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The FDA created the Data Dashboard to increase transparency and accountability by displaying and allowing the analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics.U.S. domestic and foreign inspections by fiscal year, classification, product type, etc.Warning letters, injunctions and seizures by fiscal year, product type, etc.Recalls by fiscal year, classification, product type, status, etc.Imports summary data by fiscal year, import lines, product categories, countries, etc.Import refusals by fiscal year, product categories, country, divisions, etc.Imports entry data by fiscal year, country of origin, port of entry district, etc.The Data Dashboard allows users to interactively explore, search and export information from FDAs public datasets. Here, data from different FDA systems are pulled into a central location, transformed, enriched, and linked together to highlight relationships, increase clarity, reveal trends, simplify access, and promote overall information transparency. In addition, programmatic data access is provided via an Application Programming Interface (API) and users may also subscribe to notifications about important changes and updates to the Data Dashboard site.The Data Dashboard contains data elements from FDA compliance and enforcement data sources, including Inspections, Compliance Actions, Recalls, Imports, and Food Safety Modernization Act programs. New dashboards with additional sources will continue to be added. Further information about specific data is available on the Compliance Dashboards or FSMA Data Search pages.Questions and comments pertaining to the FDA Data Dashboard and source data may be directed by email to: FDADataDashboard@fda.hhs.gov.Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated weekly and only include final actions. If you need to present more recent or more complete data for official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in electronic reading rooms or inquire about other datasets that would satisfy your needs.Certain records related to inspections listed with final classifications may not be available under FOIA until determined as closed per 21 CFR 20.64(d). The disclosure of inspectional information is not intended to interfere with planned compliance actions, therefore some information may be withheld from posting until such actions are taken.Each entry in the source data reflects the result of an inspected Project Area. Several Project Areas may be inspected during a single inspection. Therefore, the number of classifications may exceed the Inspection count. Additionally, more than one compliance program may be evaluated during an inspection, as identified in the additional details field within the Inspections Details table. In this case, the classification of the inspection is the same for all compliance programs evaluated within a Project Area.For more information on drug inspections, please visit CDERs Drug Quality, Current Good Manufacturing Practice Inspections and Compliance webpage: Pharmaceutical Inspections and Compliance.Under the Mutual Recognition Agreements (MRAs) between FDA and foreign regulatory authorities, FDA can rely upon information from drug inspections conducted by these authorities. Upon receiving these inspection reports, FDA can assess and classify them. Those inspections that are classified are available on this dashboard. For more information on MRAs, please visit Mutual Recognitions Agreement (MRA).FDA does not issue CGMP certificates at the conclusion of an inspection. Instead, this dashboard provides the outcomes, including classification and other details, of a firms most recent inspection. FDA issues CGMP Declarations to convey the CGMP status of a facility to foreign regulators, if requested by a drug manufacturer, only for drugs exported from the U.S.FDA prioritizes human drug manufacturing establishments for surveillance inspections on a risk basis. Time between surveillance inspections should not be interpreted as a measure of facility or product quality (i.e., not having been inspected in several years does not mean there should be less confidence in the facility or its products). For further information on how CDERs Office of Pharmaceutical Quality prioritizes establishments for inspection, please see CDER MAPP 5014.1 (R1), Understanding CDERs Risk-Based Site Selection Model.The Published 483s table only displays 483 reports that have been cleared and published in the OII FOIA Electronic Reading Room.Inspectional data does not include State contract inspections at this time. State contract inspections will be posted at a later date.Inspections and Citations data are only posted for inspections where all project area classifications are finalized.FDA may release and publish 483s for inspections that are not displayed on the Inspection Dashboard.Not all FDA Form 483s are generated by FDAs electronic inspection tools as some 483s are manually prepared. Citations for manually-prepared 483s will not appear in the citations data.If changes were made to the FDA Form 483 and not synchronized with the electronic inspection tools, the results will not fully reflect the actual final Form 483 that was provided to the firm.FDA has removed Medical Device Single Audit Program (MDSAP) audit reports, which are conducted by certified third-party auditors and may be considered in lieu of an FDA surveillance inspection, from the FDA Data