

Department of Health and Human Services
Food and Drug Administration

CENTER FOR VETERINARY MEDICINE

Welcome to the ONADE Animal Bioengineering and Cellular Therapies eSubmitter Program

This electronic submission tool automates the submission process for all regulatory submissions destined for CVM's ONADE's Animal Biotechnology and Cellular Therapies Team. The software contains all of the templates necessary to build any submission reviewed by ONADE's Animal Biotechnology and Cellular Therapies Team. 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 (FDCA) 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 numbers for this information collection are 0910-0032 (expires 8/31/2025) and 0910-0669 (expires XX-XX-XXXX). The burden time for this collection 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. Send comments on any aspect of this collection of information, including suggestions for reducing this burden to:

cvmesubmitter@fda.hhs.gov or to

U.S. Food and Drug Administration
Center for Veterinary Medicine
Office of New Animal Drug Evaluation
Attn: ONADE eSubmitter Program, HFV-100
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 blue dots indicates required fields. The red exclamation indicates critical required questions which must be answered in order to move forward through the submission.

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Welcome to the Office of Surveillance and Compliance eSubmitter Program

This electronic submission tool automates the submission process for all regulatory submissions destined for CVM's Office of Surveillance and Compliance (OSC). The software contains all of the templates necessary to build any submission reviewed by OSC. 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 numbers for this information collection are 0910-0032 (expires 8/31/2025) and 0910-0669 (expires XX-XX-XXXX). The burden time for this collection 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. Send comments on any aspect of this collection of information, including suggestions for reducing this burden to:

cvmesubmitter@fda.hhs.gov or to
U.S. Food and Drug Administration
Center for Veterinary Medicine
Office of Surveillance and Compliance
Attn: OSC eSubmitter Program, HFV-220
7519 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 blue dots indicate required fields. The red exclamation indicates critical required questions which must be answered in order to move forward through the submission.

CVM eSubmitter Quick Guide

The CVM eSubmitter Application enables the creation of electronic submissions of regulatory information to CVM. It contains a number of data capturing tools to permit the capture of information in a structured format and provides helpful dialog boxes to reduce redundant responses. These benefits enable CVM to improve its review process of this regulatory information. This quick guide will instruct you on the basics for using the application.

The Quick Guide includes the following sections:

- [Access the Software](#)
- [Introductory Screen](#)
- [Set Preferences](#)
- [Create a New Submission](#)
- [Submission Screen Layouts](#)
- [Enter Submission Information](#)
- [Single Screens vs. Tabular Screens](#)
- [Save Submission Entries or Changes](#)
- [Closing a Submission](#)
- [Open an Existing Submission](#)
- [Check Completeness of Submission](#)
- [Package Submission Files](#)
- [Transmitting Submissions to CVM](#)
- [User Support](#)

Access the Software

To start the CVM eSubmitter application: Go to the **Start** menu and select the **CVM eSubmitter application**, or select the **CVM eSubmitter short-cut** from the desktop.

Application Start-Up Checks

At start-up, the application performs several system checks. The primary check is to determine if the application is out-of-date. The CVM eSubmitter application attempts to perform auto-updates each time it is opened to ensure the most current submission templates and application features are always available. CVM releases updates approximately once a month.

In the event that your organization blocks these updates through the use of firewall restrictions, it is the responsibility of the organization to frequently check whether updates are available, and manually reinstall, if necessary.

Clicking the link below will display the latest updates that have been deployed for CVM eSubmitter:

[CVM eSubmitter Release History](#)



CVM eSubmitter Appears Out-Of-Date Warning Message

If the CVM eSubmitter application has not received an update within 75 days, it displays the *CVM eSubmitter Appears Out-Of-Date* warning message.

The warning message will continue to display at start-up until an update has been received or the software reinstalled.

Clicking the **Remind Me Later** option will delay future messages for 7 days, while allowing the application to function normally until the issue is rectified.



