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Report to Congressional Committees

March 2026

ANIMAL DRUGS

Strengthening Federal Incentives Could Help Address Unmet Animal Health Needs

GAO-26-107896

GAO Highlights

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GAO-26-107896 March 2026

A report to congressional committees

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What GAO Found

High development costs and limited markets have led to a lack of U.S. Food and Drug Administration (FDA)-approved animal drugs for minor animal species. These are all animals other than the most common pets, livestock, and poultry (major species). There are also few approved drugs for rare conditions in major species (called “minor uses”) or for serious or life-threatening conditions where showing a drug’s effectiveness requires complex or difficult studies.

From fiscal years 2018 through 2025, FDA conditionally approved 11 new animal drugs, all of which were for major species. Nine were for pets, and two were for cattle. As of January 31, 2026, FDA conditionally approved two additional drugs.

To get full or conditional FDA approval, sponsors must conduct studies showing evidence of the drug’s effectiveness. These studies, particularly those needed for full approval, can be expensive and difficult for some conditions and species. FDA developed guidance for alternative approaches that sponsors can use, such as foreign-generated data or adjustable sample sizes. However, FDA has not developed a benefit-risk assessment that would help it evaluate sponsors’ use of alternative approaches to demonstrating a drug’s effectiveness. Doing so, and developing related guidance for industry, could encourage sponsors to address unmet animal health needs and address the lack of FDA-approved drugs.

Examples of Unmet Animal Health Needs

Sheep and goats lack drugs to treat parasites

Aquatic species lack drugs for bacterial infections

Piglets, calves, and goats lack drugs for painful procedures like castration and tail removal

Sources: Dmitry Pichugin (sheep photo)/Lost_in_the_Midwest (fish photo)/didesign (pig photo)/stock.adobe.com. | GAO-26-107896

The conditional approval pathway and other incentives have had a limited effect on new animal drug development. Many of the unmet animal health needs that existed when the conditional approval pathway was created in 2004 remain unmet. These include the need for FDA-approved drugs to treat parasites in sheep and goats and bacterial infections in fish. Sponsors and others said that conditional approval’s flexibilities were not enough to overcome the drugs’ limited return on investment. For example, they said that conditional approval’s statutory 5-year limit for sponsors to gather enough effectiveness data to obtain full approval of their drugs is too short. FDA officials are considering policy changes to further incentivize drug development, but changing the 5-year limit on conditional approval would require congressional action. Considering an expansion to this time frame could help Congress determine whether the current limit balances multiple objectives, including increasing animal drug availability, protecting animal and human health, and maintaining incentives for sponsors to develop drugs for markets with limited profitability.

Why GAO Did This Study

Animal drugs play a vital role in preventing and treating diseases in animals. FDA regulates the safety and effectiveness of new animal drugs.

Noting the scarcity of approved drugs for minor species and minor uses, in 2004, Congress established economic incentives to encourage drug sponsors (e.g., companies) to fill this gap. These incentives included a conditional approval pathway for new animal drugs for minor species and uses. Conditional approval allows sponsors to legally sell a drug for up to 5 years while completing studies to demonstrate substantial evidence of the drug’s effectiveness. In 2018, Congress expanded this pathway to include serious conditions or unmet needs.

The Animal Drug and Animal Generic Drug User Fee Amendments of 2018 included a provision for GAO to review, by 2026, FDA’s conditional approval pathway and how it could be improved. This report (1) describes the animal drugs FDA conditionally approved in fiscal years 2018 through 2025; (2) evaluates the extent to which FDA has accepted alternative study designs for new drugs; and (3) evaluates the extent to which conditional approval has incentivized new drug development.

GAO reviewed relevant statutes, regulations, and FDA data and documents. GAO also interviewed FDA officials, animal drug sponsors, researchers, and other stakeholders, and made two site visits.

What GAO Recommends

Congress should consider expanding conditional approval’s 5-year limit. GAO is also making two recommendations to FDA, including that it incorporates a benefit-risk assessment into its animal drug evaluations. FDA agreed with the recommendations.

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Abbreviations

FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
HHS	Department of Health and Human Services
MUMS Act	Minor Use and Minor Species Animal Health Act of 2004
USDA	U.S. Department of Agriculture

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March 3, 2026

The Honorable Bill Cassidy, M.D.
Chair
The Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Brett Guthrie
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Animal drugs play a vital role in preventing and treating diseases, improving animal welfare, and ensuring that food products from treated animals are safe for human consumption. However, high drug development costs and limited markets have resulted in few drugs for minor animal species—all animals other than the most common livestock, poultry, and companion animals. Minor species include goats and rabbits, aquatic animals, and insects like honeybees. There are also few drugs available to treat uncommon diseases or conditions in major species, which include livestock, poultry, and companion animals. Drugs for uncommon conditions in the major species are referred to as minor uses in major species, or simply minor uses.

The U.S. Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, regulates the safety and effectiveness of new animal drugs. Noting the scarcity of drugs for minor uses and minor species, in 2004, Congress passed the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act).[1] This law provides new ways, which FDA calls "innovative," to bring products to market for small populations of animals where there is less economic incentive for drug sponsors to invest in the research and development necessary to

[1]Pub. L. No. 108-282, tit. I, §§ 101-102, 118 Stat. 891-905 (codified as amended at 21 U.S.C. §§ 360ccc through 360ccc–2).

obtain FDA approval.[2] The MUMS Act created a new FDA drug approval pathway called conditional approval. Conditional approval allows sponsors of drugs for minor uses and minor species to make these drugs available before collecting all necessary data on their effectiveness, but after proving they are safe in accordance with the full FDA approval standard and have demonstrated a "reasonable expectation" of effectiveness. The drug sponsor can sell the product for up to 5 years, through annual renewals, while collecting the effectiveness data needed to support full FDA approval.

Conditional approval was initially intended for drugs for minor uses and minor species, but in 2018, Congress expanded conditional approval's eligibility to include drugs that address certain common uses in the major species. Specifically, sponsors can seek conditional approval for drugs that address a serious or life-threatening disease or condition or an unmet animal or human health need (such as preventing antimicrobial resistance to drugs used in both animals and humans) where demonstrating the drug's effectiveness would require a complex or difficult study.[3]

In 2018, Congress also recognized that using alternative approaches and data sources—such as novel investigation designs, data from foreign countries, and real-world evidence—to demonstrate a drug's effectiveness can be helpful for sponsors. As a result, Congress directed FDA to issue guidance that would help drug sponsors with using alternative study designs and data sources. Sponsors can use these alternative approaches to demonstrate substantial evidence of a drug's effectiveness (for sponsors seeking full approval of a new animal drug) or

[2]FDA regulations define a sponsor as the party with interest in the development and intended or actual production and sales of a drug. Sponsor also means the person responsible for an investigation of a new animal drug or the submission of a new animal drug application for FDA's approval. A sponsor may be an individual, partnership, corporation, organization, association, government agency, or may be a manufacturer, scientific institution, or investigator. In all contexts, the sponsor is responsible for compliance with the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and regulations. See 21 C.F.R. § 516.3(b).

[3]Animal Drug and Animal Generic Drug User Fee Amendments of 2018, Pub. L. No. 115-234, § 304, 132 Stat. 2427, 2432 (amending 21 U.S.C. § 360ccc).

a reasonable expectation of a drug's effectiveness (for sponsors seeking conditional approval of a new animal drug).[4]

The Animal Drug and Animal Generic Drug User Fee Amendments of 2018 includes a provision for us to review FDA's conditional approval pathway and report by 2026 on whether any improvements are needed to incentivize animal drug development.[5] This report (1) describes all animal drugs that FDA conditionally approved in fiscal years 2018 through 2025 and any effects the conditional approval pathway has had on FDA's ability to review and approve other animal drug applications, (2) evaluates the extent to which FDA has accepted drug sponsors' alternative approaches to demonstrating clinical effectiveness in full or conditional new animal drug applications, and (3) evaluates the extent to which FDA's conditional approval pathway has incentivized the development of new animal drugs.

To conduct our work, we reviewed relevant laws, regulations, agency guidance, and published reports since 2004, when the MUMS Act was passed. We interviewed officials from FDA; the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service's Center for Veterinary Biologics, which has a similar conditional approval pathway for animal vaccines; and the Department of the Interior's Fish and Wildlife Service's Aquatic Animal Drug Approval Partnership, which conducts research to support FDA approvals of aquatic species drugs. We also interviewed representatives from selected stakeholder groups, which we identified by reviewing FDA documents for potential interviewees and using a snowball sampling approach to identify other potential interviewees.[6] Additionally, we conducted semi-structured interviews with

[4]Pub. L. No. 115-234, § 305. The Animal Drug and Animal Generic Drug User Fee Amendments of 2018 required FDA to issue guidance to sponsors on how to incorporate such "elements of investigation," which also include real-world evidence and complex adaptive investigation designs, among others, into proposed clinical investigation protocols and applications for new animal drugs or conditional approval of new animal drugs under the FD&C Act.

[5]Pub. L. No. 115-234, § 304(d).

[6]Snowball sampling is a non-probability sampling method where initial interviewees refer to other potential participants, creating a chain of referrals. We interviewed officials from the American Dairy Goat Association, American Sheep Industry Association, Animal Health Institute, American Veterinary Medical Association, Association of Fish and Wildlife Agencies, National Aquaculture Association, National Turkey Federation, United States Animal Health Association, and the Veterinary Cancer Society.

eight drug sponsors.[7] Our selected sponsors are not representative of all sponsors but provide a variety of perspectives on FDA's conditional approval pathway.

To describe the new animal drugs FDA conditionally approved from fiscal years 2018 through 2025, we analyzed information from FDA's Submission Tracking and Reporting System on new drug approvals, including conditional approvals, and their characteristics. We reviewed system manuals and other documentation and met with FDA officials to determine that the information was sufficiently reliable for the purpose of describing these drugs. To describe any effects the conditional approval pathway has had on FDA's ability to review and approve other animal drug applications, we reviewed FDA's publicly available performance reports for fiscal years 2020 through 2024. These reports allowed us to identify the timeliness of FDA's new animal drug application reviews.[8] We also reviewed data from FDA's Activity Time Reporting module on the number of hours FDA spent on new animal drug approval and conditional new animal drug approval reviews for fiscal years 2018 (when Congress expanded drugs eligible for conditional approval) through 2025. We determined that the data were sufficiently reliable for the purpose of comparing the total hours spent annually on conditional new animal drug applications with those spent on other new animal drug applications. We also reviewed FDA's publicly available Freedom of Information Summaries for all conditionally approved drugs from fiscal year 2004, when the conditional approval authority was first established, through fiscal year 2025 (see appendix I for summaries of each of these drugs).

To examine the extent to which FDA has accepted alternative approaches to demonstrating clinical effectiveness in full or conditional new animal drug applications, we reviewed FDA's guidance for industry on each alternative approach for which FDA was required to develop guidance. We obtained information from FDA on how many animal drugs were approved or conditionally approved from fiscal years 2018 through

[7]We interviewed the following drug sponsors: Anivive Lifesciences, Inc.; Boehringer Ingelheim; Elanco US, Inc.; Jaguar Animal Health; Merck Animal Health; Syndel; Vetoquinol USA; and Zoetis. The sponsors we selected own about 47 percent of all animal drugs. We selected sponsors to include those that had drugs approved under or eligible for the conditional approval pathway and that had a range of approved animal drugs (from one to over 150).

[8]These reports are designed to improve the timeliness and predictability of FDA's review of new animal drug applications, among other goals, and summarize FDA's performance results in meeting its statutory goals and commitments.

2025 that used any of these approaches. We reviewed examples of the types of evidence that are acceptable for demonstrating a drug's effectiveness. We also reviewed the goals and objectives of FDA's 2016-2025 *Foods and Veterinary Medicine Program Strategic Plan* and the Center for Veterinary Medicine's 2023 Animal and Veterinary Innovation Agenda, which describe actions that FDA will take to improve access to safe and effective animal drug products. We interviewed our selected drug sponsors and stakeholders about their experiences with and perspectives on alternative approaches to demonstrating drug effectiveness. We compared FDA's goals for using alternative study designs and data sources to its requirements for how sponsors are to demonstrate drug effectiveness.

To examine the extent to which FDA's conditional approval pathway has incentivized the development of new animal drugs, we reviewed the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, that incentivize new animal drugs for minor uses, minor species, and for life-threatening conditions or unmet animal health needs. We also reviewed the acts' drug development incentives and conditional approval's restrictions. To identify current examples of unmet animal health needs, we reviewed federal and other stakeholder reports on livestock, aquaculture, and companion animals since 2004. We identified reports of unmet animal health needs through interviews with FDA and selected stakeholders. We compared these examples of unmet health needs to the types of drugs that FDA conditionally approved since 2004 to identify any gaps. We met with the above-mentioned agencies, drug sponsors, and stakeholder groups to discuss unmet animal health needs and the effects of the current federal drug development incentives. We also conducted site visits to the University of Arkansas and Kansas State University, which have FDA-funded Animal and Veterinary Innovation Centers conducting research to support drug development for unmet animal health needs (see appendix II). We compared the current unmet animal health needs and drug sponsor and stakeholder perspectives to the MUMS Act's stated purpose of allowing the lawful use and marketing of new animal drugs for minor species and minor uses taking into account the challenges faced by sponsors while ensuring such drugs do not endanger animal or public health.

We conducted this performance audit from October 2024 to March 2026 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

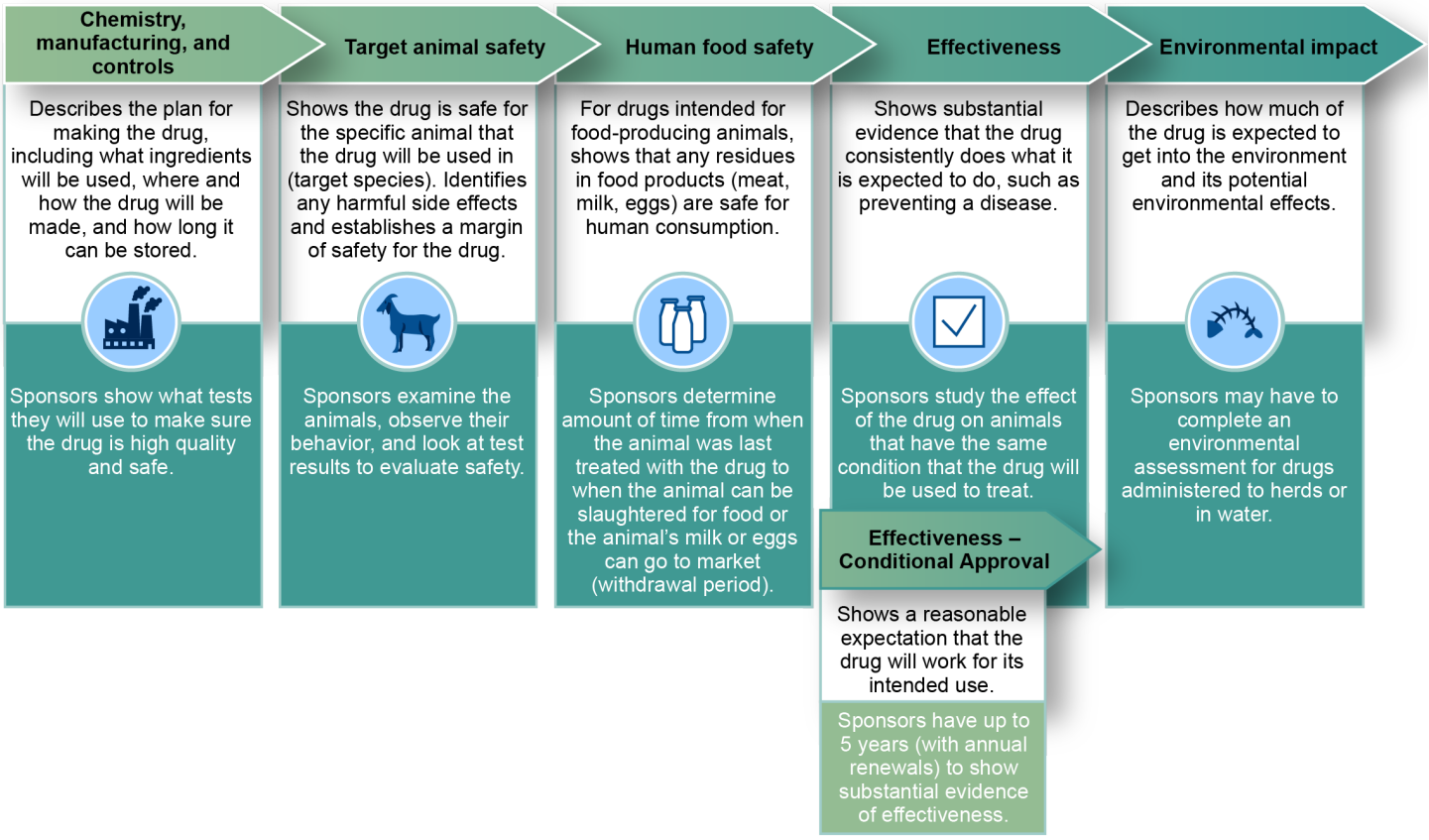
FDA's Process for Approving New Animal Drugs

FDA's Center for Veterinary Medicine reviews new animal drug applications to determine whether the drug is safe and effective when used according to the proposed label.[9] According to FDA, this process begins with drug sponsors opening an investigational file under which the sponsor provides information on the drug's safety, effectiveness, how the drug is made, and other information. The information sponsors provide to FDA is captured in what FDA describes as the five major technical sections of a new or conditional new animal drug application, which are described in figure 1.[10]

[9]The FD&C Act defines drugs as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(g)(1)(B), (C). The Center for Veterinary Medicine also regulates the safety and effectiveness of medicated animal feeds, devices, and food additives.

