

CVM eSubmitter

FileEditViewTableOutputToolsHelp

Submission Name: test
Report Type: CVM: OMUMS Indexing Submissions

Last Modified:
Date Packaged:

Outline

- CVM OMUMS Indexing Submissions
 - 1.0 Document Information
 - 2.0 Firm Information
 - 3.0 U.S. Agent Information
 - 4.0 Responsible Official Information
 - 5.0 Submitter Information

Screen: 1.0 Document Information

Department of Health and Human Services
Food and Drug Administration
CENTER FOR VETERINARY MEDICINE
Welcome to the Office of Minor Use and Minor Species Animal Drug Development (OMUMS) eSubmitter Program for Indexing.

This electronic submission tool automates the submission process for all regulatory submissions related to indexing. The software contains all of the templates necessary to build any indexing submission reviewed by OMUMS. The user will select a submission type and be presented with a question-based approach to guide them through the submission creation process. The questions asked throughout the process are founded on the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Code of Federal Regulations (CFR).

Paperwork Reduction Act Statement - A Federal agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 0910-0605 (expires 08/31/2026). The burden time for this collection of information is estimated to average 16.954 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments on any aspect of these collections of information, including suggestions for reducing the burden to cvmesubmitter@fda.hhs.gov or to U.S. Food and Drug Administration
Center for Veterinary Medicine
Office of Minor Use Minor Species
Attn: OMUMS eSubmitter Program, HFV-50
7500 Standish Place
Rockville, MD 20855

Please note: There are several icons within the software to help guide you. Most importantly, the yellow light bulb indicates additional instructions, definitions, and other helpful hints while a blue dot indicates a required field. The red exclamation point indicates critical required questions that must be answered in order to move forward through the submission.

Document Type:

Minor species Index File (Z)