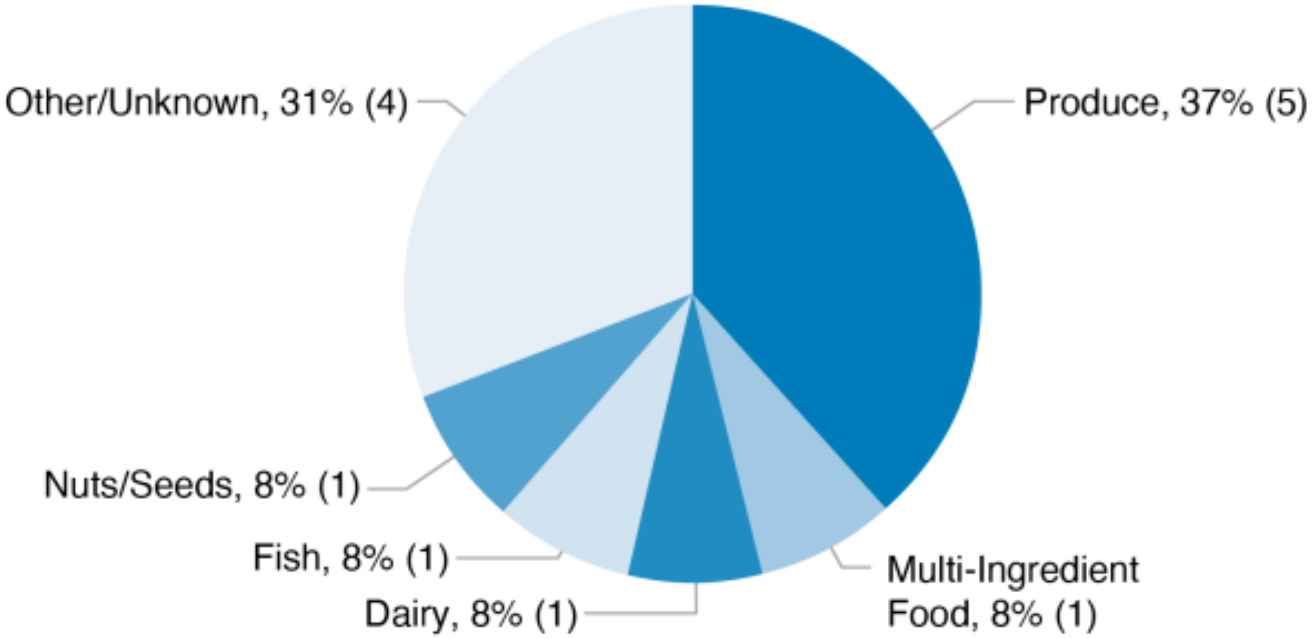
APHL

The Human Food Program

Microbial Food Safety

2024: **26 outbreak investigations** were transferred to response

Responses with Identified Product(s) Linked to Illnesses, by Associated Food Category, 2022