[10]According to FDA, new animal drug applications also include two minor technical sections: labeling, which describes what information will be included on the immediate container, package insert, and other packaging; and "all other information," which includes information about the drug that the sponsor did not submit as part of the major technical sections, such as published scientific literature.

Figure 1: Major Technical Sections of a U.S. Food and Drug Administration New Animal Drug Application and Examples of Drug Sponsor Actions



Source: GAO icons and analysis and U.S. Food and Drug Administration. | GAO-26-107896

A Center for Veterinary Medicine review team—including veterinarians, animal scientists, biostatisticians, chemists, and toxicologists—generally use a phased, or incremental, review process to assess whether the studies and other evidence the sponsor submitted demonstrate that the drug is safe and effective for its intended use, among other requirements.[11]

According to FDA, sponsors of drugs seeking conditional approval must meet the same safety, manufacturing, and other requirements as drugs seeking full approval. The difference between full and conditional approval lies in the effectiveness requirement. For full approval, the sponsor must provide substantial evidence of the drug's effectiveness.[12] For conditional approval, the sponsor must show that the drug has a reasonable expectation of effectiveness.[13] If the sponsor receives conditional approval, it can sell the conditionally approved drug legally for up to 5 years (with annual renewals) while collecting the necessary data to show substantial evidence of the drug's effectiveness. If the sponsor is unable to complete the necessary studies to demonstrate substantial evidence of effectiveness, the drug becomes unapproved and can no longer be marketed legally in the United States.

[11]Animal drugs have four pathways to legal marketing status: (1) approval, (2) conditional approval, (3) indexing, and (4) emergency use authorization. We focus on the approval and conditional approval pathways in this report. Indexed drugs are unapproved but have legal marketing status, meaning they can be sold legally for a specific use in certain minor species. Emergency use authorizations allow FDA to authorize unapproved medical products or unapproved uses of approved medical products during an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain criteria are met. In addition, FDA may authorize drugs that are compounded (e.g., formulated from bulk drugs or from mixing two or more approved drugs) under certain conditions although they are not approved by FDA.

[12]Section 512 of the FD&C Act defines "substantial evidence" as evidence consisting of one or more adequate and well-controlled investigations, including (1) a study in a target species, (2) a study in laboratory animals, (3) any field investigation that may be required by section 512 if a presubmission conference is requested by the applicant, (4) a bioequivalence study, or (5) an in vitro study by experts qualified by scientific training and experience to evaluate the effectiveness of the animal drug involved, on the basis of which it could reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. 21 U.S.C. § 360b(d)(3).

[13]The application must contain such information as the Secretary may require to show "there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 360ccc(c)(2).

Incentives and Restrictions for Conditionally Approved Drugs

The MUMS Act provided drug sponsors with incentives to develop drugs for minor species and minor uses, while ensuring appropriate safeguards for animal and human health. The act's financial incentives include competitive grants to support safety and effectiveness testing and an extended period of market exclusivity. Additionally, the Animal Drug User Fee Act of 2003 amended the FD&C Act to provide for the collection of user fees from sponsors and the authority to waive these fees when conditions are met.[14] Specifically, FDA may collect four different types of fees to cover its costs for reviewing certain animal drug applications.[15] These fees are appropriated to FDA during the annual appropriations process to help FDA carry out timely and thorough reviews.[16] Animal drug sponsors may qualify for a reduction of some or all user fees when their product is intended for use in a minor species, among other incentives. Table 1 describes the four types of fees and other incentives available to drug sponsors.

[14]Pub. L. No. 108-130, 117 Stat. 1361 (codified as amended at 21 U.S.C. § 379j-12(d)). The act added several provisions to the FD&C Act; those same provisions were further amended with each reauthorization of the act that has taken place every 5 years since 2003.

[15]21 U.S.C. § 379j–12(a).

[16]The Animal Drug User Fee Act of 2003 has been reauthorized every 5 years since 2003. For each reauthorization, FDA agrees to meet performance goals over the 5-year period for certain submissions. Details on FDA's commitments in response to the Animal Drug User Fee Amendments of 2023, Pub. L. No. 118-15, div. B, tit. III, subtit. A, ch.1, § 2304 (amending 21 U.S.C. § 379j-13), can be found in the Animal Drug User Fee Act Reauthorization Performance Goals Commitment Letter.

Table 1: Examples of Incentives to Support Drug Sponsors' Development of New Animal Drugs for Minor Uses and for Minor Species

Incentive	Description
User fee waivers	Sponsors developing drugs for minor species or minor uses may qualify for waivers or reductions of the fees that FDA is authorized to collect for certain animal drug applications. In fiscal year 2025, these included reductions or waivers of the annual sponsor fee ($137,446), animal drug product fee ($10,705), annual establishment fee ($157,702), and animal drug application fee ($581,735).
Grants to support costs of conducting safety and effectiveness testing	Sponsors (which can include drug companies and universities or their research partners) of drugs that FDA has designated as intended for use in a minor species or as a minor use are eligible for competitive grants to support the safety and effectiveness testing needed for full or conditional approval. Grantees can receive up to $250,000 per year for 2 years (maximum of $500,000). For toxicology studies, grantees can receive an additional year of funding, for a maximum of up to $750,000. Grant amounts and availability each year are dependent upon available funding.
Exclusive marketing rights	Drugs with minor use or minor species designation that receive full or conditional approval have 7 years of marketing exclusivity. Marketing exclusivity prevents FDA from approving or conditionally approving another application for the same drug in the same dosage form for the same intended use during the exclusivity period.

Source: U.S. Food and Drug Administration (FDA); GAO analysis. | GAO-26-107896

Note: FDA regulations specify the maximum number of major species animals (cats, dogs, horses, cattle, pigs, chickens, and turkeys) that are affected by a disease or condition annually for a drug to quality as a "minor use." Minor species are all species other than the major species. 21 C.F.R. § 516.3.

To help ensure appropriate safeguards for animal and human health, the law establishes restrictions on how conditionally approved drugs can be used, labeled, distributed, and marketed (see table 2).

Table 2: Restrictions on Conditionally Approved Animal Drugs

Category	Restriction
Eligibility	Antimicrobial drugs (drugs to kill or inhibit the growth of bacteria) are ineligible for conditional approval under FDA's 2018 expanded conditional approval authority, which allows conditional approval for conditions affecting the major species in certain situations.[a] Antimicrobial drugs are, however, eligible for conditional approval if the drug is for a minor species or uncommon condition in the major species (minor use).[b]
Use	Can only be prescribed for the specific intended use outlined in the conditional approval. The Animal Medicinal Drug Use Clarification Act of 1994, which provided approval for extra-label use for new animal drugs under certain circumstances, did not authorize extra-label use for conditionally approved new animal drugs.[c]
Labeling	Must carry specific labeling that states the drug is conditionally approved by FDA and includes the limitations on use. Generally, cannot be added to an existing approved drug label (i.e., "dual labeled"). According to FDA, each conditionally approved drug is required to have its own label and be sold in its own packaging. However, in October 2025, FDA stated that it intends to issue future guidance to address conditions under which it would consider dual labeling to be permissible.
Marketing	May only be conditionally approved for up to 5 years, with annual renewals. If a sponsor fails to demonstrate substantial evidence of the drug's effectiveness before the end of the 5-year period, the drug becomes unapproved and can no longer be marketed legally.

Source: GAO review of the Federal Food, Drug, and Cosmetic Act. | GAO-26-107896

[a]Drugs contained in or the product of "transgenic" animals (animals whose genomes have been intentionally modified in vitro and their progeny) are also ineligible for expanded conditional approval. 21 U.S.C. § 360ccc(j).

[b]Minor species are all species other than the major species (i.e., cats, dogs, horses, cattle, pigs, chickens, and turkeys). 21 U.S.C. § 321(oo), (pp). U.S. Food and Drug Administration (FDA) regulations specify the maximum number of major species animals that are affected by a disease or condition annually for a drug to quality as a "minor use." 21 C.F.R. § 516.3.

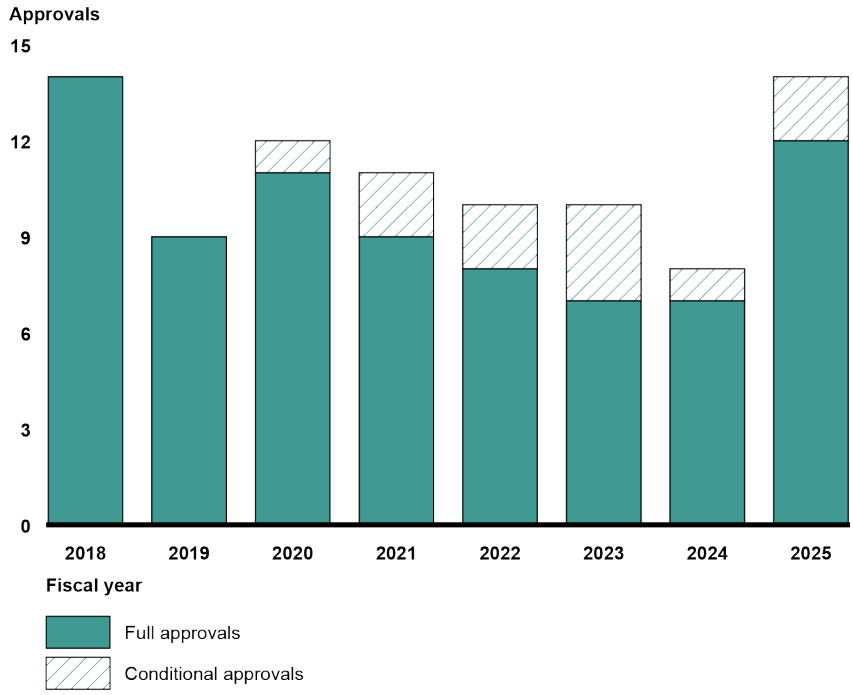
[c]Pub. L. No. 103-396, § 2(a), 108 Stat. 4153, 4153 (codified at 21 U.S.C. § 360b(a)(4)).

FDA Conditionally Approved 11 New Animal Drugs in Fiscal Years 2018 Through 2025

From fiscal years 2018 through 2025, FDA conditionally approved 11 new animal drugs and fully approved almost 80 (see fig. 2).[17] As of January 31, 2026, in fiscal year 2026, FDA conditionally approved two additional drugs.

[17]New drug approvals include drugs FDA identified as new chemical entities and original approvals. FDA also approved 68 other applications to make changes to existing drugs, including new indications and dosages, labeling or packaging changes, and approving new generic drugs. Of note are seven supplemental approvals for new species or classes of animals, which are the most significant type of FDA supplemental approval, according to FDA officials.

Figure 2: Number of New Animal Drug Approvals by Year and Type of FDA Approval, Fiscal Years 2018 Through 2025



Source: GAO analysis of U.S. Food and Drug Administration (FDA) data. | GAO-26-107896

Note: From fiscal years 2018 through 2025, FDA also approved 68 additional applications adding new indications (i.e., a new use for an existing drug), labeling and dosage changes, and other changes. Additionally, as of January 31, 2026, FDA conditionally approved two new drugs and fully approved five new drugs. FDA also approved five major supplemental applications. Of the 12 approvals so far in fiscal year 2026, three were full approvals of previously conditionally approved products.

The number of new animal drugs that FDA fully or conditionally approved varied from 14 approvals in fiscal year 2018 to eight in fiscal year 2024. The most conditional approvals (three) were in fiscal year 2023. FDA officials said there was no specific positive or negative trend to this variability, but that mergers in the animal pharmaceutical industry were one possible reason for declines in new animal drug applications. Fewer companies submitting fewer applications in turn affects the number of drug approvals.

Nearly all drugs that FDA conditionally approved since fiscal year 2018 were for major species of companion animals (cats and dogs), and FDA conditionally approved most of them under its 2018 expanded conditional approval authority. Specifically, FDA conditionally approved five drugs for dogs, two drugs for cats, and one drug for cattle under its expanded

authority. Drugs conditionally approved under the expanded authority treat a serious or life-threatening disease or condition or address an unmet animal or human need. Demonstrating their effectiveness requires what the FD&C Act refers to as a complex or particularly difficult study or studies.[18] FDA conditionally approved two additional drugs for dogs and one drug for cattle as a minor use under its MUMS Act authority. Since fiscal year 2018, FDA has not conditionally approved any drugs for minor species.

The 11 drugs FDA has conditionally approved since fiscal year 2018 mostly treat cardiac conditions, seizures, and cancer or cancer-related conditions in companion animals, as table 3 describes.

[18]Whether a study meets the threshold for "complex" or "particularly difficult" is evaluated on a case-by-case basis, according to FDA. For example, FDA considers such factors as whether the disease occurs unpredictably or is difficult to diagnose, thus making it time-consuming or challenging to recruit adequate numbers of eligible animals.

