



FDA 2021 Year in Review

Working for You



Letter from the Acting Commissioner

As we begin 2022, I, like many of you, am looking forward to all the new and hopefully interesting things that often come with the start of a new year. Last year, as we did with the year before, the FDA and nation as a whole faced unique and unprecedented challenges as we continued to navigate the COVID-19 pandemic. And while the virus has proven to be persistent, it is with a great sense of pride that I am able to highlight the strength and resilience of the FDA's workforce through it all. While much of the attention the agency received in 2021 focused on our response to the pandemic, I am pleased to note that, despite a great deal of uncertainty, the agency was able to accomplish a wide range of its priorities that are already protecting the health and well-being of millions of people living in the U.S.



The FDA has a broad public health agenda reflected in three key areas: public health and consumer protection; modernization to keep pace with evolving science and technology; and emergency preparedness and response. Since its initial inception in 1906, the FDA's work has touched nearly every area of our lives. Each day our employees work to help ensure the safety, efficacy, quality and/or lawfulness of the products we regulate. What this means is that the FDA is responsible for overseeing nearly three trillion dollars annually in medical products, food, including dietary supplements, cosmetics, and tobacco products. Combined, these products account for about 20 cents of every dollar spent on consumer goods in this country.

Every year the FDA reviews hundreds of product applications, ultimately determining which drugs, devices or biological products (e.g., vaccines) will be marketed in the U.S. The process involved is rigorous, thoughtful and always adheres to standards for safety and effectiveness. We help to ensure that the human and animal food supply is safe, sanitary, and accurately labeled, and that cosmetic products are safe and properly labeled. The agency also protects Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products, and by educating the public about tobacco products and the dangers their use poses. We also work to ensure the public has the accurate, science-based information needed to make health decisions.

This report offers just a small sampling of highlights of the agency's work in 2021. Our work in each of these areas (as well the countless efforts not mentioned) will have a profound impact on the health and safety of the American public for years to come. The report serves to demonstrate the FDA's high standards and meticulous and dynamic review process, which relies on, and is informed by, the best available science and most rigorous data.

Americans can take comfort in knowing that we apply this approach in every action we take, whether evaluating a new medical product, tracking an outbreak of foodborne illness, determining if new tobacco products meet the legal standard for marketing, or responding to the challenge of an unparalleled public health emergency.

At a time when misinformation and disinformation are so prevalent, Americans can trust and depend on the FDA for essential information, particularly as it relates to public health. It is this reliability and consistency that makes the accomplishments outlined in this report possible.

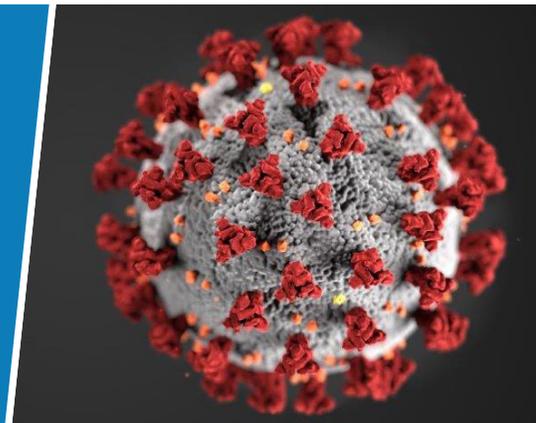
Finally, I want to commend and thank the entire FDA team, not only the thousands of FDA employees who have been working nonstop on the COVID-19 response efforts, but the many employees who have ensured that the FDA continued to meet its regular essential responsibilities. We take our public health mandate seriously, and our focus is always on the well-being of patients and consumers. The COVID-19 pandemic has challenged us, but it also has afforded us an opportunity to develop smarter responses and to better prepare for the future.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Response to the COVID-19 Pandemic

The COVID-19 pandemic remained a persistent public health issue in 2021. Throughout the year, the FDA continued to use its expertise and regulatory authorities to respond and adapt quickly as the virus continued to impact people across the U.S.