Dashboard. FDA has determined that MDSAP audits do not meet the criteria for posting on the FDA Data Dashboard.Read/hide all caveats ISTAND supports innovative, science-driven approaches that improve drug development and regulatory decision-making. FDA uses science and data to ensure that approved drugs are of a high quality, safe, and effective. Learn more about the FDAs role in reviewing, approving, and monitoring drugs in the latest videos that are now available in Spanish. Learn more Find information about most FDA-approved prescription, generic, and over-the-counter drug products. Find information about drug shortages caused by manufacturing and quality problems, delays, and discontinuations. Find information about finished drug products, unfinished drugs, and compounded drug products. The Orange Book identifies drug products approved by FDA on the basis of safety and effectiveness. Medication Guides, Drug Safety Communications, Shortages, Recalls Drugs@FDA, Orange Book, National Drug Code, Recent drug approvals Drug applications, submissions, manufacturing, and small business help Guidances, warning letters, drug compounding, international information, registration and listing CDER research programs, initiatives, and resources Prepare and respond to natural disasters, nuclear and chemical attacks Recent approvals, meetings, workshops, blogs, podcasts, stay connected Our role, mission, organization, history, leadership, job openings Learn how biosimilars are safe and effective treatment options Reducing the impact of opioid misuse and abuse Ensuring access to safe, affordable, and effective generic drugs Warning and Notice of Violation Letters to Pharmaceutical Companies FDA's current thinking on drug development and review activities Search the database, learn about root causes and potential solutions Information for consumers, health professionals, and industry Learn how to properly get rid of unused or expired medication In this section: Novel Drug Approvals at FDA "Novel" drugs are new drugs never before approved or marketed in the U.S. See Drugs@FDA for information about all of CDERs approved drugs and biological products.FDA Novel Drug Therapy Approvals for 2025No.Drug NameActive IngredientApproval DateFDA-approved use on approval date*39.Voyxactsibeprenlimab-szsi11/25/2025To reduce proteinuria in primary immunoglobulin A nephropathy in adults at risk for disease progression38.Hyrnuosevabertinib11/19/2025To treat locally advanced or metastatic non-squamous non-small cell lung cancer with tumors that have activating HER2 tyrosine kinase domain activating mutations in patients who received a systemic therapy37.Redemploplozasiran11/18/2025To reduce triglycerides in adults with familial chylomicronemia syndrome36.Komziftiziftomenib11/13/2025To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 mutation who have no satisfactory alternative treatment options35.Kygevvidoxecitine and doxribtimine11/3/2025To treat thymidine kinase 2 deficiency in patients who start to show symptoms when they are 12 years old or younger34.Lynkuetelinzanetant10/24/2025To treat moderate-to-severe vasomotor symptoms due to menopause33.Jascaydnerandomilast10/7/2025To treat idiopathic pulmonary fibrosis32.Rhapsidoremibrutinib9/30/2025To treat chronic spontaneous urticaria in adults who remain symptomatic despite H1 antihistamine treatment31.Palsonifypaltusotine9/25/2025To treat acromegaly in adults who had an inadequate response to surgery and/or for whom surgery is not an option30.Inluriyoimlunestrant9/25/2025To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, estrogen receptor-1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy29.Forzinityelamipretide9/19/2025To improve muscle strength in patients with Barth syndrome weighing at least 30 kg28.Keytruda Qlexpembrolizumab and berahyaluronidase alfa-pmph9/19/2025To treat adult and pediatric (12 years and older) solid tumor indications approved for the intravenous formulation of pembrolizumab27.Wayrilzrilzabrutinib8/29/2025To treat persistent or chronic immune thrombocytopenia that has not sufficiently responded to immunoglobulins, anti-D therapy, or corticosteroids26.Dawnzeradonidalorsen8/21/2025To prevent attacks of hereditary angioedema25.Brinsupribrensocatib8/12/2025To treat non-cystic fibrosis bronchiectasisDrug Trials Snapshot24.Hernexeoszongertinib8/8/2025To treat adults with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy23.Modeysodordaviprone8/6/2025To treat diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapyDrug Trials Snapshot22.Vizzaceclidine7/31/2025To treat presbyopia21.Sephiencesepiapterin7/28/2025To treat hyperphenylalaninemia in patients with sepiapterin-responsive phenylketonuria, in conjunction with a phenylalanine-restricted dietDrug Trials Snapshot20.Anzupgodelgocitinib7/23/2025To treat moderate-to-severe chronic hand eczema when topical corticosteroids are not advisable or produce an inadequate responseDrug Trials Snapshot19.Ekterlysebetralstat7/3/2025To treat acute attacks of hereditary angioedemaDrug Trials Snapshot18.Zegfrovysunvozertinib7/2/2025To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, with disease progression on or after platinum-based chemotherapy17.Lynozyficlinvoseltamab-gcpt7/2/2025To treat relapsed or refractory multiple myeloma after at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody16.Andembrygaradacimab-gxii6/16/2025To prevent attacks of hereditary angioedemaDrug Trials Snapshot15.Ibtrozitaletrectinib6/11/2025To