Table 3: New Animal Drugs Conditionally Approved by FDA from Fiscal Years 2018 Through 2025

Drug name	Drug sponsor	Species	Conditionally approved use	Date of first conditional approval	Conditional approval authority	Status as of January 2026
Dectomax-CA1	Zoetis Inc.	Cattle	Preventing and treating infestations caused by New World screwworm larvae and for the prevention of reinfestation for 21 days.	September 30, 2025	Expanded[a]	Pending final demonstration of effectiveness
Felycin-CA1	TriviumVet	Cats	Managing heart disease.	March 14, 2025	Expanded	Pending final demonstration of effectiveness
UpCard-CA1	Vetoquinol USA, Inc.	Dogs	Managing fluid in the lungs in dogs with congestive heart failure.	May 10, 2024	Expanded	Pending final demonstration of effectiveness
Fidoquel-CA1	Genus Lifesciences Inc.	Dogs	Controlling epileptic seizures.	September 6, 2023	Expanded	Pending final demonstration of effectiveness
Varenzin-CA1	Elanco US, Inc.	Cats	Controlling anemia associated with chronic kidney disease.	May 1, 2023	Expanded	Pending final demonstration of effectiveness
Panoquell-CA1	Ishihara Sangyo Kaisha, Ltd.	Dogs	Managing effects of pancreatitis.	November 14, 2022	Expanded	Pending final demonstration of effectiveness
Vetmedin-CA1	Boehringer Ingelheim Animal Health USA, Inc.	Dogs	Delaying onset of congestive heart failure.	June 16, 2022	Expanded	Fully approved as a supplemental indication to Vetmedin on December 19, 2025
Canalevia-CA1	Jaguar Animal Health	Dogs	Treating chemotherapy-induced diarrhea.	December 21, 2021	Minor use[b]	Pending final demonstration of effectiveness
KBroVet-CA1	Pegasus Laboratories, Inc.	Dogs	Controlling epileptic seizures.	January 14, 2021	Expanded	Fully approved on January 9, 2026
Laverdia-CA1	Anivive Lifesciences, Inc.	Dogs	Treating canine lymphoma.	January 11, 2021	Minor use	Fully approved on December 18, 2025
Baytril 100-CA1	Elanco US, Inc.	Cattle	Treating a tick-borne blood disease.	April 2, 2020	Minor use	Sponsor requested FDA withdraw approval of the drug's application in March 2023.

Source: GAO analysis of U.S. Food and Drug Administration (FDA) data. | GAO-26-107896

Note: Appendix I provides information on the four animal drugs FDA conditionally approved from fiscal year 2004 to fiscal year 2018 under its Minor Use and Minor Species Animal Health Act of 2004 authority, which was signed into law in August 2004. These included three drugs to treat cancer-related conditions in dogs and one drug to treat bacterial infections in catfish.

[a]Animal Drug and Animal General Drug User Fee Amendments of 2018, Pub. L. No. 115-234, § 304(a)(2), 132 Stat. 2427, 2436 (codified as amended at 21 U.S.C. § 360ccc(a)(1)) (authorizing expanded conditional approval for certain animal drugs that are not covered under provisions of the Minor Use and Minor Species Animal Health Act of 2004).

[b]Minor Use and Minor Species Animal Health Act of 2004, Pub. L. No. 108-282, Title I, § 102(b)(4), 118 Stat. 891, 892-902 (codified as amended at 21 U.S.C. §§ 360ccc through 360ccc–2). FDA regulations specify the maximum number of major species animals (cats, dogs, horses, cattle, pigs, chickens, and turkeys) that are affected by a disease or condition for a drug to quality as a "minor use."

In the first quarter of fiscal year 2026, FDA conditionally approved two additional drugs. One drug was conditionally approved for treating infestations caused by New World screwworm larvae in dogs. The other was conditionally approved for preventing and treating infestations caused by New World screwworm larvae and control of cattle fever tick. Both were conditionally approved under FDA's 2018 expanded conditional approval authority (see table 4).

Table 4: New Animal Drugs Conditionally Approved by FDA in First Quarter of Fiscal Year 2026

Drug name	Drug sponsor	Species	Conditionally approved use	Date of first conditional approval	Conditional approval authority
Credilio Quattro-CA1	Elanco US, Inc.	Dogs	Treatment of infestations caused by New World screwworm larvae	December 17, 2025	Expanded[a]
Exzolt Cattle-CA1	Merck Animal Health	Cattle	Prevention and treatment of infestations by New World screwworm larvae and treatment and control of cattle fever tick	December 4, 2025	Expanded

Source: GAO analysis of U.S. Food and Drug Administration (FDA) data. | GAO-26-107896

Note: The full indication for these drugs can found in the Freedom of Information summaries: 141-619 and 141-617, respectively.

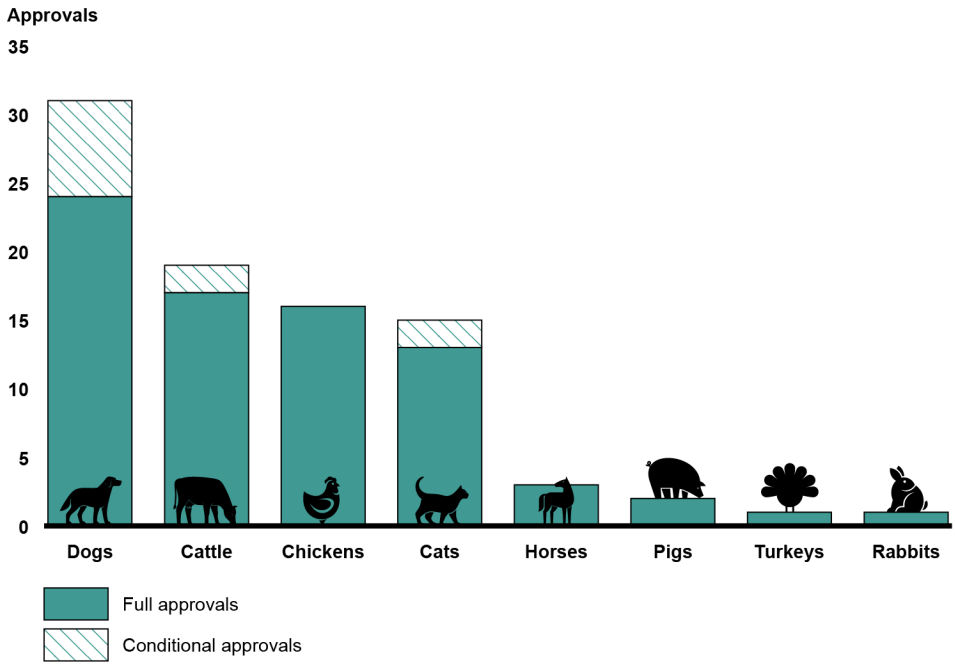
[a]Animal Drug and Animal General Drug User Fee Amendments of 2018, Pub. L. No. 115-234, § 304(a)(2), 132 Stat. 2427, 2436 (codified as amended at 21 U.S.C. § 360ccc(a)(1)) (authorizing expanded conditional approval for certain animal drugs that are not covered under provisions of the Minor Use and Minor Species Animal Health Act of 2004).

At the end of January 2026, seven of the 11 conditionally approved drugs were still conditionally approved pending their final demonstrations of effectiveness. One drug, Canalevia-CA1, will reach its 5-year deadline for demonstrating substantial evidence of effectiveness in December 2026.

While almost all of the 11 conditionally approved drugs were for major companion animal species, the nearly 80 drugs that FDA fully approved in fiscal years 2018 through 2025 were for a wider variety of major species, including chickens, pigs, and horses, and one for a minor species—rabbits (see fig. 3). However, the rabbit approval was not a therapeutic

drug for rabbits but rather was an intentional genomic alteration in rabbits.[19]

Figure 3: Number of New Animal Drugs by Species or Groups of Species and Type of FDA Approval, Fiscal Years 2018 Through 2025



Sources: GAO analysis of U.S. Food and Drug Administration (FDA) data; Nataliia/stock.adobe.com. | GAO-26-107896

Fully approved drugs also had a wider variety of uses than conditionally approved drugs. For example, fully approved drugs included products to promote weight gain in cattle, control infections in chickens, synchronize estrus cycles in dairy cows, and treat severe asthma in horses.

FDA officials told us that the agency has not requested additional staff to meet the demand of conditional approval reviews and that conditional approvals fit into their regular workload. In our review of FDA's annual performance reports and analysis of staff hour data, we did not identify any potential signs that reviewing conditional new animal drug applications negatively affected FDA's ability to review and approve other

[19]FDA approved a genetic modification that causes rabbits to produce a human protein in their milk, which researchers are using to treat bleeding disorders in humans. According to FDA documentation, under the FD&C Act, FDA regulates such modifications as new animal drugs because they are intended to affect the structure or function of the animal.

new animal drugs.[20] Since the expansion of conditional approval eligibility in 2018, FDA has consistently reported meeting its performance goals for timely drug approvals. Specifically, according to FDA's reports to Congress, the agency processed nearly 99 percent of materials related to new animal drug applications on time from fiscal years 2020 through 2024, exceeding its performance goal of 90 percent.[21]

Regulatory Requirements for Demonstrating the Effectiveness of New Animal Drugs Limit the Use of Alternative Approaches

FDA accepted sponsors' alternative approaches to demonstrating a reasonable expectation of effectiveness in eight of the 11 conditionally approved drugs from fiscal years 2018 through 2025. However, drug sponsors said that alternative approaches to conducting adequate and well-controlled studies, such as reducing sample sizes based on interim analysis, were unlikely to be sufficient for obtaining full FDA approval (see sidebar for definitions). This view is supported by FDA information showing the agency accepted alternative approaches less often for full approvals (24 of 77 drugs, or 31 percent of full approvals) compared to about 73 percent of conditional approvals.

[20]We analyzed FDA staffing data for fiscal years 2018 through 2025 and found that FDA staff spent a total of about 1.31 million hours reviewing and approving all new animal drugs. In this 8-year period, FDA spent about 3 percent of its staff hours (40,406 hours) on the 11 conditional approvals and about 97 percent (1,267,877 hours) on the remaining full approvals. Staff spent an additional 2,761 hours on conditional approvals that were in place before 2018 in this same time period and 10,467 hours on two drugs that were conditionally approved in the first quarter of fiscal year 2026.

[21]U.S. Food and Drug Administration, *Performance Report to Congress for the Animal Drug User Fee Act* (Silver Spring, MD) for fiscal years 2020 through 2024.

Reasonable Expectation of Effectiveness

This level of evidence, which is necessary for conditional FDA approval, means that the animal drug is reasonably expected to provide the intended effect when used under the conditions of use on its label.

Reasonable expectation of effectiveness may be demonstrated on the basis of pilot data in the target species or studies from published literature.

Substantial Evidence of Effectiveness

This level of evidence, which is necessary for full FDA approval, consists of one or more adequate and well-controlled studies where qualified scientific experts could fairly and reasonably evaluate the effectiveness of the new animal drug and conclude that it will have the effect it purports to have on its label.

Study designs can include randomized, placebo-controlled trials with defined clinical endpoints and large sample sizes that allow for robust statistical analysis.

Source: American Veterinary Medical Association. | GAO-26-107896

In a prior report on human drug development, we stated that developing drugs for uncommon conditions or small populations using conventional clinical investigation methods, such as randomized, placebo-controlled trials with large sample sizes, is often difficult.[22] Specifically, random assignment of patients to treatment and control groups and double-blinding are the "gold" standard for clinical trial methodology, according to FDA.[23] However, in the animal drug context, the small populations affected by uncommon conditions (some diseases affect only a few hundred animals per year) can make it impractical to conduct such trials.

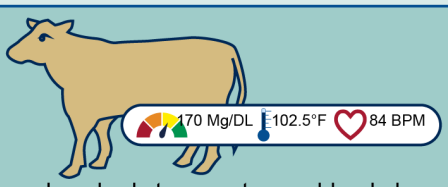
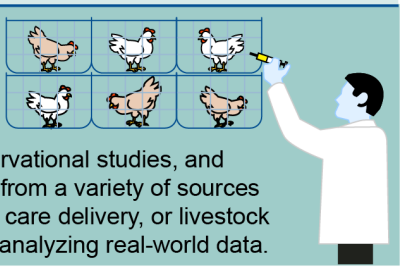
To help address these challenges, Congress directed FDA to develop guidance on how drug sponsors could use alternative approaches to demonstrate the effectiveness of new animal drugs.[24] Such approaches could be used for sponsors seeking conditional or full approval. FDA issued this guidance in 2021 (see fig. 4).

[22]GAO, *Rare Disease Drugs: FDA Has Steps Underway to Strengthen Coordination of Activities Supporting Drug Development*, GAO-25-106774 (Washington, D.C.: Nov. 18, 2024).

[23]As we have previously reported, to establish a drug's effectiveness, it is essential to distinguish the effect of the drug from other influences, including biased observations. Random assignment of trial participants to treatment and control groups and blinding are used to minimize the chance of bias by helping ensure the treatment and control groups are similar. In a double-blinded trial, neither the patients nor the investigators know who is receiving treatment. In animal drug studies using companion animals (i.e., pets), for example, blinding could include ensuring that owners (who may be responsible for observing and documenting an animal's response to a drug) are unaware of which study group their pets are in.

[24]Animal Drug and Animal Generic Drug User Fee Amendments of 2018, Pub. L. No. 115-234, § 305, 132 Stat. 2427, 2440.

Figure 4: U.S. Food and Drug Administration (FDA) Guidance on Alternative Approaches for Conducting Adequate and Well-Controlled Studies for New Animal Drug Approvals

Adaptive designs Such designs can reduce the time and cost of studies.	 Clinical effectiveness study designs that allow for prospectively planned modifications to one or more aspects of the design, such as changes to sample sizes based on interim analysis results from accumulating data from subjects in the study.
Foreign data Using foreign data can minimize the need to conduct duplicative studies.	 Data generated outside of the United States both by entities based within or outside the United States.
Biomarkers Biomarkers can help characterize response to a treatment and can be used as a surrogate endpoint.	 Defined characteristics, such as body temperature or blood glucose, measured to show health, disease, or a response to treatment.
Surrogate endpoints Surrogates are intended to predict (rather than directly measure) the biological or clinical outcome and can be used when a clinical or biological endpoint might take a very long time to study, such as in a slow progressing disease.	 Endpoints used in clinical trials that are used as a substitute for a direct measurement of a biological or clinical outcome.
Real-world evidence or real-world data These data can be used to support drug effectiveness studies in diverse animal populations.	 Evidence from ongoing surveillance activities, observational studies, and registry data. Real-world data is routinely collected from a variety of sources related to animal health and productivity, veterinary care delivery, or livestock management. Real-world evidence is derived from analyzing real-world data.

Sources: U.S. Food and Drug Administration; GAO (icons and analysis). | GAO-26-107896

As of January 2026, sponsors of the five conditionally approved drugs that used alternative study designs to show a reasonable expectation of effectiveness were in the process of completing the remaining studies to demonstrate substantial evidence of effectiveness and obtain full FDA approval. The sponsor of one drug whose 5-year deadline is in 2026 said they were uncertain whether their company would be able to complete its studies in time to receive full approval of its drug. Other sponsors of conditionally approved drugs who were working toward full approval said conducting the conventional effectiveness studies had been expensive and difficult, especially given the limited time allowed to complete them.

Sponsors also said that being able to use alternative approaches, such as real-world evidence from veterinary care delivery or livestock management, would help mitigate the expense and difficulty of the effectiveness studies needed for full approval. Given that drugs for minor species and minor uses must still demonstrate substantial evidence of effectiveness using more conventional study designs with large sample sizes, obtaining full approval for drugs to treat these small populations was practically impossible, according to one sponsor.

FDA has recognized these challenges and officials said they work with drug sponsors early in the drug development process to reach agreement on a research plan. But officials said certain methodologies that they may accept for conditional approval, such as data in a pilot study or information from published literature, would not meet full approval's standard for substantial evidence of effectiveness, which is established in statute.[25] For example, study designs to demonstrate substantial evidence of effectiveness are more likely to include randomized, placebo-controlled trials with defined clinical endpoints and sufficiently large sample sizes that allow for robust statistical analysis. Without such data, FDA officials said they have less certainty of the drug's effectiveness and less information on the risk of animals experiencing adverse events (e.g., an unwanted outcome or unexpected reaction).

However, Congress noted in the MUMS Act that because the populations may be small and conditions of animal management may vary widely, it is often difficult to design and conduct studies for minor species and minor uses to establish drug safety and effectiveness under FDA's traditional

[25]21 U.S.C. § 360b(d)(3).

new animal drug approval process. Therefore, flexible approaches to demonstrating drug effectiveness may be helpful.