Getting Started

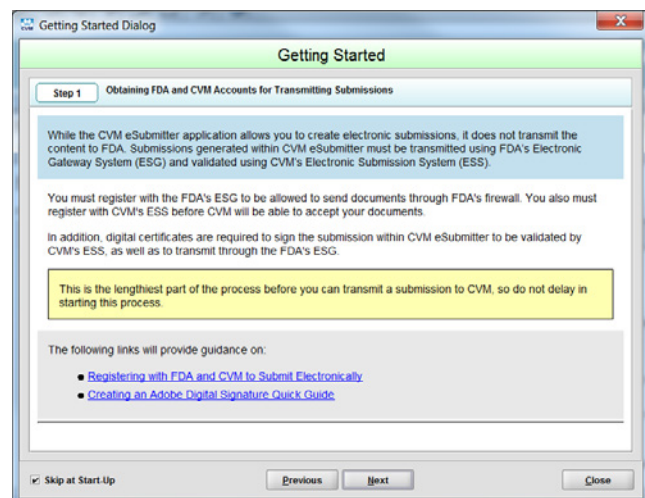
The first time CVM eSubmitter opens, it displays a *Getting Started Dialog*. The getting started feature provides valuable information that will help step you through the process of setting up your environment, all the way through preparing and packaging your first submission. Within the getting started you will find an overview of each step along with links to documents and websites that provide all the details needed to get you up and running.

Clicking the **Skip at Start-Up** option will prevent the dialog from displaying in future start-ups. However, the getting started feature can always be reopened at any time from the **Help** menu.

Getting Started Dialog

Getting started includes the following sub-sections:

- Application Overview
- Obtaining FDA and CVM Accounts for Transmitting Submissions
- Configuring the CVM eSubmitter Application
- Reviewing the Steps for Preparing a Submission
- Keeping Up with Application Updates
- Beginning Your First Submission