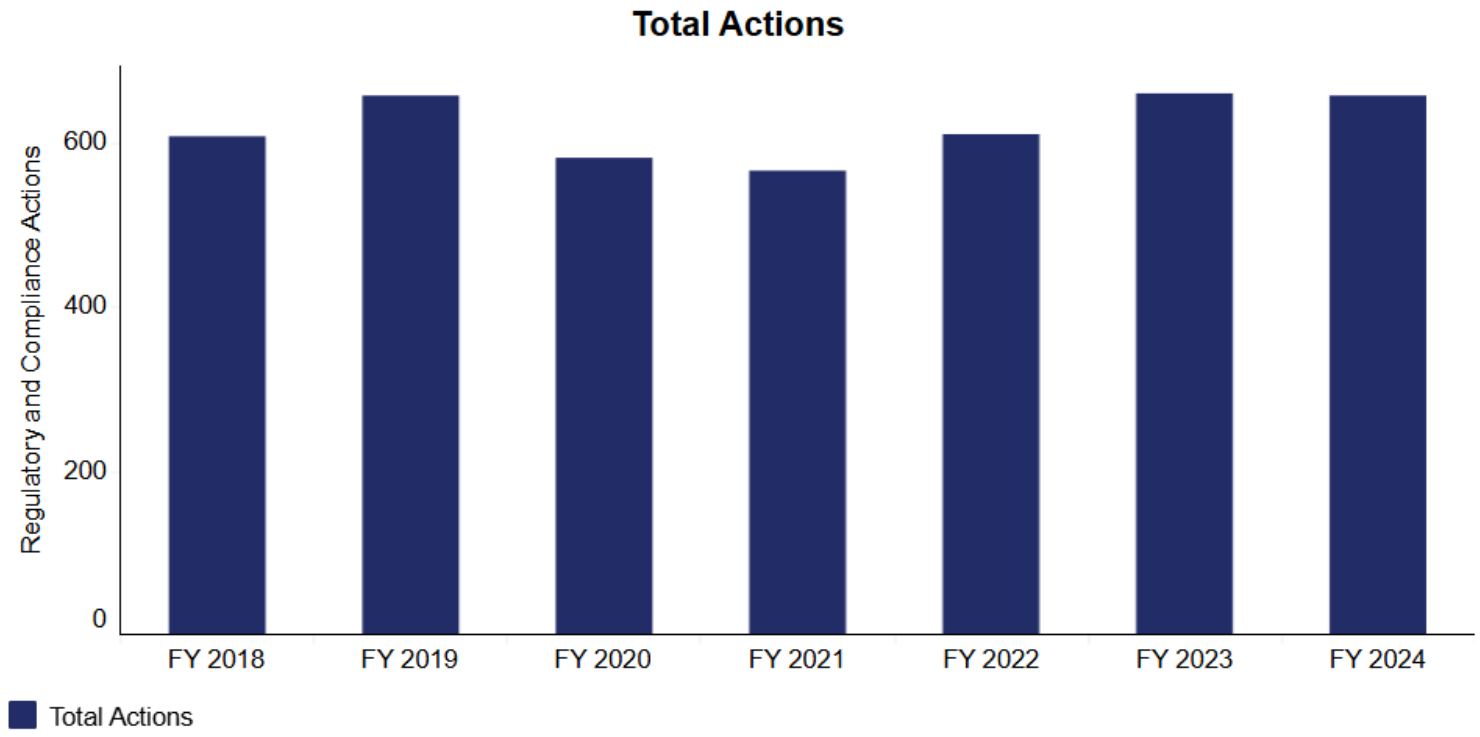


CORE Network 2022 Annual Report

The Human Food Program: Food Safety

Foods Program Regulatory & Compliance Actions

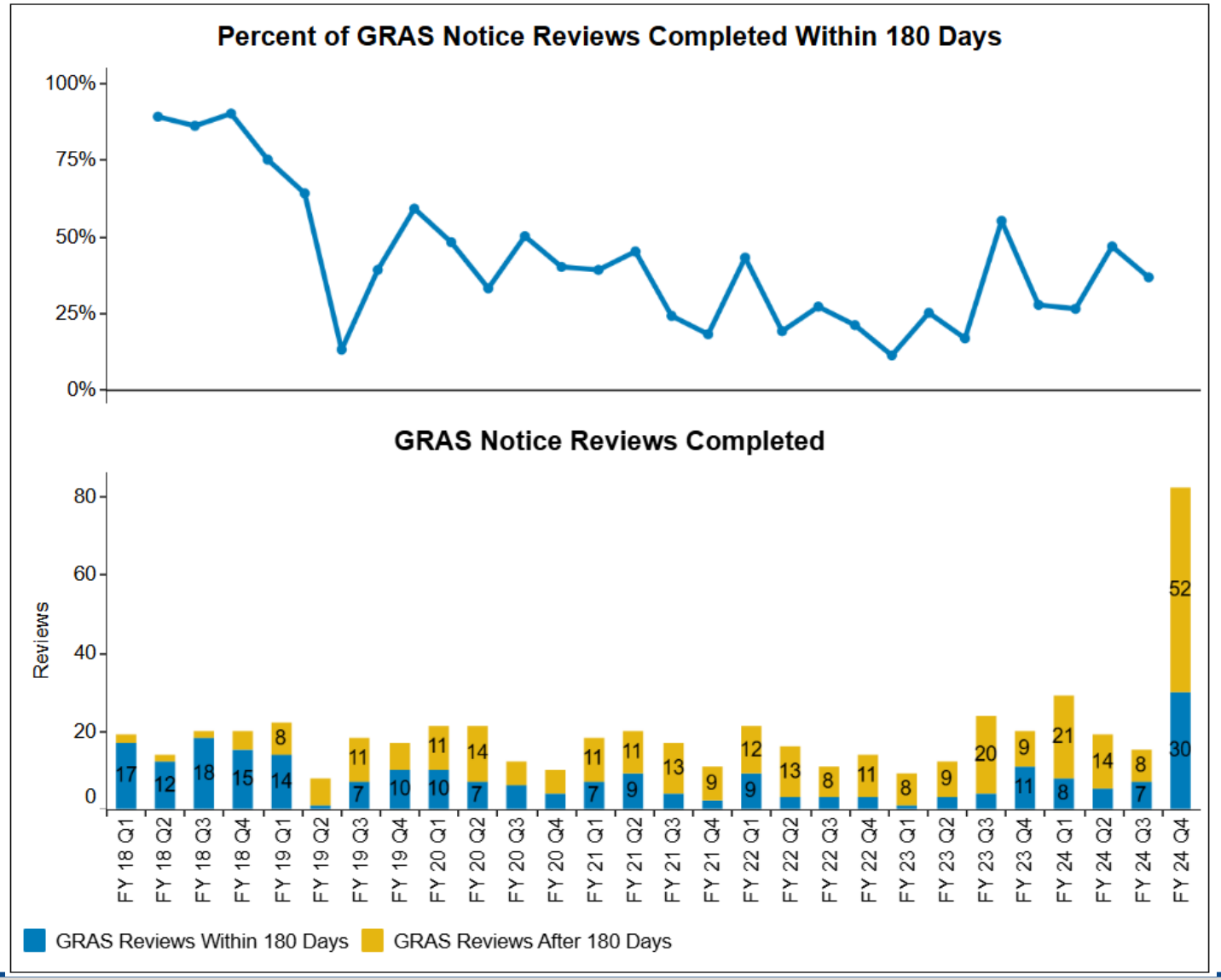
Total Actions	Advisory Cases	Administrative Cases	Detention Recommendations	Judicial Cases
4,341	1,908	7	2,382	44



FDA-Track Food Safety

The Human Food Program: Food Safety

FDA conducts premarket reviews to ensure substances added to the food supply are safe, including food and color additives. FDA also has a voluntary notification process for GRAS substances.



Generally Recognized as Safe (GRAS) Reviews Conducted by FDA & Associated Timelines

FDA-Track Food Safety

FDA Registered Facilities

FDA Registered Facilities (FDA at a Glance 2024)			
Program	**Domestic**	**Foreign**	**Total**
Animal Drugs	974	753	1,727
Animal Food	18,027	8,925	26,952
Biologics	5,386	589	5,975
Human Drugs	**3,540**	**4,419**	**7,959**
Human Food	87,252	134,368	221,620
Medical Devices	13,010	12,854	25,864
Tobacco	1,205	0	1,205
Total	**129,394**	**161,908**	**291,302**

