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**ONADE USER GUIDE**


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**CVM ESUBMITTER INFORMAL COMMUNICATION QUICK GUIDE**

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**I. INTRODUCTION**

This document describes the steps sponsors should follow when they choose to use the informal communication process to submit certain questions to the Office of New Animal Drug Evaluation (ONADE) in eSubmitter under 'ONADE Communication' submission type.

Examples of types of questions that can be submitted using this process may include:

- policy questions related to regulations and legal requirements, patents, marketing status, or controlled substances;
- issues that occur immediately before or during a study such as need for amendments and deviations, product quality issues, interim analysis, unmasking, or addition of study sites;
- scientific questions such as clarification of non-concurrence or incomplete (technical section or supplement) comments, questions on non-pivotal studies (pilot studies, dose characterization, palatability, etc.), or limited study design questions in advance of protocol submission/revision;
- Specific administrative questions related to the content and format of a proposed submission, or inquiries related to submitting a post-approval change;
- other questions requiring consultation with other FDA centers, or questions requiring input from multiple teams or divisions to fully answer; or
- requests for pre- and post-review feedback under processes outlined in [draft CVM Guidance for Industry #283](#)<sup>1</sup> titled, Priority Zoonotic Animal Drug Designation and Review Process for drugs designated as Priority Zoonotic Animal Drugs (PZAD).

**II. CREATE A NEW SUBMISSION**

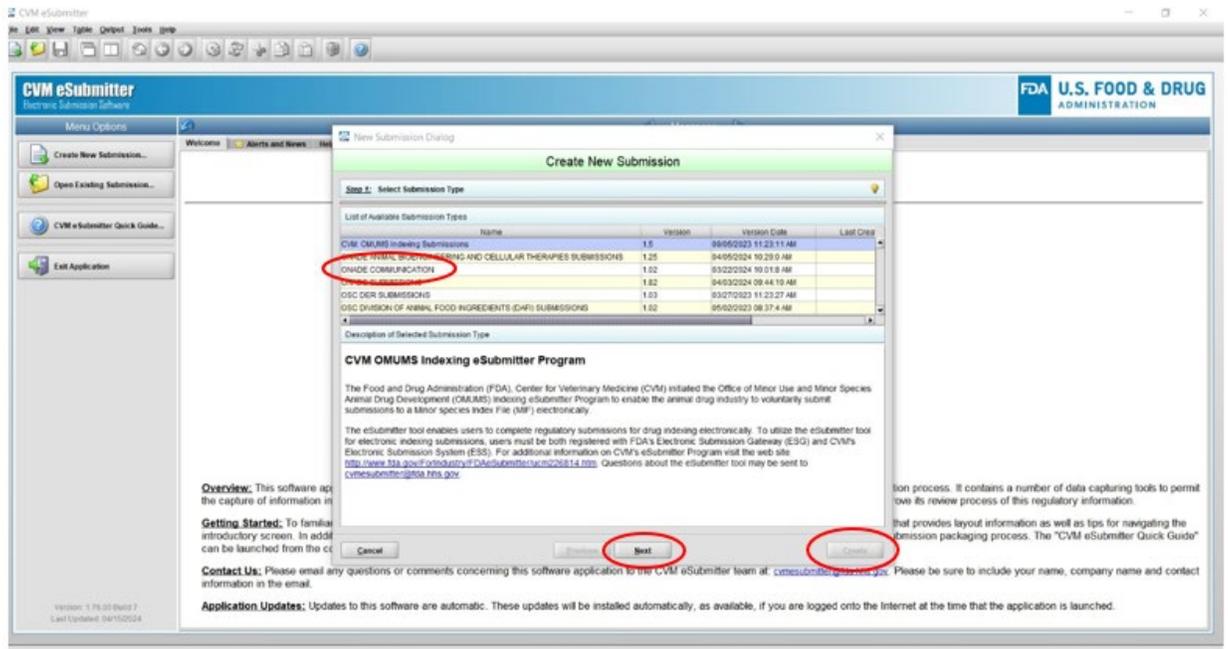
To create a new submission, click on the **Create New Submission** button from the **Menu Options** of the *Introductory Screen*, or select the **New** option from the **File** menu, or click

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<sup>1</sup> <https://www.fda.gov/media/174635/download>

the **New** button on the application tool bar to open the *Create New Submission Dialog*. Then:

1. Select 'ONADE Communication' submission type, then click the **Next** button.
2. Provide Submission Details: Descriptive Name, File Name, any Additional Comments (optional).
3. Click the Create button to generate the submission data file and open the submission within the submission data screen.



### III. DOCUMENT/FIRM INFORMATION

1. Select 'Information Communication' as the type of communication.
2. Select the applicable document type and enter the document number under which the question(s) is to be submitted. If there is no applicable file already established, establishing a GC file may be required.
3. Enter the Firm Name.
4. Select the review division which is to receive the question(s).
5. Answer the question asking whether this is an amendment to a pending submission.
  - a. Select **No** to the amendment question.
  - b. If you have already submitted your question(s), and you were instructed by ONADE to amend the submission then select **Yes**.
6. Answer the question asking if this request is about a specific drug product.