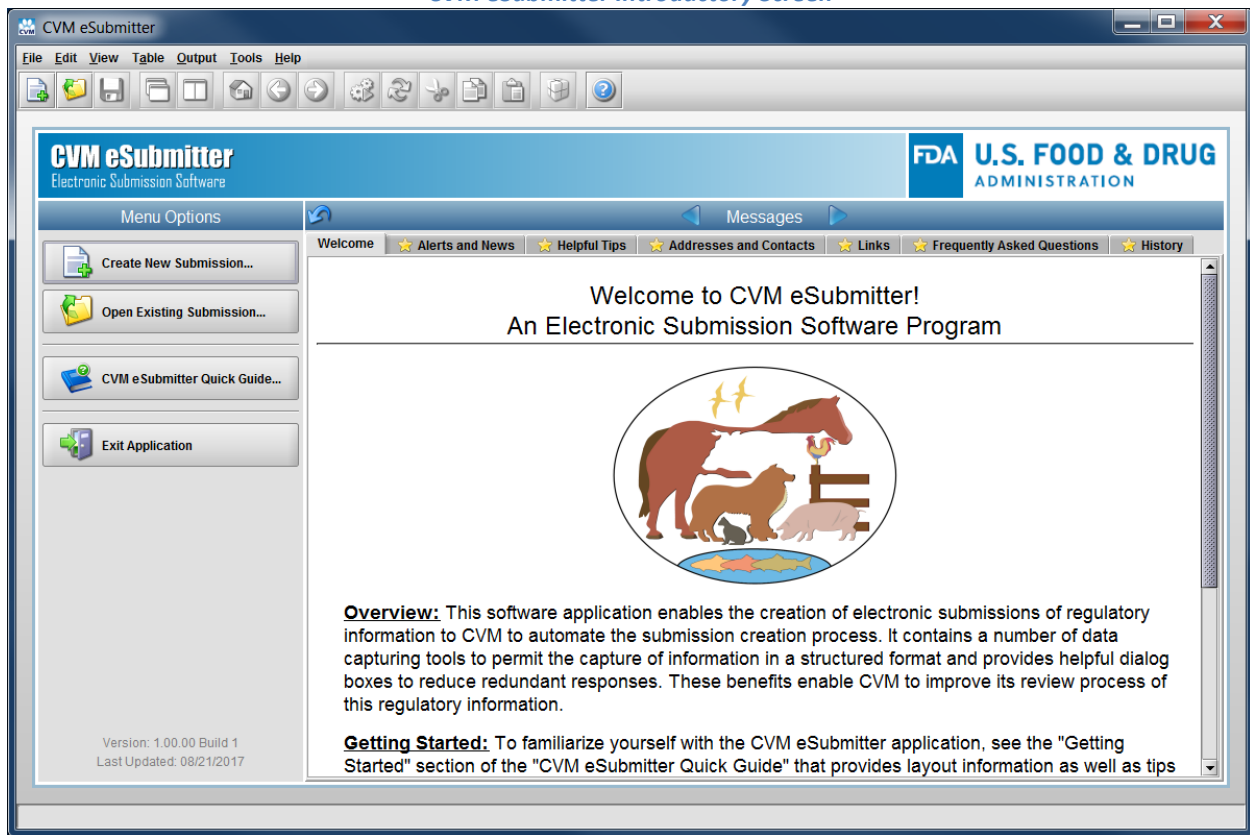


Introductory Screen

The CVM eSubmitter application window contains three distinct areas: the menu bar, tool bar, and main display area. The *Introductory Screen* is the main starting point when the CVM eSubmitter application opens and initially fills the main display area.



CVM eSubmitter Introductory Screen



The introductory screen contains the following sub-areas: the *Application Identification* at the top, common *Menu Options* along the left, and the *Informational Message Area* to the right.

The common features available from the Menu Options are as follows.

- **Create New Submission:** Allows you to create a new submission. The *Create New Submission Dialog* will appear. See the section on *Creating a New Submission* for more detailed information.
- **Open Existing Submission:** Allows you to open an existing submission. The *Open Existing Submission Dialog* will appear. See the section on *Opening an Existing Submission* for more detailed information.
- **CVM eSubmitter Quick Guide:** Launches this CVM eSubmitter Quick Guide.
- **Exit Application:** Closes the CVM eSubmitter application.
- **Application Version and Last Update Date:** Provides easy access to identify the application version and last updated date. It is located near the bottom of the menu options area.

The features available from the Informational Message Area are as follows.

- **Several Distinct Informative Tabs:** Containing the following content:
 - **Welcome Message:** Overview of the electronic submission program.
 - **Alerts and News:** List of concerns/issues and news with details.
 - **Helpful Tips:** List of helpful tips with details.
 - **Addresses and Contacts:** List of contacts and addresses with details.
 - **Links:** List of useful links.



- **Frequently Asked Questions:** Additional support based on Frequently Asked Questions (FAQ) received to date from existing users of the application.
- **History:** List of all updates to the application software.
- **Navigation Options:** Clicking directly on the message tabs or using the **Next** and **Previous** arrows on each side of the Message header.
- **Expand/Collapse Option:** Clicking the arrow located at the leftmost position of the Message header to either expand the message area to fill the application window or collapse it to its normal size.
- **Category Filter:** Within each message tab is a filter to limit the message content to an individual program within CVM. Changes to the filter setting are universal across the message tabs.
- **New Content Status Indicator:** Included within each tab name is a status indicator (i.e., *star*) identifying when new content is available since the last time viewed. By clicking the **Mark as Read?** option you indicate that you have read a message and the *star* will disappear. The *star* will only reappear when new content is available for viewing.

Set Preferences

The CVM eSubmitter application provides configuration options through application preferences. Preferences are settings that you can alter to change the way the application behaves. By adjusting the values within preferences you configure the application to best suit your working needs.

Application Preferences

Preferences includes the following configuration categories:

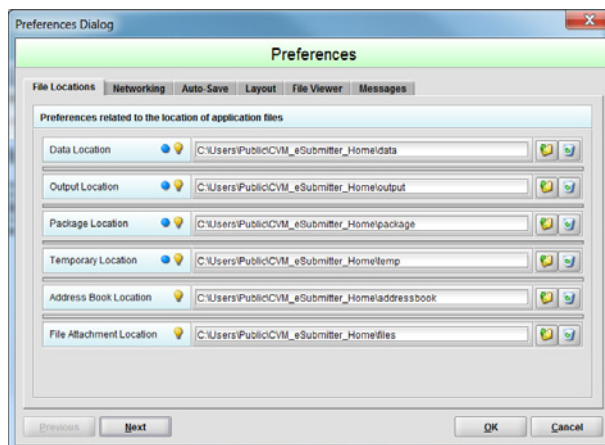
- File Locations of Working Folders
- Networking
- Auto-Save
- Starting Layout
- Adobe File Viewer Override
- Application Messages

To update application preferences, select **Preferences** from the **File** menu.

