

*Department of Health and Human Services
Food and Drug Administration*

CENTER FOR VETERINARY MEDICINE

Welcome to the Office of New Animal Product Evaluation and Office of Generic Animal Drugs eSubmitter Program

This electronic submission tool automates the submission process for all regulatory submissions destined for CVM's Office of New Animal Product Evaluation (ONAPE), and Office of Generic Animal Drugs (OGAD). The software contains all of the templates necessary to build any submission reviewed by ONAPE/OGAD. 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 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 numbers for this collection of information include 0910-0032 (expires 9/30/2028) and 0910-0117 (expires 08/31/2027). The burden time for these collections of information is estimated to average 5 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. The OMB control number for MUMS Designation is 0910-0605 (expires 08/31/2026). The burden time for this collection of information is estimated to average 4 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

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 blue dots indicates required fields. The red exclamation indicates critical required questions which must be answered in order to move forward through the submission.