ONADE USER GUIDE

CVM ESUBMITTER INFORMAL COMMUNICATION QUICK GUIDE

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[1] titled, Priority Zoonotic Animal Drug Designation and Review Process for drugs designated as Priority Zoonotic Animal Drugs (PZAD).

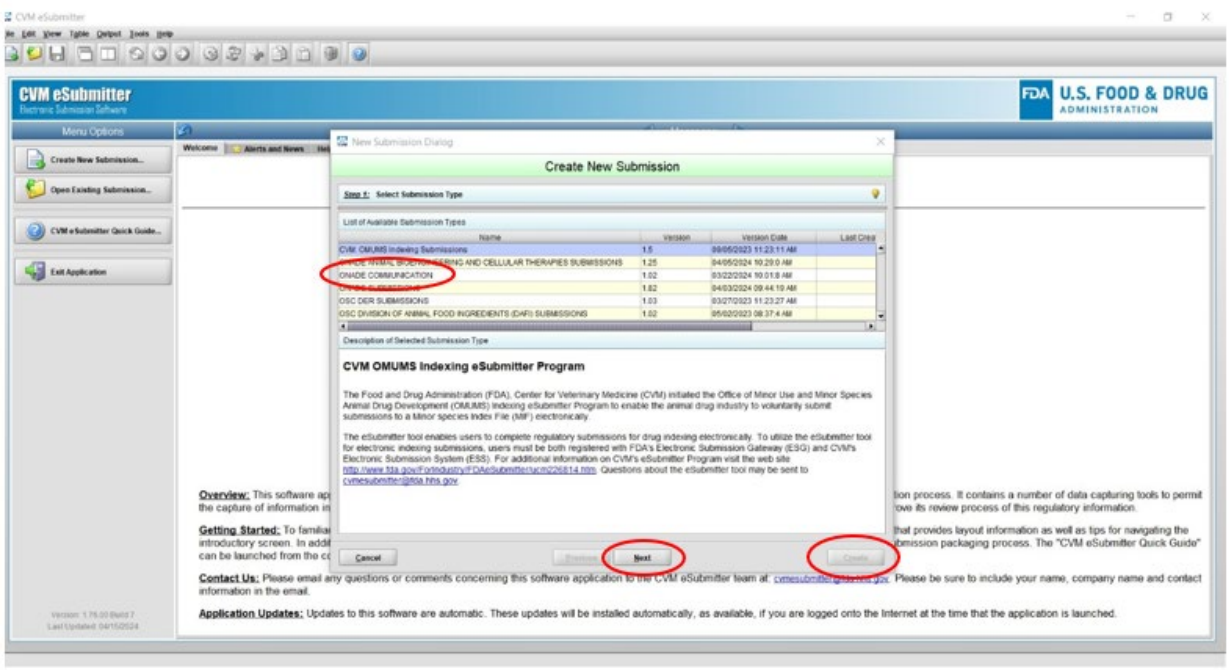
II. CREATE A NEW SUBMISSION

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

[1] https://www.fda.gov/media/174635/download

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

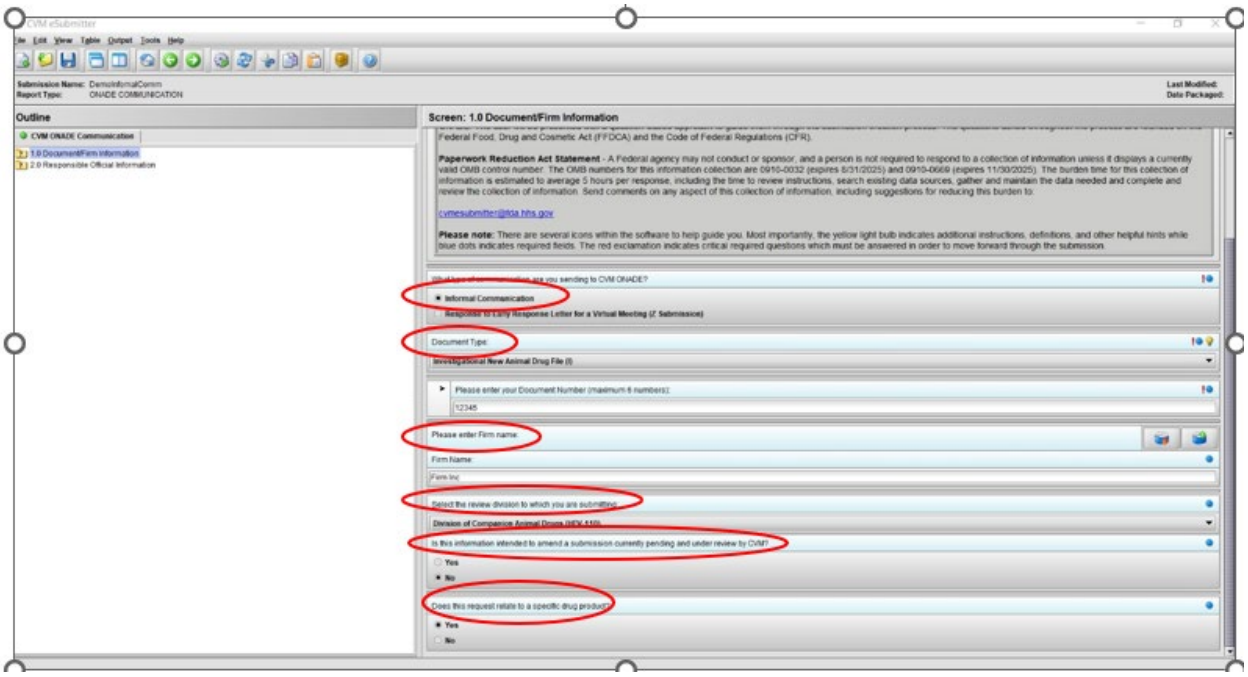
1. Select 'ONADE Communication' submission type, then click the **Next** button.