FDA has also recognized the importance of facilitating the introduction of innovative processes to carry out its animal health goals. Specifically, FDA's 2016–2025 *Foods and Veterinary Medicine Program Strategic Plan's* animal health goal includes an objective of improving access to safe and effective animal drug products, including identifying and developing new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new animal drug development.[26] Additionally, the Center for Veterinary Medicine's 2023 Animal and Veterinary Innovation Agenda states that the center will examine the use of new data sources, such as real-world data, to support novel ways to meet regulatory requirements.[27]

Although FDA has established that it wants to improve access to safe and effective animal drug products and intends to use new data sources to support alternative approaches to meeting regulatory requirements, the Center for Veterinary Medicine has not developed a benefit-risk assessment that would help it to do so. A benefit-risk assessment in a regulatory context, according to FDA guidance for human drug evaluations, means making an informed judgment as to whether the benefits (with their uncertainties) of the drug outweigh the risks (with their uncertainties and approaches to managing risks) under the conditions of use described in the product labeling.[28] These case-specific determinations require a thorough assessment of safety and effectiveness evidence along with careful consideration of a complex set of other factors.[29] Even in cases where serious risks are anticipated, FDA's guidance for human drug evaluations states that there are circumstances that may still support FDA approving a drug, such as:

[26]U.S. Food and Drug Administration, *FDA Foods and Veterinary Medicine Program Strategic Plan, Fiscal Years 2016–2025*.

[27]U.S. Food and Drug Administration, Center for Veterinary Medicine, *Animal and Veterinary Innovation Agenda* (September 2023).

[28]Department of Health and Human Services, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, *Benefit-Risk Assessment for New Drug and Biological Products, Guidance for Industry* (Silver Spring, MD: October 2023).

[29]The factors include the nature and severity of the condition the drug is intended to treat or prevent, the benefits and risks of other available therapies, and any risk management tools that might be necessary to ensure that the benefits of the drug outweigh its risks.

- Demonstrating direct and meaningful benefit of the drug on the most important clinical outcomes for a serious or life-threatening disease or condition, which could include the conditions treated by certain conditionally approved drugs.
- Determining that the drug represents a specific important advantage over currently available therapies, which, for animals without approved drugs, would include showing a benefit over the extra-label (or "off label") use of drugs approved for other species, or use of unapproved drugs from compounding pharmacies.[30]
- Demonstrating that adequate measures can be implemented to mitigate risks in the post-market setting, which could include developing post-market surveillance systems to track potential problems.

Without approved therapies, veterinarians, farmers, and others face a range of animal welfare and economic consequences. For example, veterinary and other stakeholders told us that relying on the extra-label use of drugs approved for other species or indications was often expensive or impractical. Further, extra-label use is allowable in food animals only if certain conditions are met and includes restrictions that some foreign producers who export the same animal products to the U.S. do not have to follow, which puts U.S. producers at an economic disadvantage.[31]

FDA officials said they consider benefits and risks when evaluating an animal drug's safety, which they said is inseparable from determining a

[30]According to FDA, animal drug compounding is the process of combining, mixing, or altering ingredients to create a tailored medication. The FD&C Act permits compounding of animal drugs when the source of the active ingredient is a finished FDA-approved drug, and not a bulk drug substance. A "bulk drug substance" is a substance used to make a drug that becomes an active ingredient in the finished dosage form of the drug. Animal drugs compounded from bulk drug substances are not FDA-approved and have not been reviewed by FDA for evidence that they are safe, effective, properly manufactured, accurately labeled, and adequately packaged. Unlike sponsors of approved animal drugs, compounders are not required to report adverse events and product defects to FDA regarding animal drugs compounded from bulk drug substances or to demonstrate stability and other product quality measures.

[31]For example, extra-label drug use requires a veterinarian to establish an extended withdrawal period supported by scientific information in animals treated with drugs not approved for them. Animals with short lives, like lambs, would not be able to use dewormers approved for a different species, like cattle, because the time needed for the drug to reach zero detectible residues is longer than the lamb's life. Foreign producers who export lamb to the U.S., however, can use these drugs because FDA has established allowable "tolerances" for detectible levels of specific drugs in imported products.

drug's effectiveness. Officials said the agency's approach to risk assessment for safety and effectiveness evaluations for animal drugs was detailed in a draft internal policy and procedure document.[32] Such policy and procedure documents provide reference to the rules, regulations, and instructions pertinent to the Center for Veterinary Medicine's responsibilities. In contrast, a benefit-risk assessment is a broad approach that can guide decision-making during regulatory reviews. It can clarify for drug sponsors and other stakeholders how FDA factors considerations about a drug's benefits, risk, and risk management options into certain regulatory decisions. It would also provide information to sponsors on how they may present benefit and risk information in their marketing applications, and how sponsors and FDA can interact to discuss benefit-risk considerations.[33]

Incorporating such an assessment into its review process and developing related guidance, as FDA has done for human drug evaluations, could better position FDA to consider the extent to which alternative research approaches can result in adequate and well-controlled studies that demonstrate the effectiveness of animal drugs. It could also help FDA make case-specific determinations that holistically consider all relevant factors related to demonstrating substantial evidence of the effectiveness of drugs for minor species, minor uses, and for major species with unmet needs and life-threatening conditions. Further, developing related guidance for industry could increase the clarity, transparency, and consistency of FDA's benefit-risk assessments in cases where sponsors use alternative approaches. Such guidance could encourage drug sponsors to seek approval of more treatments, ultimately addressing the lack of approved animal drugs.

[32]As of January 2026, the document was in draft form and was not publicly available. FDA officials said they intend to finalize the policy and procedure document and explore options to make it publicly available, but did not have a timeline for doing so.

[33]*Benefit-Risk Assessment for New Drug and Biological Products, Guidance for Industry*. According to FDA, it developed this guidance document in accordance with the goals associated with the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 and requirements of the 21st Century Cures Act to issue guidance relating to using relevant patient experience data and related information to inform regulatory decision-making, Pub. L. No. 114-255, § 3002, 130 Stat. 1033, 1084 (2016). We did not evaluate the extent to which FDA is implementing this guidance in its human drug evaluations or gather drug sponsor views related to human drug evaluations.

Changes to Conditional Approval Needed to Overcome Drug Development Challenges

Financial Incentives and Conditional Approval's 2018 Expansion Have Had a Limited Effect on New Animal Drug Development

Many of the unmet animal health needs that existed in 2004—such as the need for approved drugs to treat parasites in sheep and goats and bacterial infections in fish—remain unmet, according to FDA officials and representatives of animal stakeholder groups we interviewed.[34] While various new therapies to treat cardiovascular and cancer-related conditions in cats and dogs have followed the MUMS Act and its 2018 expansion, there have been no conditionally approved drugs for goats, sheep, or minor species other than catfish.[35]

[34]Animal stakeholder groups also identified a need for drugs not considered "therapeutic" but that benefit animals' health and welfare. For sheep, these include drugs to synchronize breeding cycles and chemical defleecing agents, which allow for wool removal without combs or cutters. For fish, these include short-duration sedatives and spawning aids. A non-therapeutic use affects the structure or function of an animal's body, such as sedating an animal for transport, but does not treat an illness or disease. FDA regulates all new animal drugs that diagnose, cure, mitigate, treat, or prevent disease in animals or affect the structure or function of the animal's body, which encompasses drugs for both therapeutic and non-therapeutic uses.

[35]Aquaflor-CA1 was conditionally approved for the control of mortality in catfish due to columnaris disease in 2007. In 2012, FDA fully approved Aquaflor to control mortality due to columnaris disease associated with *Flavobacterium columnare* in all freshwater finfish, including catfish. As of December 2025, there were no conditionally approved drugs for fish or other minor species.

Two Conditional Approval Pathways

Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act)

- **Minor use** – drugs for use in a major species (cat, dog, cattle, horse, pig, chicken, turkey) for diseases that occur infrequently and in only a small number of animals or in limited geographic areas and only in a small number of animals annually.
- **Minor species** – all animals that are not one of the major species.

Animal Drug and Animal Generic Drug User Fee Amendments of 2018

- Major uses in major species to treat a **serious or life-threatening conditions or address an unmet animal or human health needs** where demonstrating effectiveness would require a complex or difficult study (expanded conditional approval).

Source: U.S. Food and Drug Administration. | GAO-26-107896

The MUMS Act and its 2018 expansion (see sidebar) have also had a limited effect on drugs for unmet needs in major species. For example, FDA and others have identified a need for approved drugs to treat feline infectious peritonitis (a deadly feline coronavirus); drugs to treat, prevent, and control blackhead disease (a protozoal infection affecting the liver and digestive system) in turkeys; drugs to address the root cause of laminitis (a painful and potentially life-threatening condition affecting the hoof) in horses; and drugs where establishing effectiveness via controlled studies (such as pain control drugs for livestock) is challenging.

Drug sponsors and officials from one stakeholder group we interviewed said some of the MUMS Act's incentives, such as exclusive marketing rights, were helpful for smaller companies. However, representatives from most of the eight drug sponsors and nine stakeholder groups did not find the incentives effective at overcoming the financial realities of developing drugs for small markets where sponsors expect a limited return on investment. For example:

- **Grants for safety and effectiveness testing do not overcome sponsors' overall drug development costs.** FDA reported providing $8.4 million via the Minor Use and Minor Species Grant Program to support 72 studies through November 2025.[36] However, drug sponsors and stakeholder groups said the grant funding levels were not enough to fund an entire project, the application process was tedious and difficult, and the grants included stipulations that made them less attractive. For example, one sponsor said that the amount of staff time needed to complete the application would exceed the value of the grant. FDA officials also noted that changes to the grant program in 2017 increased grantees' workloads in some cases.
- **Exclusive marketing rights are less valuable for limited-demand drugs.** While one sponsor said that market exclusivity for minor use and minor species-designated drugs was helpful, three others said that it was of limited value in part because it runs concurrently with the conditional approval period, when sales are typically lower. Additionally, one minor species association said that marketing-focused incentives were less useful when the upfront costs of developing drugs remained high.

[36]The majority of these grants were for aquatic species research. Two studies directly supported drugs to treat cancer in dogs; these drugs later received conditional approval.

Conditional Approval's Restrictions and Statutory 5-Year Limit Have Been Disincentives to New Animal Drug Development

Sponsors and stakeholder groups said that the restrictions enacted as part of the MUMS Act and later amendments—a prohibition on extra-label (or "off label") use, an exclusion of antimicrobials from the expanded conditional approval pathway, and the 5-year deadline for sponsors to obtain full FDA approval—contributed to a lack of industry interest in pursuing conditional approval. Sponsors and stakeholders said these restrictions increased costs and may discourage veterinarians from prescribing conditionally approved drugs, among other challenges.

Additionally, conditional approval's key flexibility—a reduced effectiveness standard—was also insufficient to incentivize drug sponsors to pursue this approval pathway. Instead, more than half of the sponsors reported wanting more flexibility in the Chemistry, Manufacturing, and Controls section. Sponsors said this technical section was difficult and expensive for any drug, but the limited market size for conditionally approved drugs compounded the issue of cost and return on investment for completing this section.[37]

Restrictions on extra-label use mean sponsors cannot add conditionally approved indications to fully approved drug labels. FDA has stated that the MUMS Act's prohibition on extra-label use means that conditionally approved indications (or uses) cannot be added onto the labels of fully approved drugs. In other words, drugs cannot be "dual labeled" with both fully approved and conditionally approved indications. Congress directed the agency to determine if dual labeling could be used for conditional approval.[38] However, officials said they found it difficult to reach consensus on an approach to dual labeling, since conditionally approved and fully approved drugs have to demonstrate different levels of effectiveness.

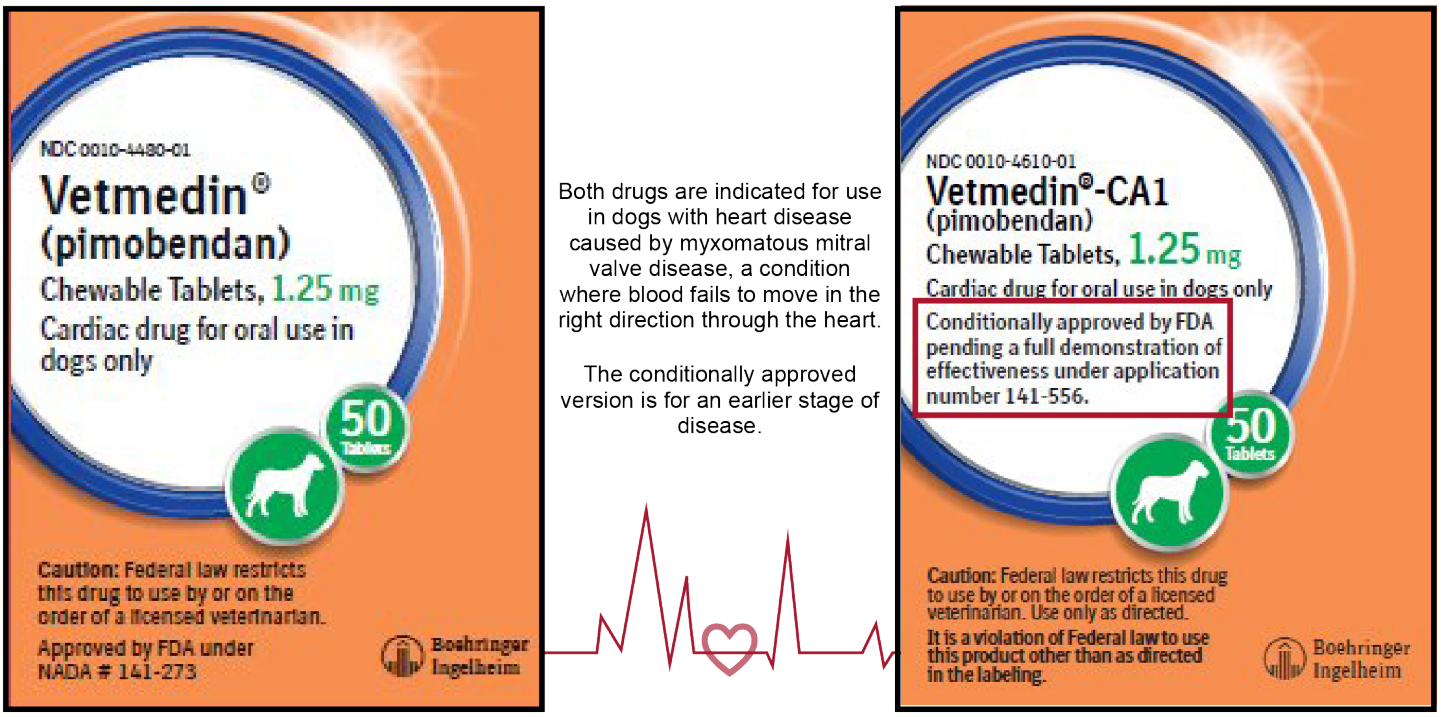
Representatives from three stakeholder groups and three drug sponsors said that FDA's prohibition on dual labeling was a disincentive. For example, one drug sponsor told us their company obtained conditional approval in 2022 to use an already-approved heart disease drug in dogs

[37]For example, one sponsor said their company considered seeking full approval of an unapproved anesthetic drug for ornamental fish that FDA allows to be sold under certain conditions. However, the sponsor could not find a manufacturer that was willing to meet the Chemistry, Manufacturing, and Controls section's manufacturing practice standards for such a limited-market drug or submit its facility to FDA inspections. The quantity of the drug being produced was too small and meeting the standards would increase the manufacturer's costs too much.

[38]Pub. L. No. 115-234 § 304(a)(3) (amending 21 U.S.C. § 360ccc(f)(2)).

to treat a different phase of the disease. Because the sponsor was prohibited from adding this conditionally approved indication to the existing label, the sponsor had to create a separate package for its conditionally approved product (see fig. 5). The sponsor said this created confusion among veterinarians and increased costs.

