U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR VETERINARY MEDICINE

Office of Minor Use and Minor Species Animal Drug Development (OMUMS)

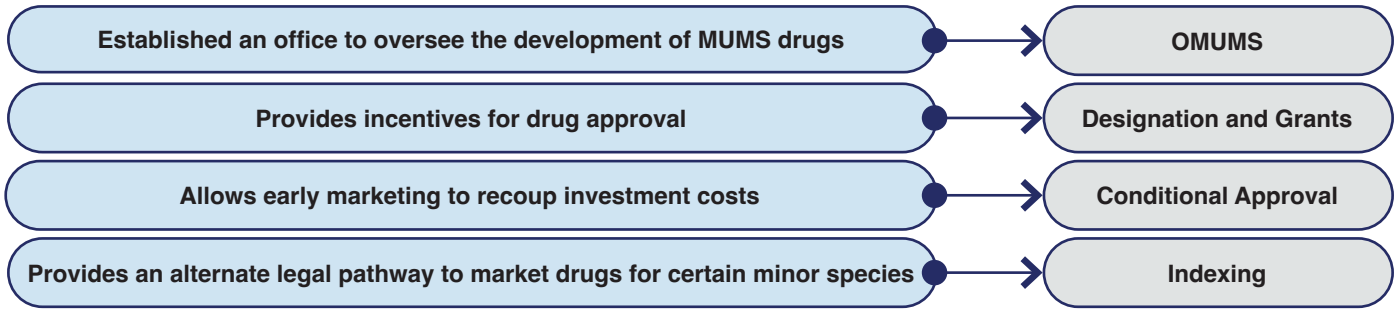
Minor Use and Minor Species (MUMS) Blueprint for Success

2026–2028

The FDA's Center for Veterinary Medicine (CVM) has developed a 3-year blueprint aimed at modernizing minor use and minor species (MUMS) programs and incentives. This blueprint prioritizes actions that can be accomplished within the FDA's existing regulatory framework, while laying the foundation for possible new solutions to address health gaps in underserved animal populations.

Background

The Minor Use & Minor Species Animal Health Act of 2004 (MUMS Act) is intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in the major animal species.[1] It is designed to help pharmaceutical companies overcome the financial barriers that discourage the development of limited-market animal drugs. The MUMS Act created the following innovative solutions to increase legal access to safe and effective drugs for these underserved populations of animals:



The Office of Minor Use and Minor Species Animal Drug Development (OMUMS) was established by the MUMS Act to lead FDA's efforts in expanding drug availability for minor uses and minor species. Since 2004, there have been successes including:

- 30 designated uses received FDA approval, 9 of which were supported by the MUMS grant program,
- 7 MUMS conditional approvals, 3 of which received full FDA approval, and
- 18 indexed minor species drugs.

OMUMS has also received recognition from external partners for providing excellent customer service and outreach. Requests for minor use determinations and indexing submissions have steadily increased over the past five years, reflecting growing demand for these programs.

1 **Major Species:** dogs, cats, horses, cattle, pigs, chickens and turkeys
Minor Species: all animals (other than humans) that are not major species
Minor Use: The intended use of a drug in a major species for an indication that occurs infrequently or in limited geographic areas and in only a small number of animals annually in the U.S.

Impact of Treatment Gaps

Despite the successes and positive trends, significant gaps persist in the availability of drugs for minor uses and minor species. While pharmaceutical companies have utilized the incentives and pathways established by the MUMS Act, substantial opportunities remain for growth and further development in this area. The scarcity of approved or indexed drugs for these animals requires veterinarians to rely heavily on extra-label drug use when treating animals under their care. In some cases, no treatment options exist. These gaps can lead to a variety of consequences, including negative impacts on animal health and welfare, agricultural economic growth, domestic food security, and U.S. competitiveness in global markets. Expanding access to safe and effective drugs for minor species agriculture industries — such as the honeybee, sheep, goat, and aquaculture sectors — can address a wide array of policy considerations, such as supporting the growth of these industries and bolstering domestic food production.

Vision of Growth

Looking forward, CVM is prioritizing key areas for modernization to address the continued and growing need for MUMS drug availability. To inform this strategy, CVM has gathered and analyzed stakeholder feedback, including insights from recent sources such as the Reagan-Udall Foundation report Transforming Animal Health in the U.S. for the 21st Century and the AVMA MUMS Roundtable convened in January 2026. CVM recognizes that meaningful, sustainable progress requires incorporating perspectives from our broad stakeholder community including veterinary practitioners, animal producers, pharmaceutical companies, and other federal and state agencies. Despite the varied interests represented, stakeholders have identified common themes and coalesced around specific strategic priorities. CVM's blueprint for fiscal years 2026–2028 reflects these shared priorities and encompasses four overarching goals.