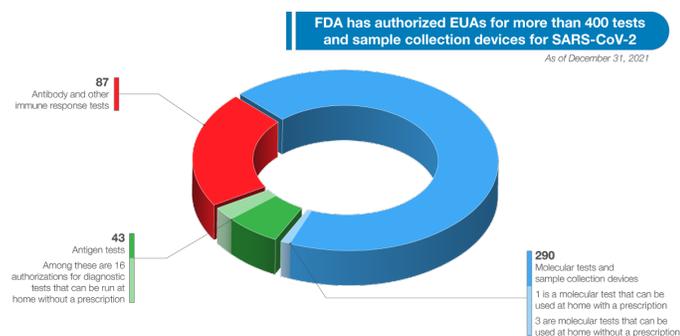
Since the first authorization for the Pfizer-BioNTech COVID-19 Vaccine in December 2020, the agency has gone on to authorize two additional COVID-19 vaccines, one manufactured by Moderna and the other by Janssen, increasing [access to COVID-19 vaccines](#). In August 2021, the agency approved the Pfizer-BioNTech COVID-19 Vaccine (marketed as Comirnaty), for use in individuals ages 16 years of age and older.



By the end of 2021, individuals as young as the age of five were eligible to receive a COVID-19 vaccine, and all individuals ages 16 and older were eligible for a single booster dose after completion of primary vaccination, which helps to provide continued protection against COVID-19. The available COVID-19 vaccines were developed without cutting corners or compromising our regulatory and scientific standards.

We also continued to facilitate treatments that meet our regulatory standards as quickly as possible. The FDA has approved one drug to treat COVID-19 and [14 therapeutics are currently authorized for emergency use](#), including antiviral drugs and monoclonal antibody treatments. The agency has authorized, approved, granted, or cleared over 2,000 additional COVID-19 medical products, including, but not limited to, molecular diagnostic, antigen and serology tests, sample collection devices, personal protective equipment, and ventilators.

SARS-CoV-2 Testing:



As of December 31, 2021, FDA has authorized over 400 tests and sample collection devices for SARS-CoV-2.

The FDA has been actively monitoring for the possible emergence of SARS-CoV-2 variants since early in the pandemic and has worked with medical product developers when a new variant (or mutation) emerges that could impact product performance. With [industry guidance laid out in February](#) and contingency plans already in place, we are well-positioned and committed to working with companies to evaluate and expeditiously address the potential impact of emerging and future viral mutations on COVID-19 tests, therapeutics and vaccines. In addition, a [Condition of Authorization](#) relating to viral mutations was added to the EUAs for authorized tests.

In our efforts to protect consumers we also identified more than [1,706 fraudulent and unproven medical products](#) related to COVID-19. We've issued more than 267 warning letters to companies and individuals selling unproven products, with nearly 71% of the recipients taking voluntary action in response.

After receiving reports of patients who required medical attention after self-medicating for COVID-19 with ivermectin intended for livestock, the FDA issued advisories that the agency has not authorized or approved [ivermectin](#) for use in preventing or treating COVID-19 in humans or animals.

We continue monitor medical product and food supply chains for potential shortages or disruptions, and help to mitigate such impacts, as necessary to protect the public health.

Supporting Diversity and Equity in Public Health



Thanks to additional funding from Congress in 2021, the agency enhanced its ability to support and expand health equity and combat health disparities.

These resources are allowing us to expand our communication and outreach efforts, establish new scientific initiatives, support novel health equity focused research, advance activities that enhance diversity in clinical trials, and better understand and address health disparities.

Ensuring people from diverse and underrepresented backgrounds have the ability to participate in clinical trials is key to advancing health equity. Participants in clinical trials should be a reflection of the U.S. and the individuals who may one day need to rely on these drugs, biological products, or devices. History has shown us that many regulated industries have often not designed or enrolled trials in a manner that reflects the different ages, races, and ethnicities of the people who may need to rely on these products, resulting in lack of information on the safety and effectiveness for certain medical products in these populations.

In 2021, the FDA Office of Minority Health and Health Equity launched the [Enhance Equity Initiative](#) that supports research projects and highlights communication resources to enhance:

- [EQUITY in clinicals](#) trials by supporting efforts to advance diversity in clinical trials.
- [EQUITABLE data efforts](#) by increasing data available on diverse groups.
- [EQUITY of voices](#) by amplifying the FDA's communication with diverse groups and to ensure stakeholders, including consumers, are informed about the FDA's efforts and to understand diverse patient perspectives, preferences, and unmet needs.