Figure 5: Example of an Animal Drug with an Approved and Conditionally Approved Indication



Because FDA has stated that conditionally approved indications cannot be added to existing products, sponsors must create separate products with unique labels. In this example, the drug, dose, and packaging are the same. Sponsors say this increases costs and can confuse veterinarians and pet owners.

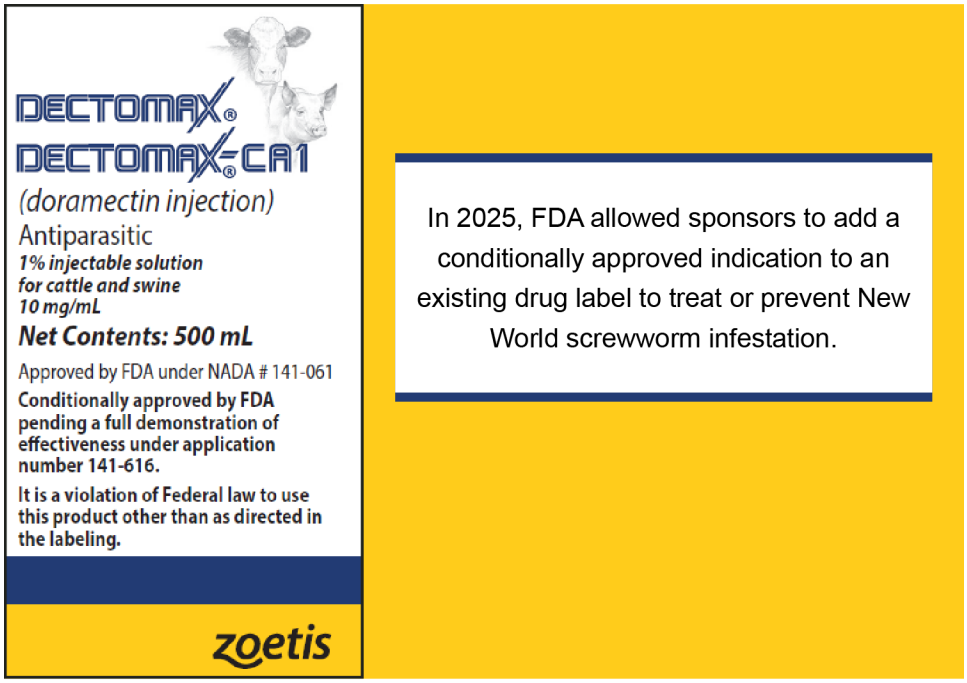
Sources: Boehringer Ingelheim Animal Health (information); National Institute of Health (photos). | GAO-26-107896

Note: On December 19, 2025, the U.S. Food and Drug Administration (FDA) fully approved Vetmedin-CA1 as a supplemental indication to Vetmedin. It is the first drug conditionally approved under FDA's expanded authority to receive full approval.

FDA officials said that a streamlined processes for adding a new indication to an existing label would be a positive improvement that would likely incentivize new drug development. Specifically, it would allow sponsors to add supplemental indications to existing labels for less cost and without the need to maintain a separate label. In October 2025, FDA issued guidance stating that it had determined that conditionally approved

uses of animal drug products used to treat or prevent New World screwworm infestations in cattle could be added to existing fully approved labels (see fig. 6).[39] FDA said in October 2025 that the agency intends to issue guidance in the future to address the conditions under which it would consider dual labeling to be permissible.

Figure 6: Example of a "Dual Labeled" Animal Drug with a U.S. Food and Drug Administration (FDA) Fully Approved and Conditionally Approved Indication



Source: GAO analysis (information) Zoetis (photo). | GAO-26-107896

Note: According to FDA, a "dual label" combines fully approved and conditionally approved indications on a single new animal drug product label and labeling. In October 2025, FDA issued guidance stating that it had determined that conditionally approved uses of animal drug products used to treat or prevent New World screwworm infestations in cattle could be added to existing fully approved labels.

The 5-year period to demonstrate substantial evidence of effectiveness for conditionally approved drugs is too short. Seven of the eight drug sponsors we spoke with said the 5-year period to legally market a conditionally approved drug while collecting evidence to obtain full approval was not long enough to overcome the drugs' limited return

[39]U.S. Food and Drug Administration, *Guidance for Industry #299, Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs with a New World Screwworm-Related Indication* (October 2025).

on investment. In fact, six drug sponsors we met with said that the statutorily defined 5-year limit on conditional approval was a disincentive. For example, some diseases progress slowly, making it difficult to gather data quickly enough to show a drug's effectiveness in 5 years, according to two sponsors. Other sponsors said that the 5-year period is closer to 4 years because sponsors have to prepare their final reports and submit them to FDA 180 days before the end of the 5-year period.

Representatives from a national veterinary association also said that the 5-year period limited the effectiveness of the conditional approval pathway. Specifically, if drug sponsors are not able to gather enough data (which could happen because they cannot enroll enough animals into their studies or results have not had enough time to appear in the data), drugs become unapproved and can no longer be marketed legally. At this point, drug compounders will enter the market and start selling an unregulated and unapproved version of the drug, since the market need still exists whether the drug has FDA approval or not. Association officials said this is not ideal for veterinarians, who would prefer to prescribe drugs with FDA approval that have demonstrated their quality and potency. Additionally, the presence of compounded drugs on the market can further disincentivize sponsors from seeking FDA approval, according to one drug sponsor. This is because the costs of obtaining FDA approval may outweigh potential returns for drugs with limited demand, whereas compounders do not incur similar approval-related costs and can get their drugs to market more quickly with lower costs.

According to a Senate report accompanying the MUMS Act, the act and the conditional approval pathway were intended to increase the availability of FDA-approved animal drugs while ensuring appropriate safeguards for animal and human health.[40] The report goes on to say that the statute's 5-year period for conditional approval sets a time frame in which the sponsor must conduct adequate and well-controlled studies to demonstrate substantial evidence of effectiveness. Conditional approval permits sponsors to sell the drug during this period to help them recoup some of their drug development costs, while the 5-year limit ensures that conditional approval remains temporary and that effectiveness data are submitted within a defined time frame. However, drug sponsors and stakeholders have said that the 5-year period is ultimately too short to

[40]S. Rep. No. 108-226, pp. 4, 14 (2004).

allow sponsors to conduct the adequate and well-controlled studies needed to meet the substantial evidence of effectiveness standard.

In contrast, USDA's Animal and Plant Health Inspection Service's Center for Veterinary Biologics has a conditional licensure pathway that includes full purity and safety evaluation, as well as a lower standard ("reasonable expectation") for efficacy, of veterinary biologics (e.g., vaccines). Yet this conditional licensure pathway does not have a statutorily imposed time limit for sponsors to demonstrate substantial evidence of effectiveness. Officials from the Center for Veterinary Biologics said that they may, in special circumstances, allow sponsors to hold a conditional license for an indefinite amount of time, with annual renewals. Officials said the center does not set firm timelines for how long a sponsor has to obtain full licensure because they want to keep the process adaptable to different situations and to balance a full product quality evaluation (that would include full efficacy and potency evaluation) with U.S. animal health needs (i.e., product availability).

As part of the Animal Drug User Fee Act reauthorization process, the FD&C Act requires FDA to identify policy recommendations and improvements.[41] FDA officials stated that in preparing such recommendations and improvements, which could include changes to incentives and restrictions, they consider input from stakeholders and sponsors and analyze effects on animal health and agency resources. FDA officials said that they are considering proposing narrowing the current exclusion of antimicrobial ingredients from the expanded conditional approval pathway to only antimicrobials of human health importance. Officials are also considering allowing for new flexibilities in the other technical sections of a new animal drug application, including in the Chemistry, Manufacturing, and Controls section.

However, any changes to the statutory 5-year limit on conditional approval would require congressional action. Considering an expansion to the statutory 5-year limit on conditional approval, and amending the statute as appropriate, could help Congress determine whether the current time frame appropriately balances multiple objectives, including increasing the availability of animal drugs to address unmet needs,

[41]21 U.S.C. § 379j-13(d). FDA officials told us that negotiations and outreach would begin in spring 2026, with industry negotiations starting in the summer and fall of 2026.

protecting animal and human health, and maintaining incentives for sponsors to develop drugs for markets with limited profitability.

Conclusions

Noting the lack of approved drugs for minor species and minor uses, in 2004 Congress introduced various drug development incentives and authorized a conditional approval pathway, which it expanded in 2018 to include drugs that address common uses in the major species. Despite some success at incentivizing new drugs for conditions affecting major species such as cats and dogs, the conditional approval pathway has been largely unsuccessful at meeting the needs of minor species and most other major species.

One challenge drug sponsors face is designing robust effectiveness studies for small populations (minor species) or uncommon conditions (minor uses) or for major species where demonstrating a drug's effectiveness is challenging (expanded conditional approval). FDA issued guidance on how drug sponsors could use alternative approaches to demonstrate a drug's effectiveness. However, FDA has not developed a benefit-risk assessment that would help it to incorporate these new data sources into its regulatory decisions. FDA said the agency's approach to risk assessment for safety and effectiveness evaluations was explained in a draft internal policy and procedure document, which provides reference to pertinent rules, regulations, and instructions. A benefit-risk assessment, on the other hand, is a broad approach that would be integrated into FDA's regulatory reviews. It would clarify for drug sponsors and other stakeholders how considerations about a drug's benefits, risk, and risk management options factor into certain regulatory decisions, among other information. Developing a benefit-risk assessment and related guidance for industry could better position FDA to consider all relevant factors related to demonstrating substantial evidence of effectiveness. Such case-specific determinations could encourage sponsors to pursue new animal drug approvals and ultimately result in greater progress addressing unmet animal health needs.

The 5-year statutory limit on how long sponsors can market their drug while conducting studies to demonstrate substantial evidence of effectiveness has limited the impact of the conditional approval pathway. Considering whether the 5-year limit on conditional approval should be expanded to support the intended balance between expanding access to animal drugs for unmet needs, safeguarding animal and human health, and encouraging sponsors to invest in drugs with limited financial returns could help inform a more effective approach.

Matter for Congressional Consideration

Congress should consider whether the statutory 5-year limit on conditional approval for animal drugs should be expanded to appropriately balance the goals of increasing drug availability to address unmet animal health needs, protecting animal and human health, and maintaining incentives for sponsors to develop drugs for markets with limited profitability, and should amend the statute as appropriate.

Recommendations for Executive Action

We are making the following two recommendations to FDA:

The Commissioner of FDA should incorporate a benefit-risk assessment into its process for evaluating whether animal drugs that use alternative study designs have demonstrated substantial evidence of effectiveness. (Recommendation 1)

The Commissioner of FDA should develop guidance for industry on its use of benefit-risk assessments in its regulatory decisions for animal drugs that demonstrate substantial evidence of effectiveness using alternative study designs. (Recommendation 2)

Agency Comments and Our Evaluation

We provided a draft of this report to the Secretary of Health and Human Services (HHS), Secretary of the Interior, and the Secretary of Agriculture for review and comment. USDA told us it had no comments on the draft report. Interior and HHS provided technical comments, which we incorporated as appropriate.

In addition to its technical comments, HHS also provided written comments, which are reproduced in Appendix III and summarized below. In its comments, HHS concurred with our recommendations. HHS noted that FDA already incorporates a benefit-risk assessment into its process for evaluating whether animal drugs that use alternative study designs and data sources have demonstrated substantial evidence of effectiveness. However, HHS agreed that FDA needs to be more transparent about how it incorporates a benefit-risk process into the evaluation of new animal drugs. HHS stated that FDA will prioritize creating a draft Guidance for Industry that describes the agency's approach to risk-based decision making by the end of 2026. Further, the agency plans to present and discuss the information in public settings, such as in meetings with industry partners, discussions with animal trade groups, and in upcoming educational conferences.

We commend FDA's proactive attention to communicating its benefit-risk assessment process and its plans to engage with animal health stakeholders. As we note in our report, it will be important for FDA to

ensure its benefit-risk assessment clarifies for drug sponsors and other stakeholders how FDA factors considerations about a drug's benefits, risk, and risk management options into its regulatory decisions. As noted in our report, FDA's benefit-risk assessment guidance should provide information to sponsors on how they may present benefit and risk information in their marketing applications and how sponsors and FDA can interact to discuss benefit-risk considerations. We continue to believe that incorporating such an assessment into its review process and developing related guidance, as FDA has done for human drug evaluations, could better position FDA to consider the extent to which alternative research approaches can result in adequate and well-controlled studies.

We are sending copies of this report to the appropriate congressional committees, the Secretary of HHS, the Secretary of the Interior, the Secretary of Agriculture and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact me at morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

//SIGNED//

Steve Morris
Director, Natural Resources and Environment

Appendix I: Animal Drugs Conditionally Approved by the U.S. Food and Drug Administration, Fiscal Years 2004 - 2025

This appendix provides summaries of each drug the U.S. Food and Drug Administration (FDA) conditionally approved in fiscal years 2004 through 2025.[1] Table 5 summarizes the four drugs FDA conditionally approved from fiscal year 2004 to 2018 under its authority provided by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act). The following pages summarize the 11 animal drugs FDA conditionally approved under its authority provided by 2018 amendments to the MUMS Act provisions of the Federal Food and Cosmetic Act (FD&C Act).[2]

Table 5: New Animal Drugs the U.S. Food and Drug Administration Conditionally Approved Under the MUMS Act in Fiscal Years 2004 to 2018

Drug name	Drug sponsor	Species	Conditionally approved use	Date of conditional approval	Status
Tanovea-CA1	VetDC, Inc. (acquired by Elanco in 2021)	Dogs	Treating canine lymphoma	December 29, 2016	Fully approved in 2021
Paccal Vet-CA1	Oasmia Pharmaceutical AB	Dogs	Treating certain mammary and squamous cell carcinomas	February 27, 2014	Withdrawn by sponsor in 2017
Kinavet-CA1	AB Science	Dogs	Treating mast cell (immune system) tumors	January 30, 2012	Conditional approval expired in 2017
Aquaflor-CA1	Schering-Plough Animal Health Corp. (acquired by Merck in 2009)	Catfish	Controlling mortality due to columnaris disease	April 13, 2007	Fully approved in 2012

Source: GAO analysis. | GAO-26-107896

Note: The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) was signed into law on August 2, 2004.

From fiscal years 2005 to 2018, FDA conditionally approved four drugs under its MUMS Act authority. From fiscal years 2018 through 2025, FDA conditionally approved another 11 drugs. Of these 15 conditionally approved drugs, FDA fully approved five (Aquaflor-CA1, Tanovea-CA1, Laverdia-CA1, Vetmedin-CA1, and KBroVet-CA1), two were withdrawn by their sponsors (Paccal Vet-CA1, Baytril 100-CA1), and one's conditional

[1]In the first quarter of fiscal year 2026, FDA conditionally approved two additional drugs. One drug, Credilio Quattro-CA1, was conditionally approved for treating infestations caused by New World screwworm larvae in dogs. The other, Exzolt Cattle-CA1, was conditionally approved for preventing and treating infestations caused by New World screwworm larvae and control of cattle fever tick. Both were conditionally approved under FDA's 2018 expanded conditional approval authority.

[2]21 U.S.C. § 360b(c)(1)(F)(ii)(III) and §§ 360ccc through 360ccc–2.

approval expired (Kinavet-CA1). Seven of these 15 drugs were pending full approval as of January 31, 2026.

The conditional approval pathway is available to a new animal drug for a

- major use in a major species to treat a serious or life-threatening conditions or address unmet animal or human health needs, and where demonstrating effectiveness would require the sponsor to undertake a complex or particularly difficult study or studies (also referred to as “expanded conditional approval”), and
- minor use (in a major species) or use in minor species.[3]

According to FDA guidance, for a drug to be eligible for expanded conditional approval, the sponsor must show, for example, that the disease or condition has substantial impact on day-to-day functioning or is associated with mortality; is zoonotic (caused by infections that may spread to people); or is widespread in food-producing animals and presents a risk to food production.