For a detailed explanation of each preference, see the *CVM eSubmitter Preferences Quick Guide* located within the Manual subfolder of the application.

Informational Tips!

- Many screens contain light bulbs, click on a light bulb to view helpful hints.
- Data entry fields that contain a blue circle denote a required response.



Create a New Submission

To create a new submission, click on the **Create New Submission** button from the **Menu Options** of the *Introductory Screen*, or select the **New** option from the **File** menu, or click the **New** button on the application tool bar to open the *Create New Submission Dialog*.

Create New Submission

Creating a new submission is a two-step process:

Step 1: Select a Submission Type

Within the first screen of the *Create New Submission Dialog* is a submission type list and description area. Selecting a type from the list displays information related to the corresponding submission type. Once you have selected an appropriate type, click the **Next** button.

Step 2: Provide Submission Details

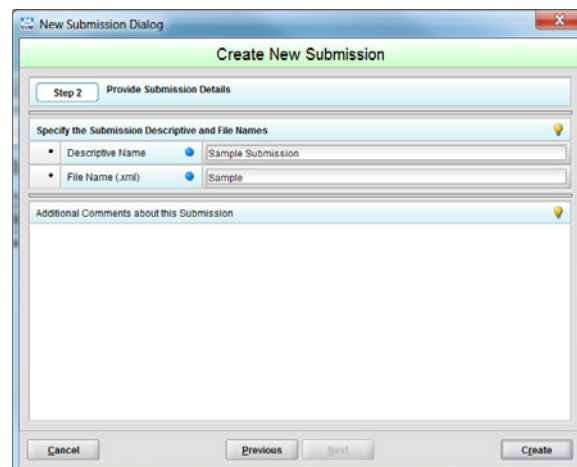
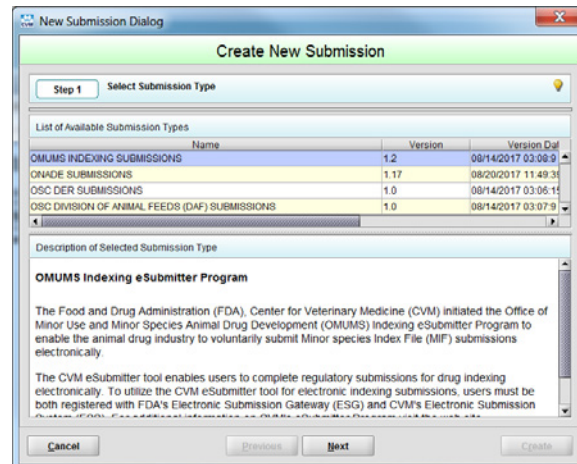
Complete the fields within the second screen of the *Create New Submission Dialog*.

Descriptive Name: Enter any descriptive name, as long as it is unique to the submission list. Use a name that distinctly identifies the report to you.

File Name: Enter a valid file name for the submission data file. Use only alphanumeric characters. Do not use symbols.

Additional Comments: Enter any additional information about this report (optional).

Click the **Create** button to generate the submission data file and open the submission within the submission data screen.