Under the Enhance Equity Initiative, the FDA also announced a [COVID-19 and Health Equity Innovation Award](#), a new award opportunity supported by funding from the American Rescue Plan Act of 2021. This award will fund innovative projects that will strengthen and advance COVID-19 health equity research. Areas of interest include proposals that focus on advancing

racial and ethnic minority participation in COVID-19/ COVID-19 variant clinical trials and proposals that support the evaluation of outcomes by demographic data including, but not limited to, ethnicity, race, age, disability, and geography, and proposals that support COVID-19 research to understand diverse patient perspectives, preferences, and unmet needs. The FDA intends to fund up to \$5,000,000 for fiscal year 2022 in support of this innovation award. It is anticipated that up to five awards will be made, not to exceed \$1,000,000 per awardee.

Another notable project was a collaboration to raise awareness about the importance of racial and ethnic minority participation in lupus clinical trials. Lupus is an autoimmune disease that has a disproportionate impact on racial and ethnic minority populations. The [U.S. Department of Health and Human Services Office of Minority Health](#) joined forces with the [FDA's Office of Minority Health and Health Equity](#) to launch the [Let's Take Charge! Campaign](#), an initiative to make lupus research more inclusive and diverse.



Advancing Our Goal of Addressing the Misuse of Prescription Drugs and Preventing Overdoses

The opioid crisis continues to be a national public health emergency, with devastating and far-reaching consequences extending into communities nationwide. Responding to this crisis remains a top priority. The FDA has long been involved in the government's response and will continue partnering with federal, state, and local officials to identify solutions in order to bend the curve.



In 2021, the [FDA furthered its commitment to addressing the national crisis of opioid abuse, misuse, addiction, and overdose on all fronts](#), with a focus on decreasing exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies; and taking action against those involved in the illegal importation and sale of unapproved and misbranded opioids.

The agency approved two new naloxone products, increasing access to naloxone and placing this important medicine in the hands of those who need it most.

In October, with the release of the U.S. Department of Health and Human Services comprehensive [Overdose Prevention Strategy](#), the FDA echoed support for building on previous work to proactively address the full spectrum of drug misuse and addiction that has evolved beyond the opioid crisis and often can result in overdose and death.

In hosting our third [Online Opioid Summit](#) in September, we continued to enhance collaboration to maximize the scope of our efforts to address the illegal availability of opioids online. To date, the FDA has issued warning letters to 51 website operators for illegally selling unapproved and misbranded opioids online in violation of the law.

We also convened a public workshop to [discuss new opportunities to improve prescriber education](#) through the Opioid Analgesic Risk Evaluation and Mitigation Strategy to ensure that the education is being delivered in a way that minimizes the burden on the

health care delivery system. The FDA will continue a series of discussions on mandatory opioid prescriber education.

Kratom: In 2021, U.S. Marshals, at the FDA's request, seized more than 207,000 units of dietary supplements and bulk dietary ingredients that are or contain kratom, including over 34,000 kilograms of bulk kratom. The FDA estimates the seized products were worth approximately \$1.3 million. The FDA continues to have significant concerns regarding the safety of kratom, the risk it may pose to public health and its potential for abuse.



Strengthening Maternal and Infant Health and Nutrition, and More



One of the cornerstones of our public health work this past year involved efforts to reduce the burden of chronic disease through improved nutrition, including during pregnancy and in early childhood.

In 2021, we coordinated with NIH on a workshop exploring the science surrounding the use of bioactive ingredients in infant formula and we continued our work on reducing babies' and young children's exposure to toxic elements in foods. Nutrition during pregnancy and in early childhood is critically important in supporting the health and wellbeing of parents and their children.

In March 2021, we issued a letter to baby and toddler food manufacturers and processors covered by the preventive control provisions of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule. The letter reminds them of their existing responsibility to consider risks from chemical hazards – including toxic elements – when conducting a hazard analysis.