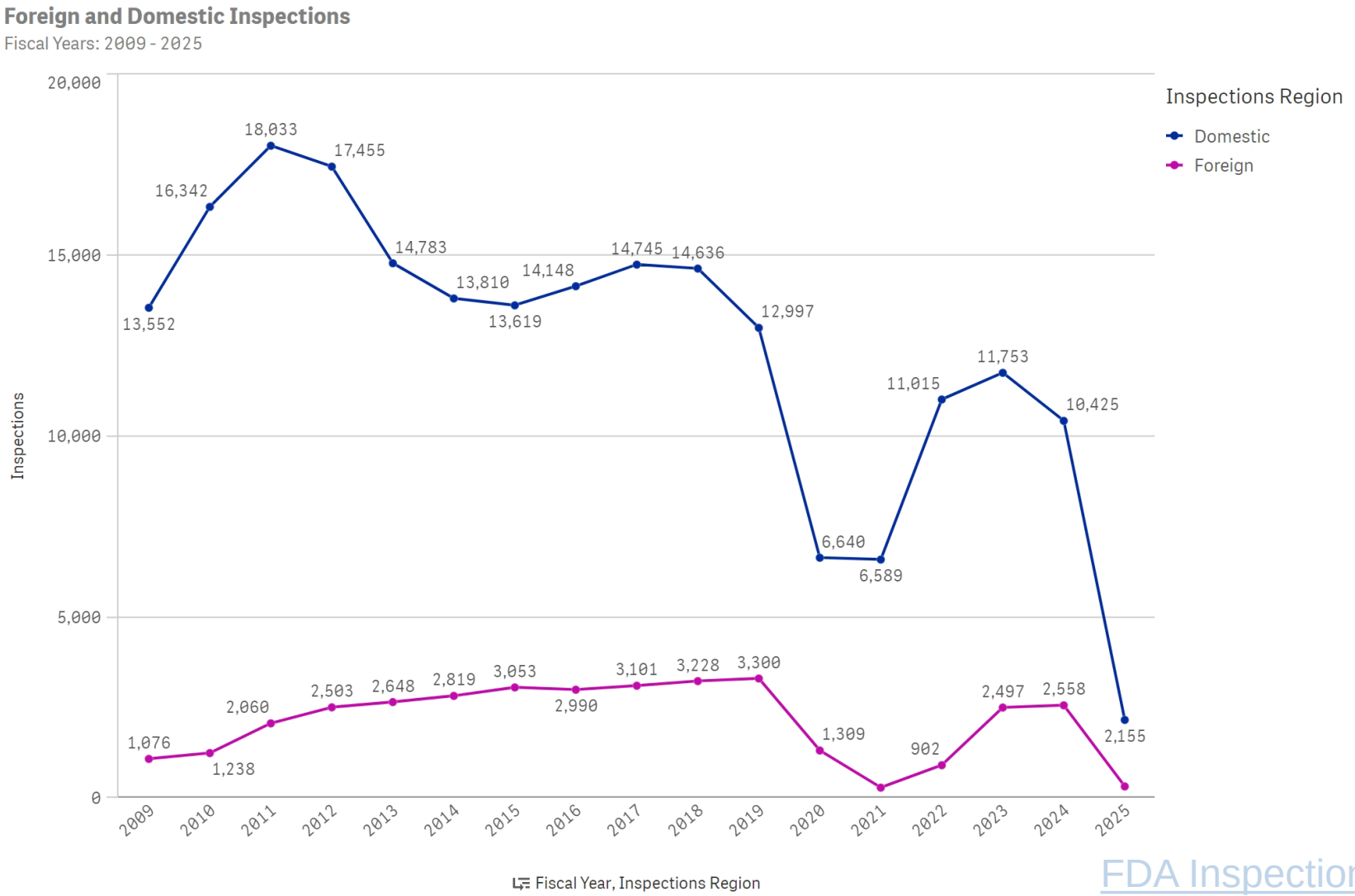
FDA at a Glance 2024

Office of Inpsections and Investigations

SAFE

FDA's **Office of Inspections and Investigations (OII)** leads all FDA field inspection, investigation, import and emergency response related activities. OII partners with internal and external agency stakeholders to identify, collect, and evaluate evidence that empowers integrated regulatory decision making. OII inspects regulated products and manufacturers, and reviews imported products offered for entry into the United States. In pursuit of its mission, OII also works with its state, local, tribal, territorial and foreign counterparts.