Submission Screen Layouts

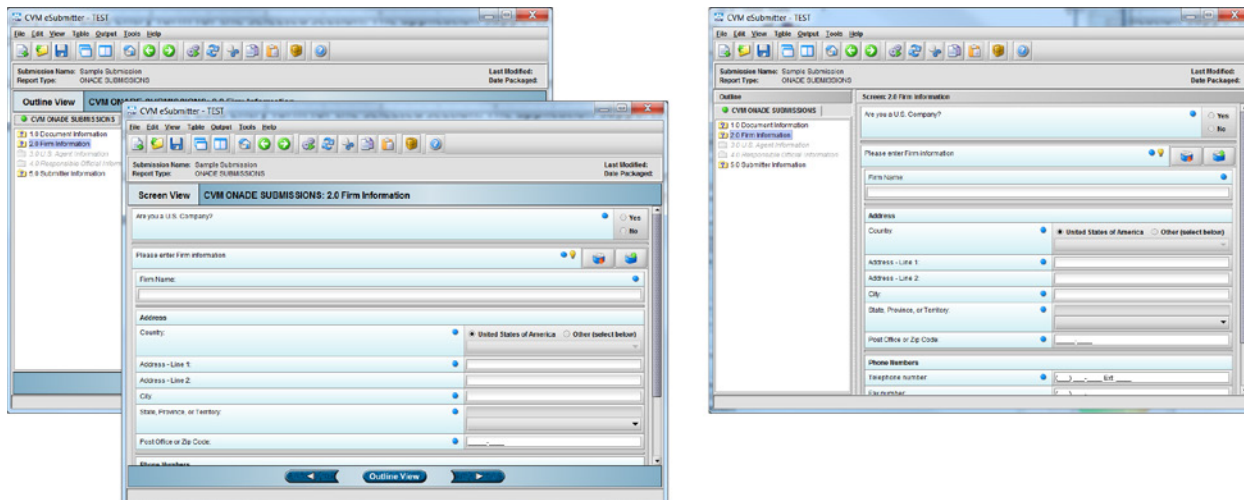
When a submission is available for data entry the main display area switches from the introductory screen to the submission data screen. The submission data screen contains two distinct display areas. The *Outline area* that provides a table of contents listing the sections contained within the submission, and the *Screen area* that displays the data entry form for the selected section. The application supports two different layout approaches for the submission data screen: *Simple* and *Extended*.

The simple layout separates the outline and screens areas across two distinct views where only one is visible at a time, while the extended layout combines the outline and screen areas into a single view with a resizable splitter between the two areas. Layout views can be switched from the **View** menu or by clicking between the **Simple** and **Extended** view options on the tool bar.



While the extended layout provides constant visible tracking of where you are within the submission, the simple layout provides better support for smaller screens. By default the layout is set to *Extended*.

Simple Layout (left) vs. Extended Layout (right)



Navigating the Submission

Navigating through the submission is as follows:

- If you are in the *Simple Layout*, use the navigation buttons on the button bar at the bottom of the screen to advance to the next and previous screens.
- If you are in the *Extended Layout*, use the outline area, and activate each section by double clicking on the section name to load the questions. You may also use the navigation arrows on the tool bar at the top to move to the next or previous section.

Enter Submission Information

Performing data entry within a submission only requires providing a response to questions as they are presented.

The following approaches are used in the collection of data within the application:

- **Common Data Entry Control Types:** Various types of controls are provided based on the types of information to be collected. The goal being to simplify data entry while also trying to improve the quality of the data collected. Examples of simple control types included are: drop-down lists with preset values, check boxes, radio button groups, plain text, numeric, dates, and tables.
- **Data Validation:** Performing checks to ensure individual data is being captured in the correct format. Providing user feedback when values are not in the correct format and not allowing invalid data to be saved until corrected.
- **Rule Validation:** Rules are condition/action-based and can work across multiple questions. They evaluate logical criteria and perform actions based on the result (e.g., If “Other” is selected from a list than a response is required to explain why “Other” was chosen).
- **Completeness:** Provides a measurement that all required responses have been provided. A submission cannot be packaged unless it is complete. Completeness indicators are provided



throughout the data entry. The *Outline* area represents sections as folders. Each folder has an indicator to identify if the section is complete. A “check mark” represents complete and a “question mark” represents that required responses are missing. In addition, a *Missing Data/Validation Issues Report* is always available from the **Output** menu to list any missing data or issues within the submission.

In addition to the simple data entry control types, there are also complex control types that support the data entry of both complex data, as well as a compound data (i.e., combination of multiple data items).