Alternatively, the guidance indicates that the sponsor must show that existing therapies do not adequately address the condition or disease’s treatment, control, or prevention. For all such drugs, FDA must determine that demonstrating the drug’s effectiveness would require a complex or difficult study, according to agency guidance. For example, FDA could determine that it would be unusually time consuming or difficult for the sponsor to enroll a sufficient number of animals to demonstrate substantial evidence of the drug’s effectiveness.

Antimicrobial drugs or drugs that are contained in or the product of transgenic animals (animals whose genomes have been intentionally modified in vitro, and their progeny) are not eligible for expanded conditional approval.

[3]FDA defines minor uses as those that occur in fewer major species animals per year than the following (i.e., a small number): 150,000 cats; 80,000 dogs; 50,000 horses; 310,000 cattle; 1,450,000 pigs; 72,000,000 chickens; and 14,000,000 turkeys. All other species, including insects and aquatic species, are minor species.

Source: Clara/stock.adobe.com. | GAO-26-107896

Dectomax-CA1 (doramectin injection)

FDA conditionally approved DECTOMAX-CA1 in September 2025 for the prevention and treatment of larval infestations of New World screwworm flies and for the prevention of reinfestation for 21 days in cattle. Screwworm larvae infest the deepest layers of living tissue, such as the skin and body cavities, and cause severe lesions and death. DECTOMAX is already fully approved for treatment and control of certain parasites in cattle and swine.

DRUG INFORMATION

Drug sponsor: Zoetis Inc.

Species addressed: Cattle

Conditional approval date: September 30, 2025

Final conditional approval expiration date: September 30, 2030, pending annual renewals

Current status: Pending a full demonstration of effectiveness

Drug indication: Prevention and treatment of infestations caused by larvae of New World screwworm flies and the prevention of reinfestation for 21 days. See the Freedom of Information Act Summary for application 141-616 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The reasonable expectation of effectiveness for the drug is based on the results of 18 study summaries provided by the sponsor. These studies were conducted in various South American countries from 1990 to 1999 and included induced and natural infestations in a variety of cattle ages, breeds, and sex.

CONDITIONAL APPROVAL SUMMARY

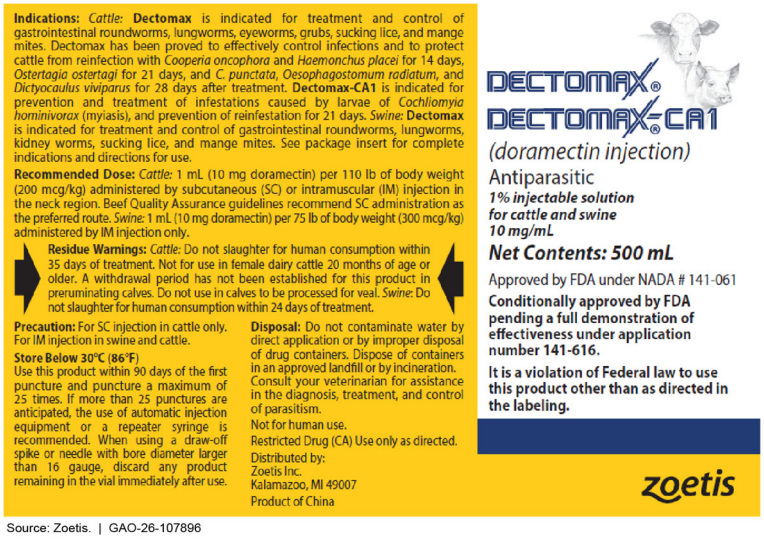
FDA determined Dectomax-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. The tissue damage caused by New World screwworm fly larva in cattle can be serious and is often deadly to the animal. Therefore, Dectomax-CA1 addresses a serious or life-threatening disease or condition.

Addresses an unmet animal health need. The prevention and treatment of New World screwworm fly larva infestations is an unmet animal health need because there is no approved animal drug in the United States for this use in cattle.

Demonstrating effectiveness requires a complex or difficult study. A demonstration of effectiveness requires a complex or difficult study design because the New World screwworm fly has been eradicated in the United States, making it impossible to conduct studies in the United States using naturally infested animals to provide substantial evidence of effectiveness. Additionally, there are significant animal welfare concerns when considering whether to conduct studies with this parasite.

Drug Label for DECTOMAX-CA1



Indications: *Cattle:* **Dectomax** is indicated for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. Dectomax has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment. **Dectomax-CA1** is indicated for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days. *Swine:* **Dectomax** is indicated for treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites. See package insert for complete indications and directions for use.

Recommended Dose: *Cattle:* 1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg) administered by subcutaneous (SC) or intramuscular (IM) injection in the neck region. Beef Quality Assurance guidelines recommend SC administration as the preferred route. *Swine:* 1 mL (10 mg doramectin) per 75 lb of body weight (300 mcg/kg) administered by IM injection only.

Residue Warnings: *Cattle:* Do not slaughter for human consumption within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. *Swine:* Do not slaughter for human consumption within 24 days of treatment.

Precaution: For SC injection in cattle only. For IM injection in swine and cattle.

Store Below 30°C (86°F)
Use this product within 90 days of the first puncture and puncture a maximum of 25 times. If more than 25 punctures are anticipated, the use of automatic injection equipment or a repeater syringe is recommended. When using a draw-off spike or needle with bore diameter larger than 16 gauge, discard any product remaining in the vial immediately after use.

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Not for human use.

Restricted Drug (CA) Use only as directed.

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007
Product of China

DECTOMAX®
DECTOMAX®-CA1
(doramectin injection)
Antiparasitic
1% injectable solution for cattle and swine 10 mg/mL
Net Contents: 500 mL
Approved by FDA under NADA # 141-061
Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-616.
It is a violation of Federal law to use this product other than as directed in the labeling.

zoetis

Source: Zoetis. | GAO-26-107896

Source: GAO. | GAO-26-107896

Felycin-CA1 (sirolimus delayed-release tablets)

FDA conditionally approved Felycin-CA1 in March 2025 to manage hypertrophic cardiomyopathy (a type of heart disease) in cats. Hypertrophic cardiomyopathy is the most common heart disease in cats and is one of the most common causes of death in cats.

DRUG INFORMATION

Drug sponsor: TriviumVet

Species addressed: Cats

Conditional approval date: March 14, 2025

Final conditional approval expiration date: March 14, 2030, pending annual renewals

Current status: Pending a full demonstration of effectiveness

Drug indication: Management of ventricular hypertrophy in cats with subclinical hypertrophic cardiomyopathy (when there is a thickening of the heart wall with no other sign of clinical symptoms of the disease). See the Freedom of Information Act Summary for application 141-604 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor used a review of published scientific literature and the results from a pilot field study to demonstrate a reasonable expectation of effectiveness. The studies described the use of the drug in lab mice and in human cardiac transplant recipients. The sponsor also conducted a pilot field study to evaluate the safety and effectiveness of Felycin-CA1 in client-owned cats with subclinical hypertrophic cardiomyopathy.

CONDITIONAL APPROVAL SUMMARY

FDA determined Felycin-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. Subclinical hypertrophic cardiomyopathy often progresses to clinical hypertrophic cardiomyopathy, which is associated with mortality and morbidity that has substantial impact on day-to-day functioning in cats. Cats may live for years in the subclinical phase (i.e., the phase where symptoms of a disease are not apparent), while others may progress to congestive heart failure or other serious conditions.

Addresses an unmet animal health need. There are no approved animal drugs currently marketed in the United States for this use in cats.

Demonstrating effectiveness requires a complex or difficult study. The demonstration of effectiveness requires a complex or difficult study because the nature of subclinical hypertrophic cardiomyopathy makes it unusually time-consuming and difficult to enroll sufficient numbers of eligible cats and requires the use of advanced diagnostic tests. Specifically, the diagnostic tests were advanced because cats were tested for a diagnosis of a variety of other cardiac diseases to be eligible for the effectiveness study.

Drug Label for Felycin-CA1

Source: TriviumVet. | GAO-26-107896

Source: Pixel-Shot/stock.adobe.com. | GAO-26-107896

UpCard-CA1 (torsemide oral solution)

FDA conditionally approved UpCard-CA1 in May 2024 to help manage a condition in which excess fluid builds up in the lungs of dogs with congestive heart failure caused by a heart valve disease. When left untreated, this disease is fatal to dogs.

DRUG INFORMATION

Drug sponsor: Vetoquinol USA, Inc.

Species addressed: Dogs

Conditional approval date: May 10, 2024

Final conditional approval expiration date: May 10, 2029, pending annual renewals

Current status: Pending a full demonstration of effectiveness

Drug indication: Management of pulmonary edema (fluid accumulation in the lungs) in dogs with congestive heart failure caused by myxomatous mitral valve disease, a condition in which the heart valve does not close completely. See the Freedom of Information Act Summary for application 141-577 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor conducted a 3-year, multi-site field study across veterinary clinics in France, Spain, and Germany. This study evaluated the effectiveness and safety of different drug dosages in 251 client-owned dogs with varying levels of heart failure severity.

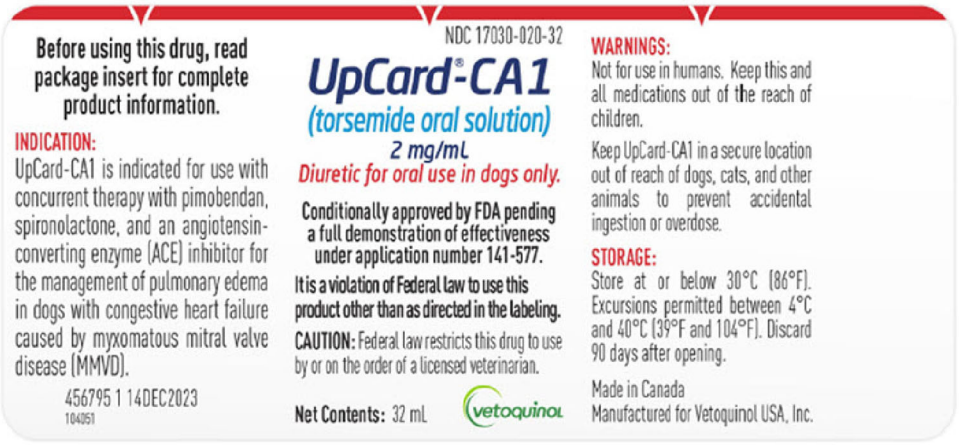
CONDITIONAL APPROVAL SUMMARY

FDA determined UpCard-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. Pulmonary edema in dogs with congestive heart failure caused by myxomatous mitral valve disease is considered a serious and life-threatening disease because, when left untreated, this disease is fatal to dogs. It most frequently occurs in smaller breed dogs, including Cavalier King Charles Spaniels, Yorkshire terriers, and dachshunds.

Demonstrating effectiveness requires a complex or difficult study. A demonstration of effectiveness requires a complex or difficult study design because the nature of the disease makes it time consuming and difficult to enroll sufficient numbers of eligible animals. Additionally, diagnosis of the disease requires the use of advanced and complicated tests.

Drug Label for UpCard-CA1



Source: Vetoquinol USA, Inc. | GAO-26-107896

Source: GAO. | GAO-26-107896

Fidoquel-CA1 (phenobarbital tablets)

FDA conditionally approved Fidoquel-CA1 in September 2023 for the control of seizures associated with idiopathic epilepsy (epilepsy of unknown cause) in dogs. Idiopathic epilepsy is a condition that affects approximately 5 percent of dogs, according to FDA. Fidoquel-CA1 is the second drug to receive FDA approval for the control of seizures in dogs with idiopathic epilepsy. The agency also conditionally approved KBroVet-CA1 for the same condition in 2021.

DRUG INFORMATION

Drug sponsor: Genus Lifesciences, Inc.

Species addressed: Dogs

Conditional approval date: September 6, 2023

Conditional approval expiration date: September 6, 2028, pending annual renewals

Current status: Pending a full demonstration of effectiveness

Drug indication: Control of seizures associated with idiopathic epilepsy in dogs. See the Freedom of Information Act Summary for application 141-578 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor used published literature to demonstrate that Fidoquel-CA1 at the conditionally approved dose has a reasonable expectation of effectiveness for controlling seizures associated with idiopathic epilepsy in dogs. The supportive publications included two clinical consensus statements on seizure management in dogs and six published clinical studies.

CONDITIONAL APPROVAL SUMMARY

FDA determined Fidoquel-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. Idiopathic epilepsy in dogs is a disease associated with morbidity that has substantial impact on day-to-day functioning. Idiopathic epilepsy is a type of seizure disorder without a known cause and is a serious or life-threatening condition that affects approximately 5 percent of dogs.

Addresses an unmet animal health need. FDA also determined the control of idiopathic epilepsy in dogs was an unmet animal health need because there is no drug fully approved in the United States for this use in dogs.

Demonstrating effectiveness requires a complex or difficult study. The demonstration of effectiveness requires a complex or difficult study because of the unpredictability of the occurrence or outcome of the disease and the need for use of advanced or complicated tests to diagnose idiopathic epilepsy.

Drug Label for Fidoquel-CA1

Source: Genus Lifesciences Inc. | GAO-26-107896

Note: Fidoquel-CA1 is prescribed at varying dosages.

Source: GAO. | GAO-26-107896

Varenzin-CA1 (molidustat oral suspension)

FDA conditionally approved Varenzin-CA1 in May 2023 for the control of nonregenerative anemia associated with chronic kidney disease in cats. Nonregenerative anemia can be a fatal condition because the cat's bone marrow is not able to produce enough red blood cells to replace the older or damaged red blood cells that are naturally removed from the blood, resulting in the inability for oxygen to be carried from the lungs throughout the body.

DRUG INFORMATION

Drug sponsor: Elanco US, Inc.

Species addressed: Cats

Conditional approval date: May 1, 2023

Final conditional approval expiration date: May 1, 2028, pending annual renewals

Current status: Pending a full demonstration of effectiveness

Drug indication: Control of nonregenerative anemia associated with chronic kidney disease in cats. See the Freedom of Information Act Summary for application 141-571 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor conducted a two-phase exploratory field study over 1 year in U.S. and European locations to evaluate the safety and effectiveness of Varenzin-CA1 in 23 client-owned cats with nonregenerative anemia associated with chronic kidney disease. The first phase was a multi-center, double-masked, randomized, placebo-controlled field effectiveness and safety study. The second phase included eight cats, all of which received the drug. Enrolled cats included both sexes, ranged in age from 4 to 17 years, and were a variety of weights and breeds.

CONDITIONAL APPROVAL SUMMARY

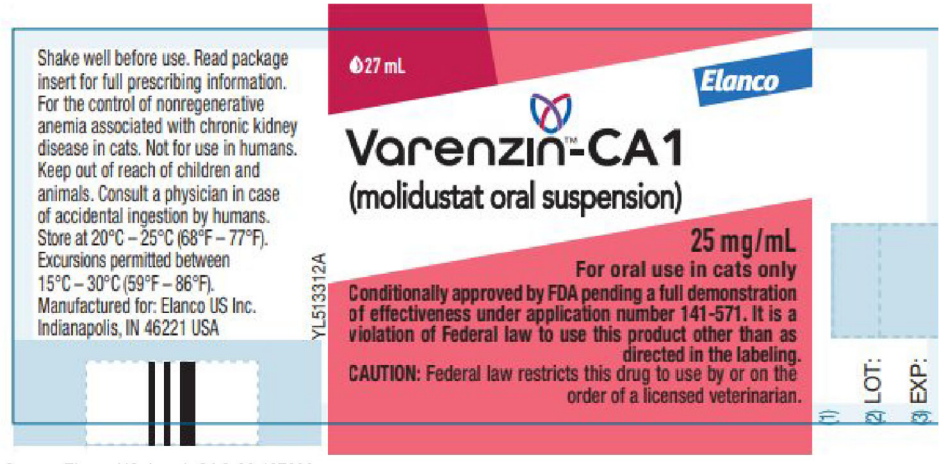
FDA determined Varenzin-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. Nonregenerative anemia associated with chronic kidney disease is a disease or condition associated with mortality and morbidity that has substantial impact on the day-to-day functioning in cats. Chronic kidney disease requires day-to-day management in cats, and nonregenerative anemia is a complication that often contributes to death or euthanasia of affected cats due to poor quality of life. Cats can develop chronic kidney disease at any age, but it is frequently diagnosed in older cats.