The release of the action plan, [Closer to Zero](#), set forth the agency's approach to reducing exposure to toxic elements in foods commonly eaten by babies and young children to the lowest possible levels. Our plan outlines a multi-phase, science-based, iterative approach to achieving our goal of getting levels of toxic elements in foods closer to zero over time. We have prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of these contaminants.

Homemade Infant Formula: We received reports of hospitalized babies who had been fed homemade infant formula and then suffered from hypocalcemia – or low calcium. We determined it was critical to inform parents and caregivers on nutritional requirements

and safety issues by issuing [Infant Formula: Safety Do's and Don'ts](#).

But the importance of nutrition and food safety extends well beyond childhood. We are equally committed to making sure that the food each of us eats every day is safe as well; foodborne illnesses also remain a significant public health challenge. The availability of safe and nutritious foods across the population is a key element of ensuring equitable health outcomes.

Sodium: Limiting certain nutrients, such as sodium, in our diets plays a crucial role in preventing diseases. The FDA took a critical step to further address preventable diet-related chronic diseases and advance health equity in issuing the final guidance, [Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods](#), that provides voluntary short-term sodium reduction targets for food manufacturers, chain restaurants and food service operators for 163 categories of processed, packaged and prepared foods.

Safer Food Whether It's Produced Here or Abroad

Eleven years ago, the [FDA Food Safety Modernization Act \(FSMA\)](#) was signed into law with a clear goal: It's not enough to respond to outbreaks of foodborne illness, we must prevent them. Under FSMA, those who grow, produce, pack, hold, import and transport our food are required to take concrete steps every day to help reduce the risk of foodborne illness.



In December 2021, the FDA issued a [proposed rule](#) that aims to enhance the safety of produce. It proposes to require farms to conduct comprehensive assessments that would help them identify and mitigate hazards in water used to grow certain produce. This is the latest step in the implementation of FSMA, and it proposes to replace some of the existing requirements for agricultural water in the [Produce Safety Rule](#). If finalized, we're confident this proposal would result in fewer outbreaks in the U.S. related to produce, protecting public health and saving lives.

We are building on FSMA through the [New Era of Smarter Food Safety](#) by helping to create a more digital, traceable and safer food system. And, the [New Era of Smarter Food Safety blueprint](#), creates a roadmap toward helping reduce the number of foodborne illnesses and protecting consumers from other food safety hazards.

Activities in 2021 under the [New Era of Smarter Food Safety initiative](#) include:

- **Enhanced Food Traceability:** We launched the New Era of Smarter Food Safety Low or No-Cost Tech-Enabled [Traceability Challenge](#), calling for the submission of food traceability solutions that utilize economic models that are affordable for even the smallest producers and can scale to some of the largest firms – all with an eye toward encouraging widespread adoption.
- **Predictive Analytics:** We created a new data analysis tool called [21 Forward](#) to help identify where there could be disruptions in food supply continuity

due to food worker absences because of the pandemic. We use COVID-19 human transmission forecast data from the Centers for Disease Control and Prevention to identify areas where COVID-19 could impact key segments of the food system.

- **Import Screening:** We have been conducting a pilot program that leverages artificial intelligence (AI) to strengthen our ability to predict which shipments of imported foods pose the greatest risk of violation and use that information to better target import review resources.
- **Inspections:** The New Era blueprint calls for an exploration of new ways to conduct inspections. Despite the COVID-19 pandemic, the agency continued remote inspections of importers subject to the Foreign Supplier Verification Programs (FSVP) requirements. Thanks to the verification programs, the FDA can request records electronically from importers to help ensure that their foreign food suppliers are meeting U.S. safety standards. As a result, the FDA conducted a record number of FSVP inspections in 2021.

Protecting the Public - Particularly Young People - From Harmful Effects of Tobacco Products



The FDA continues to apply a science-based approach to regulating an evolving tobacco product landscape and protecting the public – especially kids – from the addiction, death and disease caused by tobacco products.

In 2021 we committed to advancing two regulations that will dramatically change the landscape. Specifically, one proposed product standard prohibiting menthol in cigarettes and another prohibiting all characterizing flavors (including menthol) in cigars to publish as proposed rules by the end of April 2022. Prohibiting menthol – the last allowable flavor – in cigarettes and prohibiting flavors in cigars will help save lives, particularly among those disproportionately affected by these deadly products.