Complex data entry controls include:

- Contact and Address Information copied from the Address Book
- File Attachments
- Rich Text Content (formatted text, lists, tables)

Address Book

Contact, firm, and address information is considered to be compound data due to the inherent nature of the relationship between the data. It also presents an opportunity for a high level of reuse. As a result, the application provides a built-in *Address Book* capability to gather commonly used contact, firm, and address information.

Address Book

Contact and Firm data collection will typically be preceded with buttons that interface with the *Address Book* (see buttons circles in red)

The first button provides an option to **Copy From** the address book to fill in the related fields on the screen, while the second button provides an option to **Copy To** the address book the information from the fields on the screen.

The most common approach to building the address book is to manually enter address information into the submission data entry when first used, and select **Copy To** address book to preserve it for future submissions. However, there is also an address book option on the **Tools** menu that allows direct entry into the address book.

The screenshot shows a form titled "Please enter Responsible Official Information" with two buttons in a red box: a globe icon and a document icon. The form is divided into several sections:

- Contact:** Includes fields for Title (e.g., Mr, Ms), First/Given Name (John), Middle Name (A), Last Name (Smith), Degree(s) (e.g., Ph.D., J.D.) (PhD), Occupation Title (Chemist), and Email Address (jsmith@abc.com).
- Address:** Includes fields for Firm Name (ABC Company), Country (United States), Address - Line 1 (1111 Main Street), Address - Line 2 (Building 10), City (Rockville), State (Maryland), International State, Province, Territory, and Postal or Zip Code (21704).
- Phone Numbers:** Includes Telephone Number ((301) 555-1212 Ext. _____) and Fax Number ((301) 555-1515).
- Reference Numbers (for the Firm Name specified above):** Includes D&B D-U-N-S Number (123456789).

File Attachment

Submission forms are designed to collect both discrete data (i.e., individual fields on a form), as well as file attachment references to be included within the submission package. In addition, some questions may support only one reference to a file attachment, while others might offer the option to attach multiple files.



The types of files that can be attached are limited. CVM eSubmitter currently supports the following types of file:

- Portable Document Form (pdf)
- eXtensible Markup Language (xml)
- SAS XPORT (xpt)

The types of files supported can be further restricted on a question by question basis.

File names should not contain more than 250 characters. Do not use symbols when naming the files for attachments. For example, do not use slashes (/) (\), tildes (~), asterisks (*), periods (.), brackets [], single quotation marks ('), double quotation marks (") or parentheses ().

Attaching a File

Attaching a file is a multi-step process:

Initiate to Add a File Reference from a Question

Click the **Add File** (i.e., Plus Sign) button from a File Attachment type question to open the file attachment dialog.

Option 1. Check Existing File Attachment List

Check the list of files that have already been attached for the submission. A file can only be attached once, but it can be referenced across multiple questions. If the file is already in the previously attached list, select the file, and click the **Attach Selected File** button.

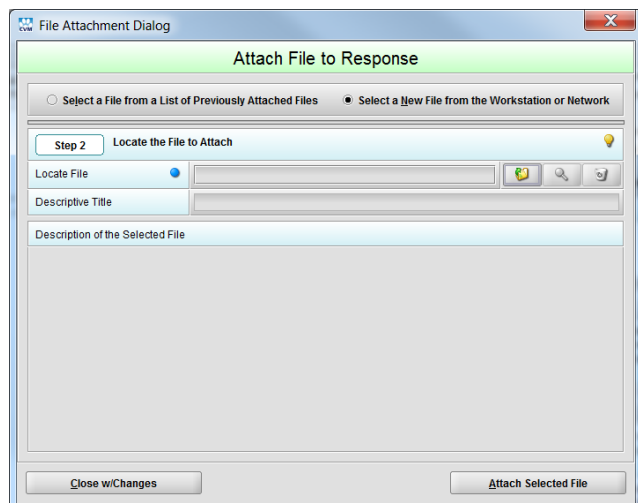
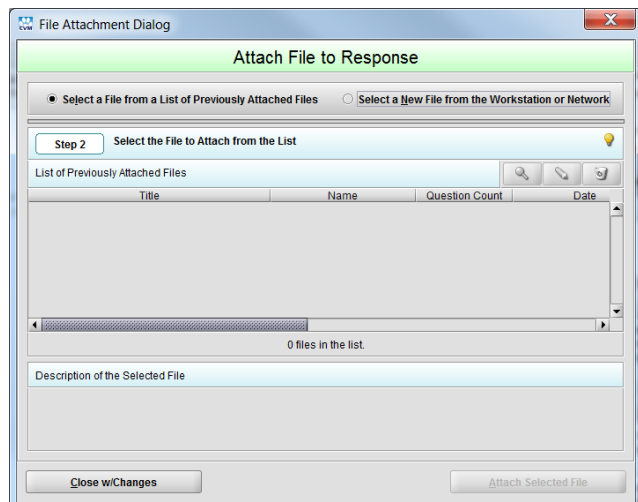
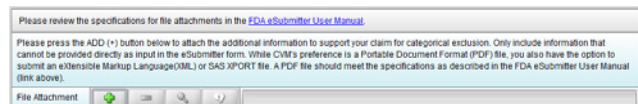
Option 2. Select a New File to Add to the File Attachment List