Addresses an unmet animal health need. The control of nonregenerative anemia associated with chronic kidney disease in cats is an unmet animal health need because there are no approved animal drugs currently marketed in the United States for this use in cats.

Demonstrating effectiveness requires a complex or difficult study. The demonstration of effectiveness requires a complex or difficult study because of the long study duration needed to determine effectiveness for this use.

Drug Label for Varenzin-CA1



Source: Elanco US, Inc. | GAO-26-107896

Source: GAO. | GAO-26-107896

Panoquell-CA1 (fuzapladib sodium for injection)

FDA conditionally approved Panoquell-CA1 in November 2022 for the management of acute onset of pancreatitis in dogs. Acute onset of pancreatitis is the sudden and temporary inflammation of the pancreas. Acute onset of pancreatitis may take a mild, swelling form or a more severe, hemorrhagic (bleeding from within or around the pancreas) form.

DRUG INFORMATION

Drug sponsor: Ishihara Sangyo Kaisha, Ltd.

Species addressed: Dogs

Conditional approval date: November 14, 2022

Final conditional approval expiration date: November 14, 2027, pending annual renewals

Current status: Pending a full demonstration of effectiveness

Drug indication: Management of clinical signs associated with acute onset of pancreatitis in dogs. See the Freedom of Information Act Summary for application 141-567 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor conducted a 2-year pilot field study in 61 client-owned dogs diagnosed with acute onset of pancreatitis. The study was randomized, blinded, and placebo-controlled. Enrolled dogs were of both sexes with a range of ages, weights, and breeds.

CONDITIONAL APPROVAL SUMMARY

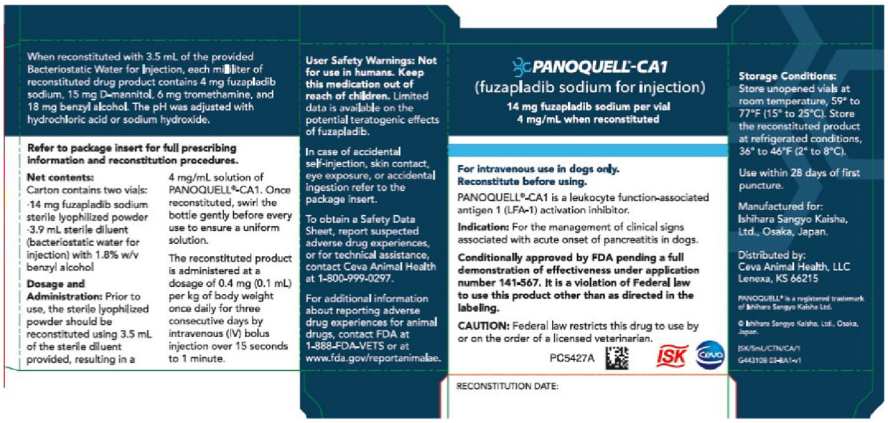
FDA determined Panoquell-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. The condition, acute onset of pancreatitis in dogs, is a disease or condition associated with mortality and morbidity that has substantial impact on day-to-day functioning. Previously, this condition could only be managed through supportive care, such as intravenous fluids, pain medication, anti-emetics, and diet changes.

Addresses an unmet animal health need. The management of clinical signs associated with acute onset of pancreatitis in dogs was also determined to be an unmet animal health need because there are no approved drugs in the United States for this use in dogs.

Demonstrating effectiveness requires a complex or difficult study. The demonstration of effectiveness requires a complex or difficult study because of the difficulty in diagnosing the disease.

Drug Label for Panoquell-CA1



Source: Ishihara Sangyo Kaisha, Ltd. | GAO-26-107896

Source: Pixel-Shot/stock.adobe.com. | GAO-26-107896

Vetmedin-CA1 (pimobendan chewable tablets)

FDA conditionally approved Vetmedin-CA1 in June 2022 for delaying the onset of congestive heart failure in dogs with preclinical myxomatous mitral valve disease, a condition in dogs where an abnormal heart valve allows blood to leak backward, impacting the ability of the heart to pump blood and resulting in an enlarged heart, or cardiomegaly. If left untreated, this condition may lead to heart failure and fluid accumulation in the lungs.

DRUG INFORMATION

Drug sponsor: Boehringer Ingelheim Animal Health USA, Inc.

Species addressed: Dogs

Conditional approval date: June 16, 2022

Current status: Fully approved on December 19, 2025

Drug indication: Delay of onset of congestive heart failure in dogs with early (B2) stage of preclinical myxomatous mitral valve disease. See the Freedom of Information Act Summary for application 141-273 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor conducted a long-term (6-year), multi-center field study including the U.S., United Kingdom, and Europe in 363 client-owned dogs. Dogs were randomized in a 1:1 ratio to receive the drug or a control. Reasonable expectation of effectiveness was based on the length of time from the first treatment to when the dog developed left-sided congestive heart failure or died or was euthanized due to cardiac disease.

CONDITIONAL APPROVAL SUMMARY

FDA determined Vetmedin-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. Congestive heart failure in dogs is a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Therefore, the conditionally approved use addresses a serious or life-threatening disease or condition.

Addresses an unmet animal health need. The delay in onset of congestive heart failure in dogs with preclinical myxomatous mitral valve disease was also determined to be an unmet health need because there are no approved animal drugs currently being marketed in the United States for this use in dogs.

Demonstrating effectiveness requires a complex or difficult study. The demonstration of effectiveness requires a complex or difficult study because of the need for a long study duration to establish effectiveness.

Drug Label for Vetmedin-CA1

Source: Boehringer Ingelheim Animal Health USA, Inc. | GAO-26-107896

Source: GAO. | GAO-26-107896

Canalevia-CA1 (crofelemer delayed-release tablets)

FDA conditionally approved Canalevia-CA1 in December 2021 to treat chemotherapy-induced diarrhea in dogs. Diarrhea is a common side effect of chemotherapy in dogs, which can be so severe that cancer treatment must be halted.

DRUG INFORMATION

Drug sponsor: Jaguar Animal Health

Species addressed: Dogs

Conditional approval date: December 21, 2021

Final conditional approval expiration date: December 21, 2026

Current status: Pending a full demonstration of effectiveness

Drug indication: Treatment of chemotherapy-induced diarrhea in dogs. See the Freedom of Information Act Summary for application 141-552 for the full indication.

FDA authority for conditional approval: MUMS Act

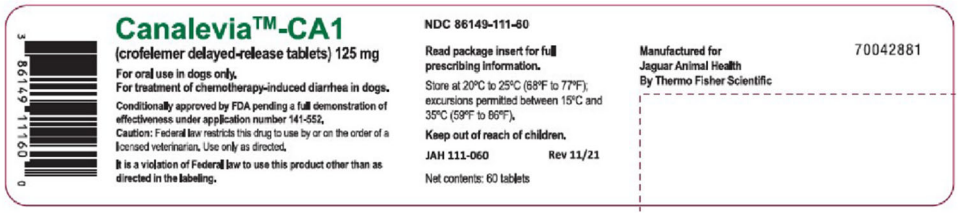
CONDITIONAL APPROVAL SUMMARY

Based on a minor use assessment, FDA estimated the rate of occurrence of chemotherapy-induced diarrhea in dogs in the United States to be below FDA's regulatory threshold of a "small number" of dogs on an annual basis, as defined above. Therefore, the use of Canalevia-CA1 for the treatment of chemotherapy-induced diarrhea in dogs in the U.S. was eligible for conditional approval as a minor use in a major species.

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor conducted an approximately 2-year pilot clinical field effectiveness study in 61 shelter-housed and client-owned dogs with general acute (not chemotherapy-induced) diarrhea. The study was multi-center, randomized, masked, and controlled. The effectiveness analysis included 24 dogs (12 treated and 12 control). Enrolled dogs were between 2 months and 12 years of age with fecal scores of 4 (watery, liquid stool with little particulate matter visible) or 5 (severe watery stool with no particulate matter visible).

Drug Label for Canalevia-CA1



Source: Jaguar Animal Health. | GAO-26-107896

Source: GAO. | GAO-26-107896

KBroVet-CA1 (potassium bromide chewable tablets)

FDA conditionally approved KBroVet–CA1 for the control of seizures associated with idiopathic epilepsy (epilepsy of unknown cause) in dogs. It works by providing a consistent and reliable source of potassium bromide, an anticonvulsant.

DRUG INFORMATION

Drug sponsor: Pegasus Laboratories, Inc.

Species addressed: Dogs

Conditional approval date: January 14, 2021

Current status: Fully approved on January 9, 2026

Drug indication: Control of seizures associated with idiopathic epilepsy in dogs. See the Freedom of Information Act Summary for application 141-615 for the full indication.

FDA authority for conditional approval: Expanded Conditional Approval

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor retrospectively evaluated the medical records of client-owned dogs that were previously treated with potassium bromide to control their idiopathic epilepsy. To be included in the study, the dogs must have received the same total daily dose of potassium bromide for at least 60 days and received only potassium bromide to control their seizures. The sponsor reviewed 189 cases spanning a 5-year period and determined that 27 were valid for establishing effectiveness and safety.

CONDITIONAL APPROVAL SUMMARY

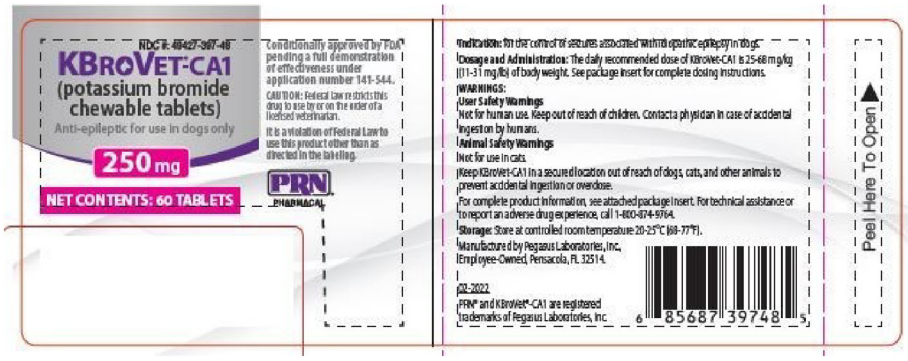
FDA determined KBroVet-CA1 to be eligible for expanded conditional approval because it controls a serious or life-threatening disease or condition or addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies.

Addresses a serious or life-threatening disease or condition. The condition, idiopathic epilepsy in dogs, is a disease or condition associated with morbidity that has substantial impact on day-to-day functioning in dogs. Idiopathic epilepsy is a type of seizure disorder without a known cause and is a serious or life-threatening condition that affects approximately 5 percent of dogs, according to FDA.

Addresses an unmet animal health need. The control of idiopathic epilepsy in dogs was also determined to be an unmet animal health need because, at the time, there were no approved drugs being marketed in the United States for this use in dogs.

Demonstrating effectiveness requires a complex or difficult study. Based on the unpredictability of the occurrence or outcome of the disease or condition, and the need for use of advanced or complicated tests to diagnose idiopathic epilepsy, FDA determined that the demonstration of effectiveness required a complex or particularly difficult study or studies.

Drug Label for KBroVet-CA1



Source: Pegasus Laboratories, Inc. | GAO-26-107896

Source: GAO. | GAO-26-107896

Laverdia-CA1 (verdinexor tablets)

FDA conditionally approved Laverdia-CA1 in January 2021 to treat dogs with lymphoma. Laverdia-CA1 prevents certain proteins from leaving the nucleus of cancer cells, thereby allowing these proteins to control the growth and prevent the spread of cancerous cells in dogs.

DRUG INFORMATION

Drug sponsor: Anivive Lifesciences, Inc.

Species addressed: Dogs

Conditional approval date: January 11, 2021

Current status: Fully approved on December 18, 2025

Drug indication: Treatment of lymphoma in dogs. See the Freedom of Information Act Summary for application 141-614 for the full indication.

FDA authority for conditional approval: MUMS Act

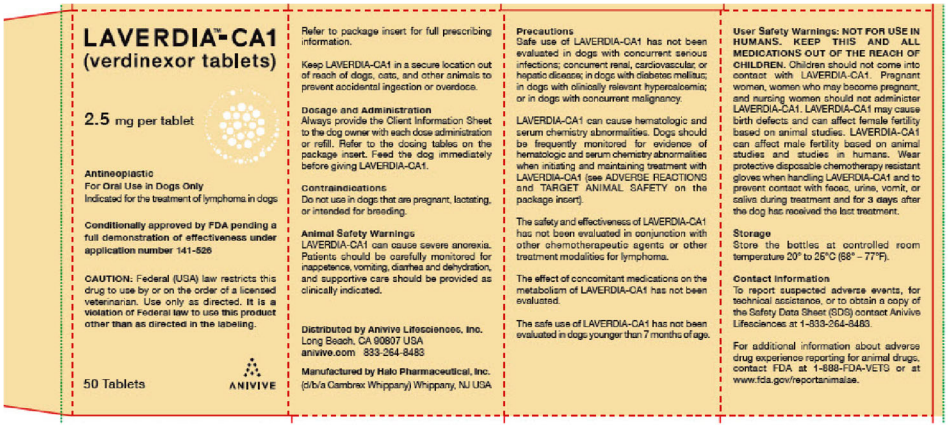
CONDITIONAL APPROVAL SUMMARY

Based on a minor use assessment, FDA estimated the rate of occurrence of lymphoma in dogs in the United States to be below FDA's regulatory threshold of a "small number" on an annual basis, as defined above. Therefore, the use of Laverdia-CA1 for the treatment of lymphoma in dogs in the United States is eligible for conditional approval as a minor use.

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

The sponsor conducted a 1-year field effectiveness study in 58 client-owned dogs with lymphoma. Dogs were either newly diagnosed with lymphoma or in their first relapse after completing a chemotherapy regimen. The study included dogs of varying breeds, weights, and sexes. A majority of the dogs had lymphoma stage III, which is an advanced but curable form of cancer.

Drug Label for Laverdia-CA1



LAVERDIA™-CA1
(verdinexor tablets)

2.5 mg per tablet

Antineoplastic
For Oral Use in Dogs Only
Indicated for the treatment of lymphoma in dogs

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-526

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. It is a violation of Federal law to use this product other than as directed in the labeling.

50 Tablets

ANIVIVE

Refer to package insert for full prescribing information.

Keep LAVERDIA-CA1 in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Dosage and Administration
Always provide the Client Information Sheet to the dog owner with each dose administration or refill. Refer to the dosing tables on the package insert. Feed the dog immediately before giving LAVERDIA-CA1.

Contraindications
Do not use in dogs that are pregnant, lactating, or intended for breeding.

Animal Safety Warnings
LAVERDIA-CA1 can cause severe anorexia. Patients should be carefully monitored for inappetence, vomiting, diarrhea and dehydration, and supportive care should be provided as clinically indicated.

Distributed by Anivive Lifesciences, Inc.
Long Beach, CA 90807 USA
anivive.com 833-264-8483

Manufactured by Halo Pharmaceutical, Inc.
(d/b/a Cambrex Whippany) Whippany, NJ USA

Precautions
Safe use of LAVERDIA-CA1 has not been evaluated in dogs with concurrent serious infections; concurrent renal, cardiovascular, or hepatic disease; in dogs with diabetes mellitus; in dogs with clinically relevant hypercalcemia; or in dogs with concurrent malignancy.