Goal 1: Optimize Existing MUMS Regulatory Frameworks

CVM will maximize the effectiveness of existing MUMS Act incentives and pathways by taking the following actions, which can be accomplished with current authorities and resources:

- **Re-evaluate the small number thresholds for minor uses, potentially increasing access to incentives to support development of drugs to treat rare diseases, such as cancer in dogs.**
- **Develop a new indexing guidance to help pharmaceutical companies navigate the regulatory process, thereby facilitating the legal marketing of more drugs for minor species.**
- **Reexamine the criteria for indexing eligibility to identify opportunities for increased flexibility to expand drug availability for minor species with limited treatment options, such as wildlife.**
- **Review the MUMS Grant Program to ensure that its eligible funding categories include the full range of development costs authorized for grant support by the MUMS Act.**

Goal 2: Explore New Pathways to Market for MUMS Products

Stakeholders have indicated to CVM that both enhancements to existing pathways and new regulatory mechanisms are needed to facilitate MUMS drug development. This feedback aligns with a recent Government Accountability Office study (GAO-26-107896) which noted that improvements to conditional approval could increase animal drug availability. CVM will consider seeking statutory authority from Congress for the following enhancements and new regulatory pathways to expand treatment options for minor uses and minor species:

- **Modify the existing limitations on the marketing and labeling of conditionally approved animal drugs to make the pathway more attractive and viable for MUMS drug developers.**
- **Establish a new MUMS approval pathway that leverages regulatory decisions from trusted foreign partners with comparable standards, enabling efficient use of limited drug development resources while ensuring product safety and effectiveness.**
- **Expand the indexing pathway to increase access to legally marketed treatments for minor species, including exploring an indexing process for food-producing minor species that maintains human food safety protections.**

Goal 3: Explore New Incentives to Encourage MUMS Product Development

Existing MUMS incentives are well-utilized and have received positive stakeholder feedback. However, there is consensus that the MUMS drug pipeline would be strengthened by enhancing current incentives and introducing new ones. CVM will consider seeking appropriate new statutory authorities from Congress to further support innovation in this critical area, such as:

- **Extend the period of marketing exclusivity for designated MUMS drugs to better incentivize the development of these treatments.**
- **Establish a MUMS drug priority voucher program to stimulate additional MUMS drug development.**
- **Revise major and minor species definitions as needed, particularly in cases where population decline creates barriers to drug development.**
- **Make animal drugs eligible for MUMS incentives when development costs are not expected to be recovered from U.S. sales within a reasonable timeframe.**

Goal 4: Enhance Partnerships and Engagement

Sustained engagement with MUMS stakeholders is essential to identify emerging animal health needs, understand barriers to drug development, and ensure CVM's initiatives remain responsive to real-world challenges. CVM is committed to cultivating research partnerships with academic institutions and other public and private partners that will generate critical information to increase MUMS drug availability. To foster collaboration and advance MUMS drug development, CVM will focus on the following priority areas for partnership and engagement, which can be accomplished with existing authorities, though the level of investment will depend on resource availability:

- **Establish new Animal and Veterinary Innovation Center (AVIC) partnerships focused on MUMS regulatory science or therapeutic areas.**
- **Increase the award limit on MUMS grants to strengthen financial support for companies pursuing approvals.**
- **Explore additional research partnerships and grant models, including public-private partnerships, to spur innovation and broaden participation.**
- **Strengthen engagement with MUMS stakeholders to promote knowledge sharing, leverage diverse expertise, and foster a collaborative environment.**
- **Increase staffing for OMUMS and improve operational efficiency to better support MUMS drug developers throughout the regulatory process.**

Moving Forward

This blueprint outlines initiatives to expand access to safe and effective treatments for minor uses and minor species, building a more robust pipeline of animal health tools for veterinarians, pet owners, and animal producers. The benefits extend even further and support key policy goals of the broader administration — improved drug access strengthens domestic food security, supports the economic sustainability of minor species agricultural sectors, enhances the health and welfare of companion animals, supports conservation efforts for wildlife and endangered species, and ensures veterinarians across all practice areas have the therapeutic tools needed to address emerging health challenges. CVM is committed to prioritizing MUMS modernization and looks forward to implementing and proposing solutions to create lasting, positive change for animal health.