With these actions, the FDA will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products. We believe these actions will launch us on a trajectory toward ending tobacco-related disease and death in the U.S.

Premarket Review: Over the last year, the agency has worked to review premarket applications for millions of products. The vast majority of these applications are for Electronic Nicotine Delivery Systems (ENDS) products. Applications for ENDS products and other deemed new tobacco products on the market as of Aug. 8, 2016 were required to be submitted to the FDA by Sept. 9, 2020. The agency has taken action on over 98% of the applications submitted by that deadline, including issuance of Marketing Denial Orders (MDOs) for over 1.1 million flavored ENDS whose applications lacked sufficient evidence that allowing the products to be marketed would be appropriate for the protection of the public health; and issuance of Refuse-To-File letters for

over 5 million products. Marketing granted orders were also issued for three ENDS (one device and two tobacco-flavored products). From January 2021 through September 2021, the agency issued over 170 warning letters to firms that have over 17 million e-cigarette products listed with the FDA and that had not submitted timely premarket applications for these products. These warning letters include a letter to a company with over 15 million products listed with the FDA that did not submit an application. As of Oct. 7, 2021, the FDA has also issued warning letters to 20 companies that received MDOs.

Compliance and Enforcement: The FDA has a comprehensive compliance and enforcement program to monitor industry compliance with regulatory requirements, and to restrict access and marketing of tobacco products, including e-cigarettes to youth.

In 2021, as part of the Youth Tobacco Prevention Plan and consistent with the FDA's policy to prioritize the enforcement of certain e-cigarettes and other deemed products on the market, the agency has conducted over 39,000 retail inspections and issued more than 4,500 warning letters and civil money penalties while working to protect the health and safety of all stakeholders involved in the compliance check process.

Tobacco Retailer Inspection Program: As of Nov. 30, 2021, the FDA had contracts for tobacco retailer compliance check inspections in approximately 56 states and territories. In 2021 retailer inspections continued to be conducted but have not yet completely returned to the pre-pandemic level of inspectional activity.

Consumer Safety and Protection, Fraudulent Claims and Illegal Sales

The FDA is committed to protecting U.S. consumers from unproven products sold with false or misleading claims and we'll continue to hold companies accountable by alerting the public about products that potentially place consumers at risk.



During the COVID-19 pandemic, we have remained vigilant in protecting consumers from fraudulent products. Some people and companies are trying to profit by selling unproven and illegally marketed products that make false claims, such as being effective against COVID-19. Unlike the products approved or authorized by the FDA, fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the agency for safety and effectiveness and might be dangerous.

Operation Quack Hack leverages agency expertise and advanced analytics. As of Dec. 31, 2021, the agency has uncovered nearly 2,100 fraudulent products, issued more than 267 warning letters, and sent more than 651 abuse complaints to domain registrars and online marketplaces, who then removed listings for fraudulent COVID-19 products.

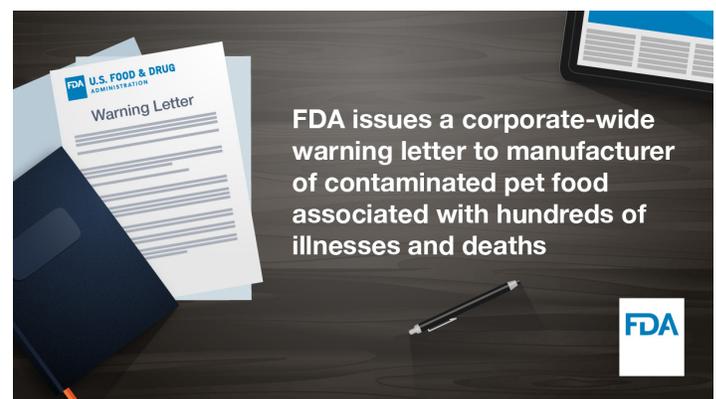
Non-COVID related actions we took in 2021 to protect patients and consumers from fraudulent and potentially unsafe products included:

Fraudulent claims to treat diabetes: In partnership with the Federal Trade Commission (FTC), we posted warning letters to 10 companies for illegally selling purported dietary supplements that claim to cure, treat, mitigate, or prevent diabetes.