LAVERDIA-CA1 can cause hematologic and serum chemistry abnormalities. Dogs should be frequently monitored for evidence of hematologic and serum chemistry abnormalities when initiating and maintaining treatment with LAVERDIA-CA1 (see ADVERSE REACTIONS and TARGET ANIMAL SAFETY on the package insert).

The safety and effectiveness of LAVERDIA-CA1 has not been evaluated in conjunction with other chemotherapeutic agents or other treatment modalities for lymphoma.

The effect of concomitant medications on the metabolism of LAVERDIA-CA1 has not been evaluated.

The safe use of LAVERDIA-CA1 has not been evaluated in dogs younger than 7 months of age.

User Safety Warnings: NOT FOR USE IN HUMANS. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. Children should not come into contact with LAVERDIA-CA1. Pregnant women, women who may become pregnant, and nursing women should not administer LAVERDIA-CA1. LAVERDIA-CA1 may cause birth defects and can affect female fertility based on animal studies. LAVERDIA-CA1 can affect male fertility based on animal studies and studies in humans. Wear protective disposable chemotherapy resistant gloves when handling LAVERDIA-CA1 and to prevent contact with feces, urine, vomit, or saliva during treatment and for 3 days after the dog has received the last treatment.

Storage
Store the bottles at controlled room temperature 20° to 25°C (68° – 77°F).

Contact Information
To report suspected adverse events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS) contact Anivive Lifesciences at 1-833-264-8483.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or at www.fda.gov/reportanimalae.

Source: Anivive Lifesciences, Inc. | GAO-26-107896

Source: Clara/stock.adobe.com. | GAO-26-107896

Baytril 100 CA-1 (enrofloxacin)

FDA conditionally approved Baytril 100-CA1 in April 2020 for the treatment of clinical anaplasmosis, a disease caused by a bacteria transmitted by the bite of an infected tick, in cattle.

DRUG INFORMATION

Drug sponsor: Elanco US, Inc.

Species addressed: Cattle

Conditional approval date: April 2, 2020

Current status: Withdrawn by sponsor

Drug indication: Treatment of clinical anaplasmosis associated with *Anaplasma marginale*, a bacterium that affects blood cells. See the Freedom of Information Act Summary for application 141-527 for the full indication.

FDA authority for conditional approval: MUMS Act

REASONABLE EXPECTATION OF EFFECTIVENESS STUDY SUMMARY

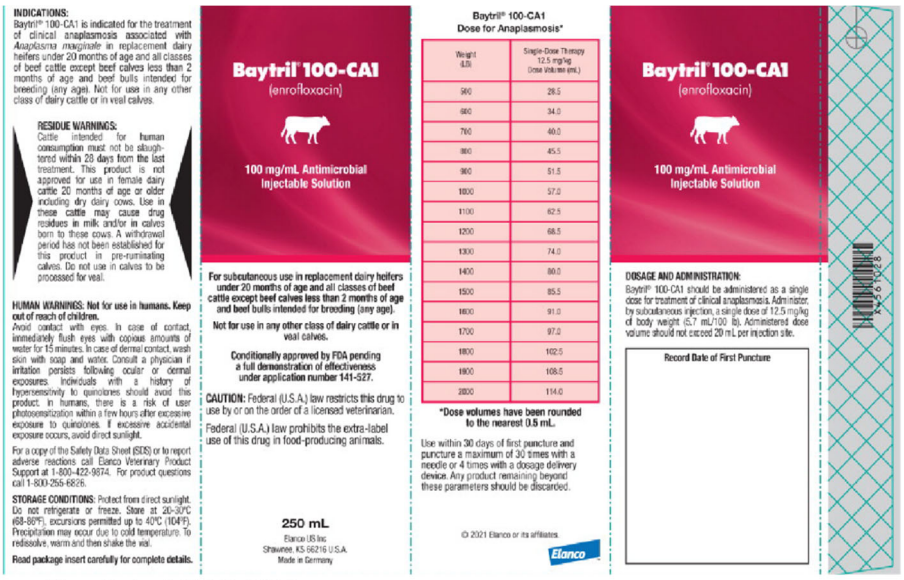
The sponsor used a combination of published literature and reports from studies the sponsor conducted to demonstrate reasonable expectation of effectiveness for using Baytril 100-CA1 to treat clinical anaplasmosis in cattle. This information evaluated effectiveness across a variety of study designs, including differences in dose, frequency, duration, and route of administration; animal class and age; infection method; and product formulation.

CONDITIONAL APPROVAL SUMMARY

Based on a minor use assessment, FDA estimated the number of cattle with clinical anaplasmosis on an annual basis is lower than FDA's regulatory threshold of a "small number" of cattle, as defined above. Therefore, the use of Baytril 100-CA1 for the treatment of clinical anaplasmosis in cattle in the United States is eligible for conditional approval as a minor use.

According to Elanco US, Inc. officials, the company was not able to enroll enough animals in its study to demonstrate substantial evidence of effectiveness at the level FDA required within the 5-year approval window. Accordingly, Elanco US Inc. withdrew its application in March 2023 and the product is no longer marketed for the conditionally approved indication.

Drug Label for Baytril 100-CA1



Source: Elanco US, Inc. | GAO-26-107896

Appendix II: Examples of Research Funded by U.S. Food and Drug Administration's Animal and Veterinary Innovation Centers

In 2024, the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine established Animal and Veterinary Innovation Centers as part of its ongoing commitment to encourage development of innovative products to better support animal health and veterinary interventions. These Animal and Veterinary Innovation Centers are to further the principles outlined in the FDA's *Animal and Veterinary Innovation Agenda*, which communicates the agency's plans to address critical unmet needs affecting animal and human health.[1]

According to FDA, it will partner with academic research institutions to drive research in the priority area of developing products for minor uses (i.e., uncommon conditions) in major species (cats, dogs, horses, cattle, pigs, chickens, and turkeys), minor species (all other species), and unmet veterinary medical needs in major species that create a significant animal or public health burden.[2] Funding may be renewed for up to 4 additional years pending suitable progress and availability of funds.

FDA officials and university researchers are conducting foundational research in these areas of unmet need so that sponsors (e.g., drug companies) may use the information to inform their drug development efforts. Specifically, many animal health needs are unmet because of the limited return on investment to drugs for minor species, minor uses, or complex challenges. By taking on some of the research costs, FDA seeks to enable sponsors to leverage the information into future new drug applications.

This appendix summarizes information about the research conducted at the two Animal and Veterinary Innovation Centers FDA established to support the priority area of developing products for minor uses or minor species and addressing unmet veterinary medical needs. The center at the University of Arkansas is seeking to understand the transmission and prevention of a deadly turkey disease. The center at Kansas State University is developing a validated model to evaluate the effectiveness of pain medications in livestock.

[1]U.S. Food and Drug Administration, Center for Veterinary Medicine, *Animal and Veterinary Innovation Agenda* (Sept. 2023).

[2]FDA also established centers to address two other priority areas: (1) emerging animal disease threats, including Highly Pathogenic Avian Influenza virus, and (2) intentional genomic alterations in animals with a focus on alterations that support agricultural resilience, food security, animal health, or public health. These other priority areas are outside the scope of this report.

Understanding How to Prevent a Deadly Turkey Disease

Researchers at the University of Arkansas, in partnership with Clemson University, have a cooperative agreement with FDA for $3.2 million over 5 years to develop insights about disease transmission and to potentially find an existing FDA-approved drug to fight histomonosis, a parasitic infection known as blackhead disease.

What is the unmet animal health need?

Blackhead disease, which causes the liver and digestive tract of infected birds to become inflamed and develop ulcers (shown below), has no FDA-approved vaccines or therapeutics.

Figure 7: Blackhead Disease Causes Liver and Digestive System Ulcers (Right) and Is 70 to 100 Percent Fatal in Affected Turkey Flocks

Sources: IBRESTER/stock.adobe.com (left) and University of Arkansas, Lesleigh Beer (right). | GAO-26-107896

Mortality in affected turkey flocks can reach up to 100 percent, according to FDA.[3]

What needs to be known about this disease to develop a treatment?

The University of Arkansas and Clemson University are researching how the *H. meleagridis* parasite, which causes histomonosis, moves from host to host in turkey flocks, which could provide information on how to develop measures, including new drugs, to prevent transmission. Historically, researchers and farmers believed that blackhead infections moved through turkey flocks when turkeys would eat worms that were infected with *H. meleagridis*. However, researchers observed that healthy turkeys could contract blackhead disease when housed with infected turkeys in the absence of a vector (such as an earthworm carrying *H. meleagridis)*.

Several infection and transmission routes for *H. meleagridis* in commercial poultry flocks have been proposed, but researchers have so far been unable to identify exactly how histomonosis spreads. University of Arkansas and Clemson University researchers are therefore investigating how the different cell stages of *H. meleagridis* can play a key part in its survival and transmission among hosts. Specifically, preliminary studies from the University of Arkansas and Clemson University found that *H. meleagridis* can survive the lower pH of a turkey's digestive tract and form cyst-like structures. These cyst-like structures end up in the turkey's feces droppings, which are then eaten by other birds.

What comes next?

The researchers aim to (1) demonstrate that the cyst-like structure is the causative agent for *H. meleagridis* infection via the fecal-oral route in field settings and determine biological and environmental cues for cyst formation, (2) understand the specific cellular processes behind how *H. meleagridis* forms cysts, and (3) screen commercially-available compounds for their ability to inhibit cyst formation while evaluating the efficacy of the top compounds.

Achieving these aims can facilitate the development of preventative and therapeutic strategies, including new drugs. Specifically, identifying drugs with low toxicity and minimal side effects would greatly facilitate their widespread use in the market, according to researchers at the University of Arkansas. Further, identifying how compounds that are already FDA-

[3]Prior to 2015, farmers could use an arsenic-based animal drug to prevent blackhead disease in poultry. But the company that made the drug voluntary stopped marketing it and asked FDA to withdraw the drug's approval due to concerns about inorganic arsenic levels in birds treated with the drug.

approved and used for other infectious diseases could be used to prevent blackhead disease infections could significantly reduce drug development costs. Reduced drug development costs could encourage drug sponsors to seek FDA approval or conditional approval of drugs for this specific use.

Developing Models to Evaluate Pain Medications in Livestock

Researchers at Kansas State University, in partnership with North Carolina State University, have a cooperative agreement with FDA for approximately $4.6 million over 5 years to develop models that can reliably and consistently evaluate the efficacy of analgesics (pain medications) in goats, calves (as shown in fig. 8), and piglets, with the goal of supporting new drug approvals.

Figure 8: Each Year, Millions of Calves and Other Farm Animals Undergo Painful Procedures or Develop Painful Conditions Such as Lameness

Source: melissahemken.com/stock.adobe.com. | GAO-26-107896

Approved pain medications would improve on-farm animal welfare by controlling pain in a manner that is safe for the animal and the consumer and compliant with U.S. regulations, according to the researchers.

What is the unmet animal health need?

Kansas State University researchers told us that it is important to have FDA-approved drugs for pain that are effective and have established withdrawal times. However, there is currently no standardized way to show the effectiveness of pain medications that has been acceptable to FDA. As a result, there are no FDA-approved drugs for pain relief in livestock for commonly performed procedures such as castration, dehorning, and tail docking.[4] Sixty-five million piglets, 15 million calves, and 1 million goats undergo these painful procedures annually. During their lives, livestock also commonly develop painful conditions such as lameness.

In the U.S., the transdermal formulation of flunixin meglumine (a nonsteroidal anti-inflammatory drug) is the only FDA-approved drug for pain control in cattle. However, it is approved specifically for pain associated with foot rot in cattle, a bacterial infection in the animal's foot tissues. The use of flunixin meglumine for the treatment of pain not originating from foot rot, or use of any other nonsteroidal anti-inflammatory drug or local anesthetic (e.g., lidocaine) to treat any type of pain in livestock is allowable only within the confines of a valid veterinarian-client-patient relationship under specific conditions referred to as "extra-label" (or off label) drug use. Some pain-relieving drugs are prohibited entirely from extra-label use in food animals, such as in dairy cows with painful infections. When producers use unapproved pain medications in food animals, they must follow an extended withdrawal period to ensure that no drug residues enter the food supply, which can be expensive or impractical.

What needs to be known to develop a treatment?

Detecting pain, and measuring pain relief, in animals is challenging because prey species (like cattle) have evolved to conceal signs of pain from predators, according to Kansas State University researchers and others. Accordingly, the Kansas State researchers hypothesize that there are interactions between behavioral outcomes (such as changes in posture, vocalizations, facial expressions) and analytical biomarkers (such as cortisol levels or brain chemicals) that can be measured together to create validated models that provide a complete picture of an animal's pain. Researchers also hypothesize that more advanced analysis of how a drug is absorbed, distributed, metabolized, and eliminated by the body

[4]Kansas State University researchers noted that the United Kingdon and Canada each have at least eight approved drugs to manage pain in livestock for these and other procedures or conditions.

and how a drug affects the body can help identify the lowest effective dose of pain medication in livestock for a given procedure.

What comes next?

The researchers aim to study common painful conditions and procedures. In goats and calves, researchers aim to (1) establish pain biomarkers (behavioral and analytic) and evaluate the effect of collecting concurrent behavioral and analytic biomarkers and (2) determine the efficacy of transdermal flunixin meglumine and identify the optimal dose. For piglets, researchers aim to (1) develop a model to describe the efficacy of flunixin meglumine and (2) validate the predictions of this model.

The researchers expect that a validated model that relates the dosage of a drug to its safety and effectiveness can help encourage drug sponsors to seek FDA approval of drugs specifically for pain in livestock because it can allow them to consistently demonstrate drug effectiveness. Researchers hope that by developing such models they can streamline the drug development processes, helping to lower sponsor costs, and ultimately supporting approval of safe and effective pain medications for multiple species.

Appendix III: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

February 6, 2026

Steve Morris
Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"ANIMAL DRUGS: Strengthening Federal Incentives Could Help Address Unmet Animal Health Needs"** (GAO-26-107896).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Gary Andres
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - ANIMAL DRUGS: STRENGTHENING FEDERAL INCENTIVES COULD HELP ADDRESS UNMET ANIMAL HEALTH NEEDS (GAO-26-107896)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

GAO Recommendation 1

The Commissioner of FDA should incorporate a benefit-risk assessment into its process for evaluating whether animal drugs that use alternative study designs and data sources have demonstrated substantial evidence of effectiveness.

HHS Response

HHS concurs with this recommendation. FDA already incorporates a benefit-risk assessment into its processes for evaluating whether animal drugs that use alternative study designs and data sources have demonstrated substantial evidence of effectiveness. FDA agrees it needs to be more transparent about how it incorporates a benefit-risk process into the evaluation of new animal drugs. Therefore, FDA will prioritize a response to recommendation 2 below.

GAO Recommendation 2

The Commissioner of FDA should develop guidance for industry on its use of benefit-risk assessments in its regulatory decisions for animal drugs that demonstrate substantial evidence of effectiveness using alternative study designs and data sources.

HHS Response

HHS concurs with this recommendation. FDA will prioritize the creation of a draft Guidance for Industry for clearance that describes our approach to risk-based decision making in the approval of new animal drugs by the end of 2026. FDA will target the presentation and discussion of the information in publicly available settings such as meetings with our industry partners, discussions with animal trade groups, and/or the ADUFA V Educational Conference in 2027.

Appendix IV: GAO Contact and Staff Acknowledgements

GAO Contact

Steve Morris, morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Ruth Solomon (Assistant Director), Charlotte Gamble (Analyst in Charge), Kevin Bray, Chad Clady, Tara Congdon, Rebecca Hendrickson, Cindy Korir-Morrison, Amber Sinclair, Zachary Stickelman, Sara Sullivan, and Brennan Williams made key contributions to this report.

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