FDA Inspections : A 2009 - 2025



FDA Inspections Dashboard

Center for Tobacco Products

The Center for **Tobacco Products** is charged with regulating the manufacture, distribution, and marketing of tobacco products, educating the public about the dangers of using tobacco products and promoting and supporting strategies that ensure a healthier life for everyone

The Alliance for a Stronger FDA

Overview: How is the FDA Funded

February 18, 2025

About the Alliance

FDA revenue and expenditures are unique compared to most federal agencies. Notably:

- Budget Authority (BA) funding is paid by taxpayers and provides FDA with the broadest and most flexible means of responding to all its responsibilities; all other funding comes with restrictions
- User fees (fees paid by the regulated industries) are a large portion of the overall FDA budget
  - Each user-fee program has specific spending parameters

User Fee Programs

User fees are intended to supplement, not replace BA funding. The following are the individual user fee programs for different medical products:

- Human Medicines: Prescription drugs and biologics (PDUFA), Biosimilars (BsUFA), Generic drugs (GDUFA), Over-the-counter drug (OMUFA)
- Medical devices (MDUFA)
- Animal Medicines: Prescription animal drugs (ADUFA), Generic animal drugs (AGDUFA)

User fees are only available for purposes specified in law and in 5-year negotiated agreements.

FDA uses both BA and user fees to fund ongoing medical product programs and new initiatives. FDA tracks and audits to assure user fee funds are only allocated to permitted purposes.

User Fee Programs

Tobacco User Fees are appropriated annually, based on section 919 of the FDCA

- Entire tobacco control program is funded by user fees (no BA/taxpayer monies appropriated for tobacco)

It is a self-contained regulatory program that is not negotiated with industry

Note: The Alliance's funding requests are for BA only, so tobacco is never included in our appropriations requests