Click the **Select File** button (i.e., folder image) to open the file browser dialog and navigate to the file to be added.

Once selected, add a **Descriptive Title** for the file (a title is required and must be unique across all file included within a submission).

Finally, click the **Attach Selected File** button.

Once a file has been selected you will return to the question and the question will be updated to reflect the file chosen.



Rich Text

The application supports rich text responses formatted in the HyperText Markup Language (HTML). Not all questions allow HTML responses, but some do based on the nature of the expected response (e.g., tables, lists, special symbols, equations). The most common approach for including HTML responses in a submission is to copy and paste the formatted content from an existing document (e.g., Word). The Operating System (OS) will automatically perform the translation of the source rich text into HTML.

Single Screens vs. Tabular Screens

The application supports two types of data entry screens:

- Singular
- Tabular

Singular Screen

Singular screens only support one instance of the data collected. In the example at the right, this submission supports the entry of only one Product Description.

Within the outline area, Singular screens are referenced by a single folder.

Tabular Screen

Tabular screens support multiple instances of the data collected. In the example provide at the right, this submission supports the entry of Type II Master Files.

Within the outline area, Tabular screens are referenced by a double folder.

Tabular screens support three views:

- **Detail:** Displays the individual questions for data entry
- **List:** Displays a list referencing all items included
- **Info:** Displays guidance information describing the options available

In general, tabular screens support adding, editing, and deleting; navigation between items; and reordering.

| Item | File Type | File Number | Information Covered |
|------|-----------|-------------|---------------------|
| 1 | DMF | 00001 | |
| 2 | VMF | 00002 | |
| 3 | DMF | 00003 | |

Some tabular screens may be linked together through a parent/child relationship. If this parent/child relationship exists, you will see a header bar on the child screens indicating which list item within the parent table you are currently entering data for.



Save Submission Entries or Changes

While moving through a submission, any changes made to question responses are automatically updated within memory (e.g., the user made a change to a question response, went to another section of the submission, and returned to see that the changes to the response were still in effect).

There are two approaches to saving your changes:

1. Click the **Save** button on the tool bar or select the **Save** option from the **File** menu when you are at a point that you want to save your progress.
2. Turn on **Auto-Save** and provide a time **Interval** within the Preferences and the application will automatically perform saves based on the interval provided. To learn more about auto-save review the *CVM eSubmitter Preferences Quick Guide* located with the Manual subfolder of the application.

Saves will not be performed while there is a validation issue within the response of the current question. The validation issue will need to be corrected before a save can be completed. In addition, the application will remind you to save if data has been changed and you are about to perform an operation that would result in losing your changes (e.g., such as opening another submission or exiting the application).

Closing a Submission

To close a submission, select the **Close** option from the **File** menu. Once closed, the application will return to displaying the *Introductory Screen*.