2. Provide Submission Details: Descriptive Name, File Name, any Additional Comments (optional).
3. Click the Create button to generate the submission data file and open the submission within the submission data screen.



III. DOCUMENT/FIRM INFORMATION

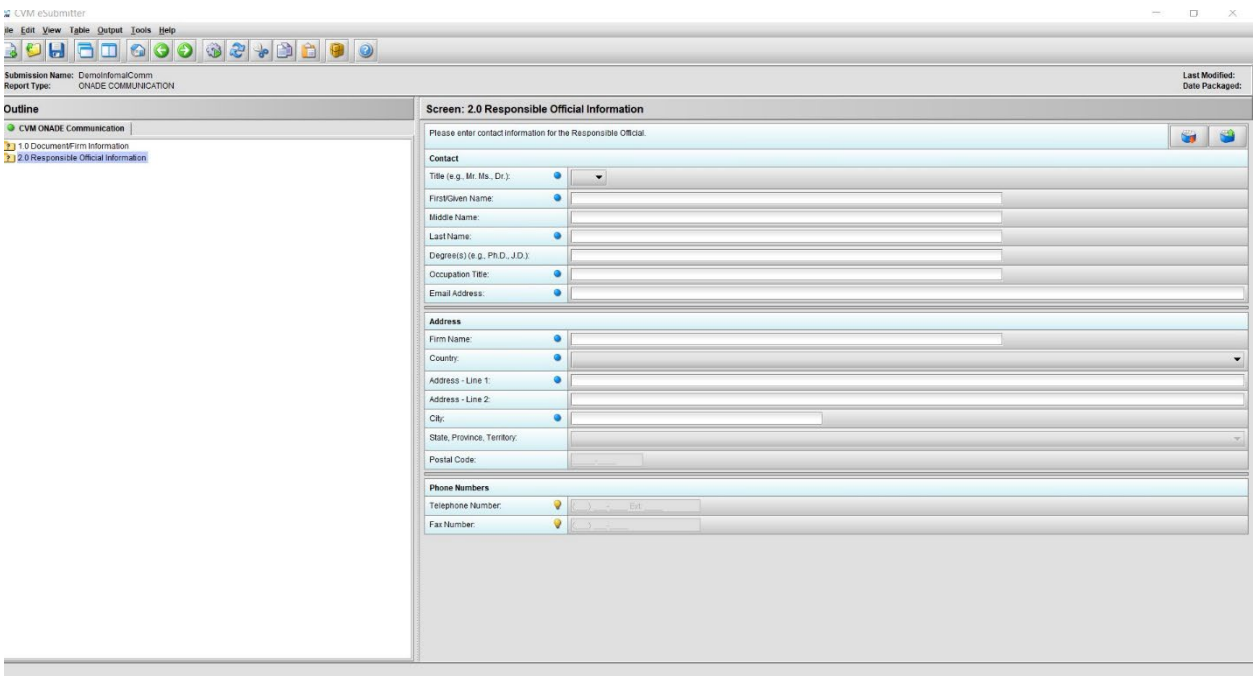
1. Select 'Information Communication' as the type of communication.
2. Select the applicable document type and enter the document number under which the question(s) is to be submitted. If there is no applicable file already established, establishing a GC file may be required.
3. Enter the Firm Name.
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.