Contaminated Pet Food: We issued a corporate-wide warning letter to Midwestern Pet Foods, Inc. after inspections of its manufacturing sites revealed apparent violations and conditions likely contributing to the illness or death of hundreds of dogs. The inspection of the plant was triggered by reports of illness or death in dogs that had eaten SPORTMiX

brand dry dog food manufactured by Midwestern.

Illegal Sale of Purported Dietary Supplements Claiming to Treat Infertility: In partnership with the FTC, we issued warning letters to five companies for illegally selling purported dietary supplements that claim to cure, treat, mitigate, or prevent infertility and other reproductive health disorders in violation of the law.



FDA issues a corporate-wide warning letter to manufacturer of contaminated pet food associated with hundreds of illnesses and deaths

Increasing Patient Access to Generics, Biosimilars and OTC Options



The FDA continues to be steadfast in our commitment to provide patients with alternative high-quality, affordable medical products that are proven to be safe and effective.

First Time Generic Drugs: First generics are especially important because they represent the first opportunity for generic competition – and are generally sold at significantly lower prices than the brand name products. The agency considers first generics important to public health and prioritizes their review.

FDA-approved generic medicines work in the same way and provide the same clinical benefit and generally the same risks as their brand-name counterparts. In 2021 we approved more than 90 first generics, involving treatments for a range of diseases, including diabetes, arthritis, ulcerative colitis, anemia, and a number of different cancers.

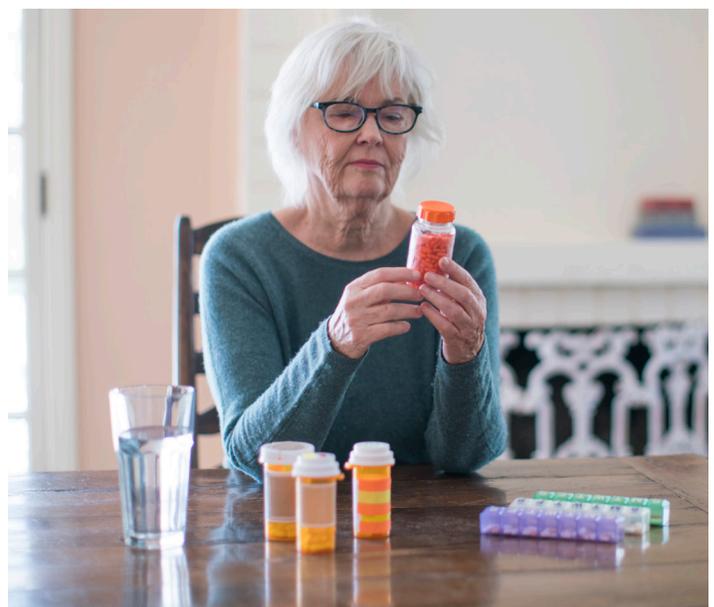
Biosimilars: We have now approved 33 biosimilars for 11 different reference products. Once on the market, approved biosimilar and interchangeable biosimilar products can play a role in facilitating broader access to treatments for many serious health conditions.

In July, we approved the first interchangeable biosimilar insulin product, indicated to improve glycemic control in adults and pediatric patients with Type 1 diabetes mellitus and in adults with Type 2 diabetes mellitus. Semglee (insulin glargine-yfgn) is both biosimilar to, and interchangeable with, Lantus (insulin glargine), a long-acting insulin analog.

In October, we approved the first interchangeable biosimilar product to treat certain inflammatory diseases. Cyltezo (adalimumab-adbm), originally approved in August 2017, is both biosimilar to, and interchangeable with, Humira (adalimumab) for

Cyltezo's approved uses. Cyltezo was the second interchangeable biosimilar product approved by the agency and the first interchangeable monoclonal antibody.

Medical Devices: In October, we issued a landmark proposal intended to improve access to and reduce the cost of hearing aid technology for millions of Americans. The agency proposed a rule to establish a new category of over-the-counter (OTC) hearing aids. When finalized, the rule would allow hearing aids within this category to be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist.