Open an Existing Submission

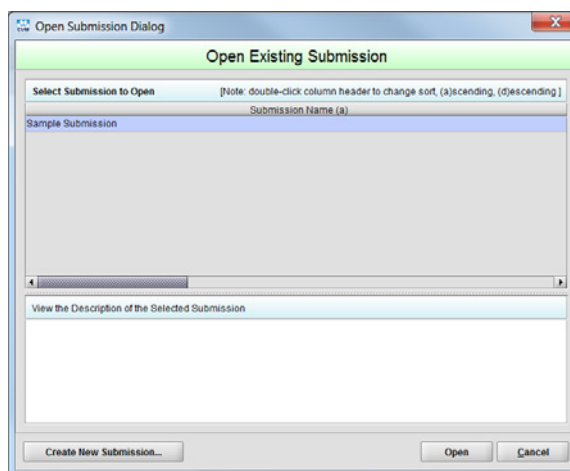
To open an existing submission, click on the **Open Existing Submission** button from the **Menu Options** of the *Introductory Screen*, or select the **Open** option from the **File** menu, or click the **Open** button on the application tool bar to open the *Open Existing Submission Dialog*.

Open Existing Submission

The Open Existing Submission Dialog allows you to select an existing submission or create a new one. As you create new submissions they will be added to this list.

The available options are:

- **Open:** Opens the selected submission within the list by either clicking the button or double clicking on the select item
- **Cancel:** Closes the dialog with no changes
- **Create New Submission:** Opens the *Create New Submission Dialog*



Check Completeness of Submission

To check for completeness, you must identify if any data is missing or validation issue remain within your submission content. You will not be able to package your submission until it is complete.

Select the *Missing Data/Validation Issues Report* from the **Output** menu to open the report within your default browser. The report will either state that there are no missing data or validation issues, or it will identify the questions and screens where the problems are located. After fixing any issues, you are ready to proceed to the packaging process.

Package Submission Files

After completing the submission data entry and verifying that there is no missing or invalid information, you are ready to package the files for submission. For a detailed explanation of the packaging process, see the *CVM eSubmitter Packaging Quick Guide* located within the Manual subfolder of the application.

Transmitting Submissions to CVM

While the application allows you to create electronic submissions, it does not transmit the content to FDA. Submissions generated within CVM eSubmitter must be transmitted using FDA's Electronic Gateway System (ESG) and validated using CVM's Electronic Submission System (ESS).

For a detailed explanation of registering with the FDA's ESG and CVM's ESS, see the *Registering with FDA and CVM to Submit Electronically* located within the Manual subfolder of the application.

User Support

For CVM eSubmitter Program Support Contact: cvmesubmitter@fda.hhs.gov.

For FDA Electronic Submission Gateway (ESG) Support Contact: ESGHelpDesk@fda.hhs.gov.

For CVM Electronic Submission System (ESS) Support Contact: cvmdcu@fda.hhs.gov.



| | | |
|--|--|---|
| Guidance | Import Data | Reset Form |
| DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine | Electronic Submission System Participant Management | Form Approved: OMB No. 0910-0454 Expiration Date: 11/30/2019 |
| <small>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 current valid OMB control number. The public reporting burden for the collection of information is estimated to vary from 5 to 10 minutes, with an average of 8 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.</small> | | |

I. SECTION I – Registration / Information:

Select 'Add', 'Delete' or 'Change' then complete the required information.

ADD <Coordinators Only>
 DELETE <Coordinators Only>
 CHANGE

| | | | |
|----------------------------|----------------------------------|----------------------|----------------------|
| Stakeholder Name: | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Stakeholder Company Name: | <input type="text"/> | | |
| Company Address 1: | <input type="text"/> | | |
| Company Address 2: | <input type="text"/> | | |
| City: | <input type="text"/> | St/Prov: | <input type="text"/> |
| | | Postal Code: | <input type="text"/> |
| Country: | <input type="text" value="USA"/> | | |
| Stakeholder Phone: | <input type="text"/> | | |
| Stakeholder Email Address: | <input type="text"/> | | |

II. SECTION II – Digital Signature Validation:

I certify that the applied digital signature is mine.

| | | |
|----------------------------|----------------------|----------------------|
| Stakeholder Name: | <input type="text"/> | <input type="text"/> |
| Stakeholder Email Address: | <input type="text"/> | |