

FDA Center for Veterinary Medicine Office of Minor Use and Minor Species Animal Drug Development (OMUMS)

Minor Use/Minor Species (MUMS) Grants

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What are MUMS Grants?

Money to defray the costs of safety and effectiveness studies needed to support a New Animal Drug Application (NADA) for products for minor uses and minor species





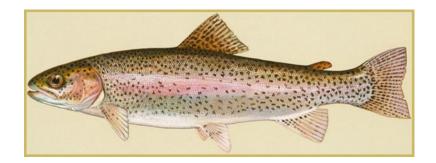
Who is eligible to apply?

- 1. Pharmaceutical sponsors developing MUMS drugs for FDA approval
 - The sponsor must have already opened an Investigational New Animal Drug (INAD) file with FDA/CVM
 - The sponsor must already hold a MUMS designation granted by FDA/CVM/OMUMS for that drug for a specified intended use
 - CVM's Office of New Animal Drug Evaluation (ONADE) must have already reviewed and accepted the study protocol
- 2. Their research partners
 - The sponsor needs to submit a letter to the INAD file identifying the partnership



What kind of studies can be funded?

- 1. Clinical effectiveness studies
- 2. Target animal safety (TAS) studies
- 3. Human Food Safety studies (residue, toxicology, microbial)
- 4. Environmental safety studies
- 5. Certain manufacturing studies supportive of effectiveness or TAS





How much grant money is available?

- The amount is always dependent upon available funding
- The Statute authorizes \$2 million (or more)
- Authorization \neq Appropriations
- Appropriation typically varies from \$500,000 to 1 million/year
- Grants are available for:
 - Up to \$250,000 for up to 2 years (applicant needs to justify why they need funding for more than 1 year)
 - Up to 250,000 for up to 3 years only for long-term toxicological studies



When are the application periods?

- There are two open application periods per Fiscal Year (FY)
- The second open period in FY has the money left over from the first round
- Funding Opportunity Announcement #PAR-24-216 contains detailed information about application dates: https://grants.nih.gov/grants/guide/pa-files/PAR-24-216.html
 FY2025 Part 1 open period: 5/24/2024 to 7/26/2024
 FY2025 Part 2 open period: 11/29/2024 to 1/31/2025
 FY2026 Part 1 open period: 5/23/2025 to 7/25/2025

FY2026 Part 2 open period: 11/28/2025 to 1/30/2026



What is the process?

FIRST: FDA/CVM/OMUMS must "designate" the product for a specific intended use at the request of the pharmaceutical sponsor

AND

FDA/CVM/ONADE must review and accept the study protocol

THEN: Allow up to 6 weeks to obtain the registrations that are needed to apply (note: do #1 and #2 below first):

- 1. Acquire a DUNS number
- 2. System for Awards Management (SAM): must renew registration annually
- 3. eRA Commons: applicant and all Program Directors/Principal Investigators one-time registration
- 4. <u>https://www.grants.gov</u>: one-time registration



Applying for a MUMS grant

There are multiple options to submit your application through Grants.gov. You must use one of these submission options to access the application forms:

- 1. Use the NIH ASSIST system to prepare, submit and track your application
- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application
- 3. Use Grants.gov Workspace to prepare and submit your application, and eRA Commons to track your application



Applying for a MUMS grant

- Don't wait until the last minute to apply. Allow time to fix unexpected errors in the application
- Resource SF424 (R&R) Application Guide (Research Instructions)

https://grants.nih.gov/grants/how-to-apply-application-guide.html





What happens next

- The FDA's Office of Acquisitions and Grant Services (OAGS) retrieves the applications and they are then screened for eligibility by OMUMS
- An Objective Review Panel evaluates qualified applications for scientific and technical merit based on criteria defined in the Funding Opportunity Announcement
- Following completion of the review process, FDA/OAGS will inform you of the approval status of your application and whether they will fund it in full or partially, based on availability of funds
- If the MUMS Grant Program does not fund your application, you may reapply in the next round



How long to spend MUMS grant monies?

- Grantees need to use the money during the 12-month performance period that follows the date of the award
- Multi-year funding can be approved for long-term, more complex studies





More information:

Designation:

https://www.fda.gov/animal-veterinary/development-approvalprocess/minor-useminor-species#designation

Designations List:

https://www.fda.gov/animal-veterinary/minor-useminorspecies/designations-list

Questions about the MUMS Grant Program:

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MUMS Grant Funding Opportunity Announcement:

https://grants.nih.gov/grants/guide/pa-files/PAR-24-216.html