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).



V. GENERAL INFORMATION

Under the General Information tab:

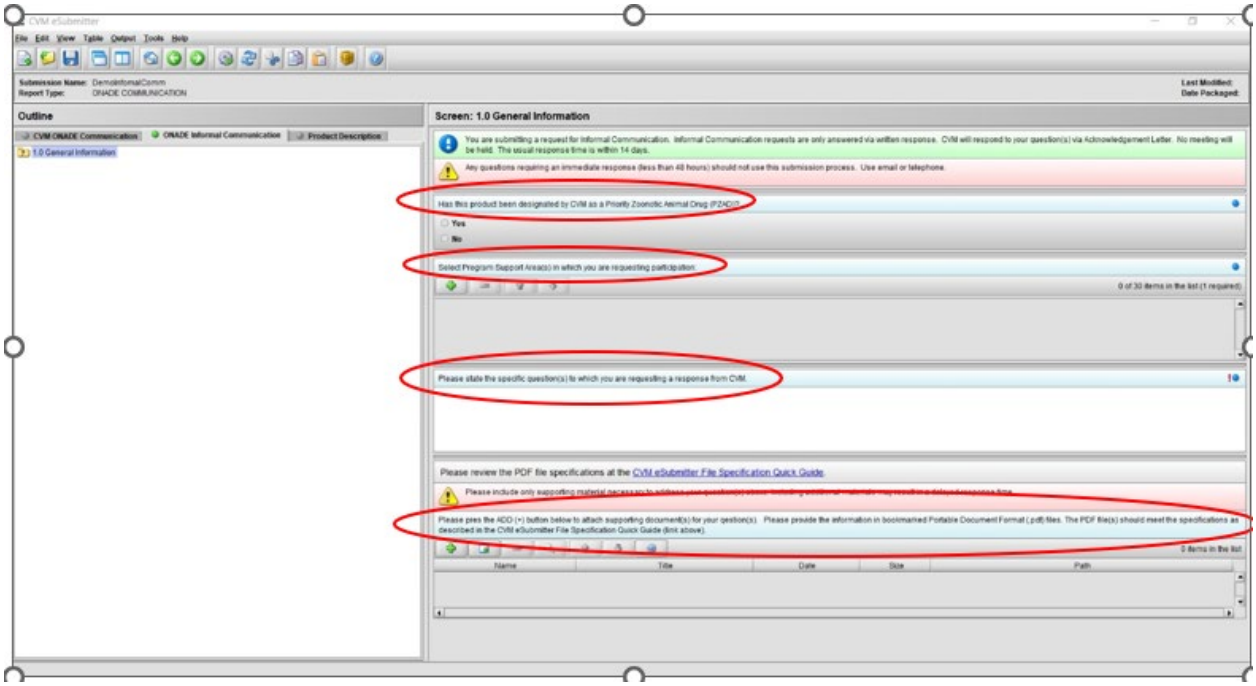
1. Answer the question asking if the product has been designated a Priority Zoonotic Animal Drug.

    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.



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.