Innovative Diagnostics and New Medical Treatments

During 2021, the FDA approved 50 novel drugs and therapeutic biologics, as well as new uses for already FDA-approved drugs, to treat a wide range of medical conditions. The agency also approved more than 10 new biological products (including vaccines) and cleared, approved, or authorized more than 95 novel medical devices to help improve patient health.



A few highlights include:

Lung Cancer: Lumakras (sotorasib) is the first treatment for adult patients with non-small cell lung cancer whose tumors have a specific type of genetic mutation called KRAS G12C and who have received at least one prior systemic therapy. This is the first approved targeted therapy for tumors with any KRAS mutation, which accounts for approximately 25% of mutations in non-small cell lung cancers.

Obesity: Wegovy (semaglutide) was approved for chronic weight management in adults with obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol), for use in addition to a reduced calorie diet and increased physical activity. This under-the-skin injection is the first approved drug since 2014 for chronic weight management in adults with general obesity or who are overweight.

Autism Spectrum Disorder: We authorized marketing of a new device to help diagnose autism spectrum disorder (ASD). The Cognoa ASD Diagnosis Aid is a machine learning-based software intended to help health care providers diagnose ASD in children 18 months through 5 years of age who exhibit potential symptoms of the disorder. Autism spectrum disorder can delay a child's physical, cognitive and social development, including motor skill development, learning, communication and interacting with others.

Rare immune disorder in children: Rethymic was approved for the treatment of pediatric patients with congenital athymia. It is the first thymus tissue product

approved in the U.S. Congenital athymia is a rare immune disorder in which a child is born without a thymus – an organ that plays a critical role in helping the body learn to fight infections.

Animal Health: We also help keep animals healthy, whether it's your dog, cat, horse, livestock, or even wildlife or exotic animals. In 2021, we approved the first treatment for lymphoma (a type of cancer) in dogs and conditionally approved a lymphoma treatment available in pill form, as well as conditionally approved the first-ever treatment for canine epilepsy. The agency also approved several new generic animal drugs, which can increase treatment options and reduce the cost of care for pet owners and animal caretakers. When we learned about shortage of a critical heart drug for dogs, we worked to help bring in the same product from other countries.



Modernizing Our Information Technology and Data Management



Data have always formed the basis of the FDA's science-based regulatory decision making. Good data management, built into the FDA's work, ultimately helps us to meet and advance our mission. Data and data science are cross-cutting issues where we must continue to improve our competency. If science is the brain of the agency, data is its circulatory system, and the technology is the musculoskeletal system.

To keep pace with evolving science and technology as our world has become more connected, data from new sources are helping us understand, for example, how medical products are performing or how we can pinpoint the source of a foodborne illness.

In 2021, we began an agency-wide data modernization and enhanced technologies initiative. The effort allows us to take a collaborative, centralized approach to modernizing our technical IT infrastructure and the way we manage data across the FDA.

In September, we announced the [reorganization of the FDA's information technology, data management and cybersecurity functions into the new Office of Digital Transformation](#). The office has been realigned to report directly to the FDA commissioner, elevating the office and its functions to the agency level.

The reorganization incorporates and builds on the priorities reinforced in the [Data Modernization Action Plan \(DMAP\)](#) and the [Resiliency Roadmap for FDA Inspectional Oversight](#) released in March and May respectively. As of Sep. 30, 2021, the FDA has exceeded the Base-Case Scenario projections for FY21, completing more than twice as many domestic surveillance oversight activities than projected in the Roadmap. The [New Era blueprint](#), DMAP, and Resiliency Roadmap are components of a one-FDA approach to protecting consumers and the public health.

By consolidating data systems and migrating to a reliable hybrid cloud environment, the FDA can move closer to the speed of industry in streamlining

workflows, reducing the cost of maintaining data and network security, and improving the timeliness of delivery of services.

When the FDA applies more advanced technologies to its work, the agency can help facilitate innovative development of FDA-regulated products and new methods of generating and analyzing data to evaluate whether those products meet the FDA's standards that patients depend upon.

To do this, the FDA must also invest in its own programs to keep pace with the tremendous changes taking place in how human and animal medical products are being developed and produced so that we can help ensure their responsible development.





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