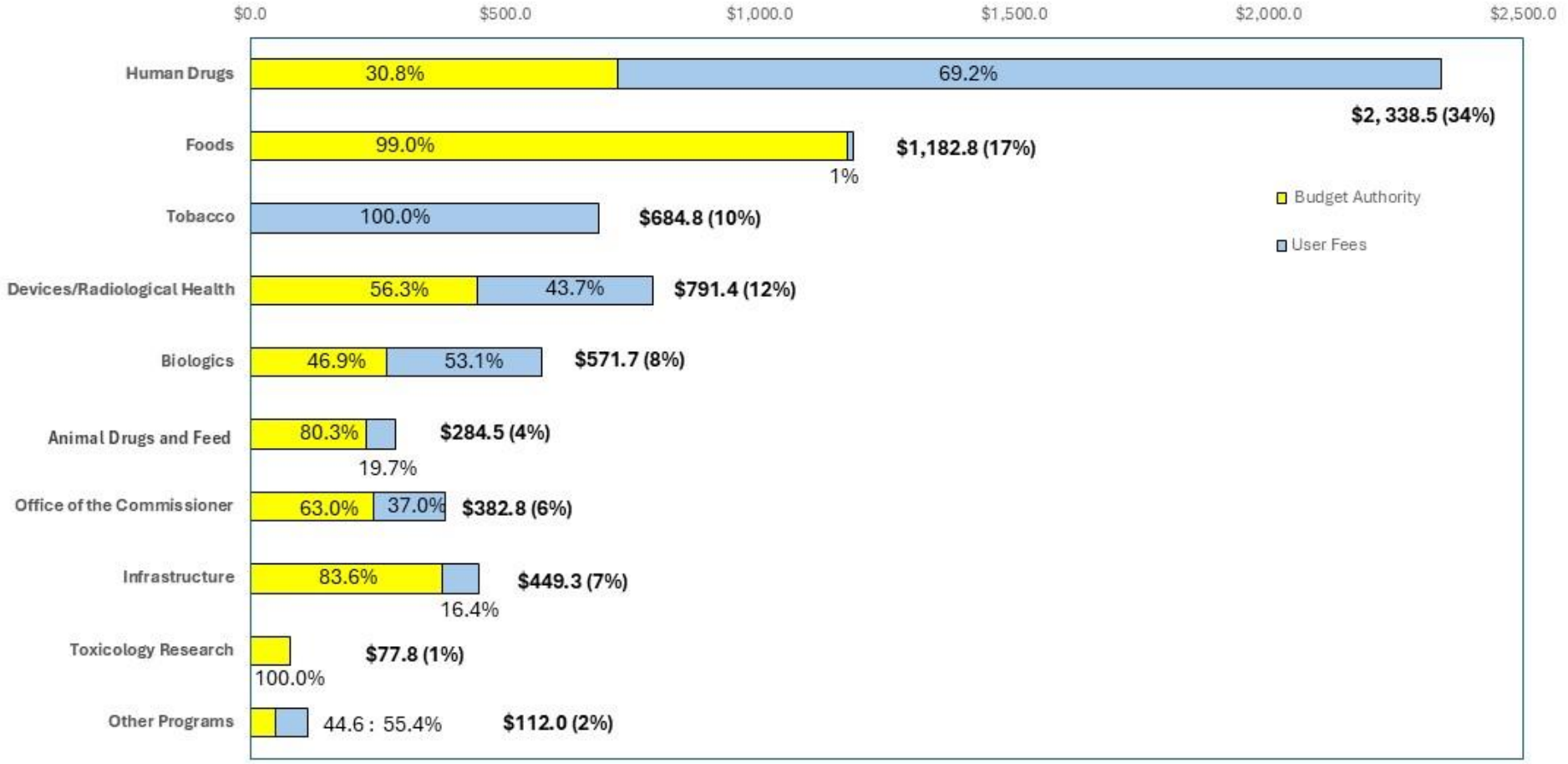
FDA Funding – Budget Authority & User Fees

FDA FY 24 Budget: ≈ $6.9 billion

- $3.6 billion from federal budget authorization ‘budget authority’ (52%)
- $3.3 billion from industry user fees (48%) (40% if tobacco is excluded)

FDA at a Glance 2024

Distribution of FDA FY2024 Budget (Millions of Dollars)



Notes: Infrastructure includes rent, rent-related activities, FDA buildings and facilities, and White Oak consolidation. Other Programs includes Export Certification and Color Certification Fund.

FDA at a Glance 2024

FDA Funding – Budget Authority & User Fees

Program	Funding (M)	% Funding	% Budget Authority	% User Fees
Human Drugs	$2,338.5	34%	30.8%	69.2%
Foods	$1,182.8	17%	99.0%	1.0%
Tobacco	$684.8	100%	0%	100.0%
Devices/Radiological Health	$791.4	12%	56.3%	43.7%
Biologics	$571.7	8%	46.9%	53.1%
Animal Drugs and Feed	$284.5	4%	80.3%	19.7%
Office of the Commissioner	$382.8	6%	63.0%	37.0%
Infrastructure	$449.3	7%	83.6%	16.4%
Toxicology Research	$77.8	1%	100.0%	0.0%
Other Programs	$112.0	2%	44.6%	55.4%

21st Century Cures – Funding Ending in 2025

21st Century Cures funding has been appropriated annually for 9-years and ends 2025

- Funds available for activities specified in the Cures Act (medical product development programs)
- Per-year monies peaked in FY 20 at $75m and declined each year; $50 million may be provided in 2025
- Monies derived from CHIMPS (Changes In Mandatory Programs; not traditional BA, not user fees)

THANK YOU FOR YOU TIME & ATTENTION

Please Contact Us with Any Additional Requests for Information

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