- a. Select **Yes** if your question(s) is related to a specific drug product. If you select Yes, you will be required to complete the product description in screen 7.0.

The screenshot shows the 'Screen: 1.0 Document/Firm Information' in the CVM eSubmitter application. The interface includes a menu bar, a toolbar, and a navigation pane on the left. The main content area contains the following elements:

- Informal Communication:** A section with a red exclamation mark icon and a dropdown menu set to 'Informal Communication'. Below it is a link: 'Response to Early Response Letter for a Virtual Meeting (2 Submissions)'. This section is circled in red.
- Document Type:** A dropdown menu currently set to 'Investigational New Animal Drug File (I)'. This section is circled in red.
- Document Number:** A text field with the value '12345'. A prompt above it says 'Please enter your Document Number (maximum 6 numbers)'. This section is circled in red.
- Firm Name:** A text field with the value 'Firm, Inc.'. A prompt above it says 'Please enter Firm name'. This section is circled in red.
- Review Decision:** A dropdown menu set to 'Division of Companion Animal Drugs (DCV, ADA)'. A prompt above it says 'Select the review division to which you are submitting'. This section is circled in red.
- Amendment Status:** A question: 'Is this information intended to amend a submission currently pending and under review by CDMP?'. The 'Yes' radio button is selected. This section is circled in red.
- Specific Drug Product:** A question: 'Does this request relate to a specific drug product?'. The 'Yes' radio button is selected. This section is circled in red.

#### IV. RESPONSIBLE OFFICIAL INFORMATION

Enter the contact information for the responsible official in screen 2.0 and navigate to the next screen using the navigation buttons (green arrows).

The screenshot shows the 'Screen: 2.0 Responsible Official Information' in the CVM eSubmitter application. The form is titled 'Please enter contact information for the Responsible Official.' and includes the following sections:

- Contact:** Fields for Title (e.g., Mr., Ms., Dr.), First/Given Name, Middle Name, Last Name, Degree(s) (e.g., Ph.D., J.D.), Occupation Title, and Email Address.
- Address:** Fields for Firm Name, Country, Address - Line 1, Address - Line 2, City, State, Province, Territory, and Postal Code.
- Phone Numbers:** Fields for Telephone Number and Fax Number.

## V. GENERAL INFORMATION

Under the General Information tab:

1. Answer the question asking if the product has been designated a Priority Zoonotic Animal Drug.
  - a. Select 'Yes' if requesting pre- and post-review feedback for a designated Priority Zoonotic Animal Drug.
2. Select the program support area(s) from which input is being requested.
3. Enter question(s) and attach any supporting document(s), if needed, in the appropriate fields.

Note: Specific questions must be entered into the applicable template section for eSubmitter to proceed with the submission. Supporting documents may be attached but should be limited to material directly related to the question presented.

The screenshot displays the '1.0 General Information' screen in the CVM eSubmitter application. The interface includes a menu bar at the top, a submission name and type, and an outline on the left. The main content area is divided into several sections:

- A blue header section: "Screen: 1.0 General Information".
- A green informational banner: "You are submitting a request for Informal Communication. Informal Communication requests are only answered via written response. CVM will respond to your question(s) via Acknowledgment Letter. No meeting will be held. The usual response time is within 14 days."
- A yellow warning banner: "Any questions requiring an immediate response (less than 48 hours) should not use the submission process. Use email or telephone."
- A question: "Has this product been designated by CVM as a Priority Zoonotic Animal Drug (PZAD)?" with radio buttons for "Yes" and "No".
- A section for selecting program support areas: "Select Program Support Area(s) in which you are requesting participation." with a list of 0 of 30 items.
- A text input field: "Please state the specific question(s) to which you are requesting a response from CVM."
- A section for attaching supporting documents: "Please review the PDF file specifications at the CVM eSubmitter File Specification Quick Guide." and "Please include only supporting material because you will submit a complete submission package. Please provide the information in bookmarked Portable Document Format (.pdf) files. The PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above)." Below this is a table with columns for Name, Title, Date, Size, and Path, and a "0 Items in the list" indicator.

## VI. PACKAGE AND TRANSMIT THE SUBMISSION

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 on FDA.gov (<https://www.fda.gov/media/139159/download?attachment>) or within the Manual subfolder of the application.

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 additional information about registering, visit the CVM

eSubmitter Resource Center page at <https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center>

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.

## **VII. REFERENCES**

CVM eSubmitter Packaging Quick Guide

<https://www.fda.gov/media/139159/download?attachment>

## **VIII. VERSION HISTORY**

May 1, 2024 – Original version.