treat locally advanced or metastatic ROS1-positive non-small cell lung cancerDrug Trials Snapshot14.Enflonsiaclesrovimab-cfor6/9/2025To prevent respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV seasonDrug Trials Snapshot13.Tryptyracoltremon5/28/2025To treat the signs and symptoms of dry eye diseaseDrug Trials Snapshot12.Emrelistelisotuzumab vedotin-tllv5/14/2025To treat locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression after prior systemic therapyDrug Trials Snapshot11.Avmapki Fakzynja Co-Packavutometinib and defactinib5/8/2025To treat KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) after prior systemic therapyDrug Trials Snapshot10.Imaavynipocalimab-aahu4/29/2025To treat generalized myasthenia gravisDrug Trials Snapshot9.penpulimab-kcqxpenpulimab-kcqx4/23/2025In combination with either cisplatin or carboplatin and gemcitabine, to treat adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC), or as a single agent while on or after platinum-based chemotherapy and at least one other prior line of therapyDrug Trials Snapshot8.Vanrafiaatrasentan4/02/2025To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progressionDrug Trials Snapshot7.Qfitliafitusiran3/28/2025To prevent or reduce the frequency of bleeding episodes in hemophilia A or BPress ReleaseDrug Trials Snapshot6.Blujepagepotidacin3/25/2025To treat uncomplicated urinary tract infectionsDrug Trials Snapshot5.Romvimzavimseltinib2/14/2025To treat symptomatic tenosynovial giant cell tumor for which surgical resection will potentially cause worsening functional limitation or severe morbidityDrug Trials Snapshot4.Gomeklimirdametinib2/11/2025To treat neurofibromatosis type 1 who have symptomatic plexiform neurofibromas not amenable to complete resectionDrug Trials Snapshot3.Journavxsuzetrigine1/30/2025To treat moderate to severe acute painPress ReleaseDrug Trials Snapshot2.Grafapextreosulfan1/21/2025For use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation for acute myeloid leukemia and myelodysplastic syndromeDrug Trials Snapshot1.Datrowaydatopotamab deruxtecan-dlnk1/17/2025To treat unresectable or metastatic, HR-positive, HER2-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic diseaseDrug Trials Snapshot*The listed FDA-approved use on this website is for presentation purposes only. To see the FDA-approved conditions of use [e.g., indication(s), population(s), dosing regimen(s)] for each of these products, please see the most recently approved Prescribing Information (or Label) available at Drugs@FDA. You can search by drug name, active ingredient, or application number. Back to Top In this section: News & Events Latest Press Announcements November 2025 October 2025 Sign up to receive FDA Press Releases. Get regular FDA email updates delivered on this topic to your inbox. Back to Top In this section: About FDA Espaol Approvals of FDA-Regulated Products Is It Really "FDA-Approved?" Recalls, Market Withdrawals, and Safety Alerts FDA News and Events Back to Top In this section: Safety The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See Additional information about recalls for a more complete listing. The Recalls, Market Withdrawals & Safety Alerts are available on FDAs website for three years before being archived. To search archived content, visitSearch FDA Archiveand input the name of the product and/or company name in the Search terms box as well as the year to get the most inclusive search results. To scroll through archived Recalls, Market Withdrawals & Safety Alerts content by year, see theRecall and Safety Alerts Archive. Date Brand Name(s) Product Description Product Type Recall Reason Description Company Name Terminated Recall Excerpt 11/26/2025 Locatelli Grated Pecorino Romano Cheese Food & Beverages, Foodborne Illness Potential presence of Listeria monocytogenes. Wegmans Food Markets, Inc. 11/26/2025 Ambriola, Locatelli, Members Mark, Pinna, and Boars Head Cheese Food & Beverages, Foodborne Illness Potential to be contaminated with Listeria monocytogenes The Ambriola Company 11/26/2025 Anthonys Barbecue Sauce May contain undeclared Anchovy (fish). Anthonys BBQ Sauce 11/26/2025 Prairie Farms Fat Free Milk Food & Beverages, Contaminants May contain food-grade cleaning agents Prairie Farms 11/26/2025 Choceur Bark candy with nuts and fruit Food & Beverages, Allergens Undeclared pecans and wheat Silvestri Sweet, Inc. 11/25/2025 Belevini Dried Whole Salted Smelt, Mullet, Goby Food & Beverages, Foodborne Illness Potential to be contaminated with Clostridium botulinum. Mamtakim, Inc. 11/24/2025 Boars Head Chicken Caesar Salad and Wrap Food & Beverages Due to the potential presence of Listeria monocytogenes Supreme Service Solutions, LLC. 11/20/2025 Prime Food Lava Buns Food & Beverages, Allergens Undeclared milk allergen Prime Food Processing LLC 11/19/2025 Majestic Chef Pan Milk Pan 24cm Food & Beverages Product has the potential to be contaminated with significant levels of lead (Pb) which may leach into food SHATA TRADERS INC 11/18/2025 Jenis Passion Fruit Dreamsicle Ice Cream Bars Food & Beverages, Allergens Undeclared allergen - soy, wheat. Jenis Splendid Ice Cream Back to Top Get answers to your questions and report problems with FDA-regulated products. Resources for Former FDA EmployeesReport a product problemTell us about a problem with an FDA-regulated product. We review every submission to monitor product safety. 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