

Center for Veterinary Medicine (CVM)
Animal Biotechnology Info Rounds

AR3: CVM eSubmitter

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These slides provide general information about review process and procedures.
For questions or information related to a specific product, please contact CVM.



Overview

This document provides developers of intentional genomic alterations (IGAs) in animals and animal cells, tissues, and cell- and tissue-based products (ACTPs) with an overview of the CVM eSubmitter program. Specifically, this document focuses on:

- getting started using eSubmitter for IGAs in animals and ACTPs,
- selecting a **Document Type**¹,
- selecting a **Submission Type**, and
- selecting a **Submission Classification Code**.

¹ eSubmitter uses the term “Document Type” to refer to the field that indicates the type of application or file that will be opened [e.g., New Animal Drug Application (NADA), Veterinary Master File (VMF), etc.]; this term can be used interchangeably with “File Type”



Getting Started with CVM eSubmitter

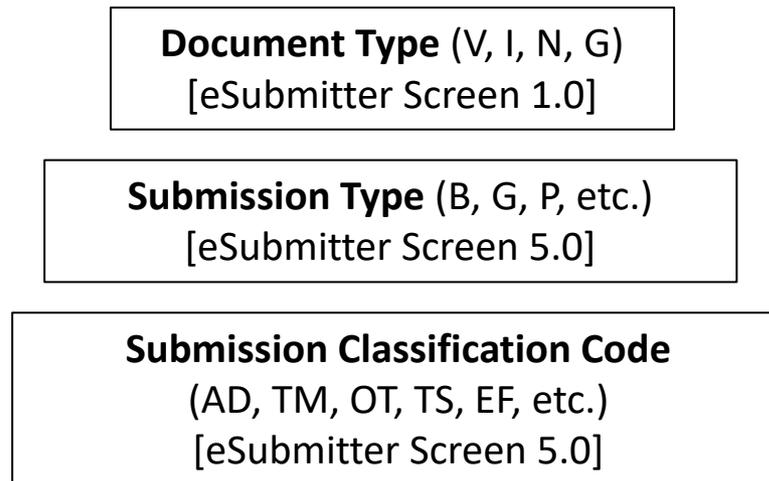
For a basic understanding of CVM eSubmitter, watch the recording of “Webinar 2: How to Use the eSubmitter Tool”. The webinar covers how to:

- Download and install CVM eSubmitter,
- Launch eSubmitter and basic navigation,
- Create a new submission,
- Use the address book feature,
- Understand business rules (responses trigger template changes),
- Attach files,
- Finalize and package a submission, and
- Submit data, information, and requests to CVM and view CVM responses.

To view the webinar, see the website: <https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center>

Document Types, Submission Types, and Submission Classification Codes

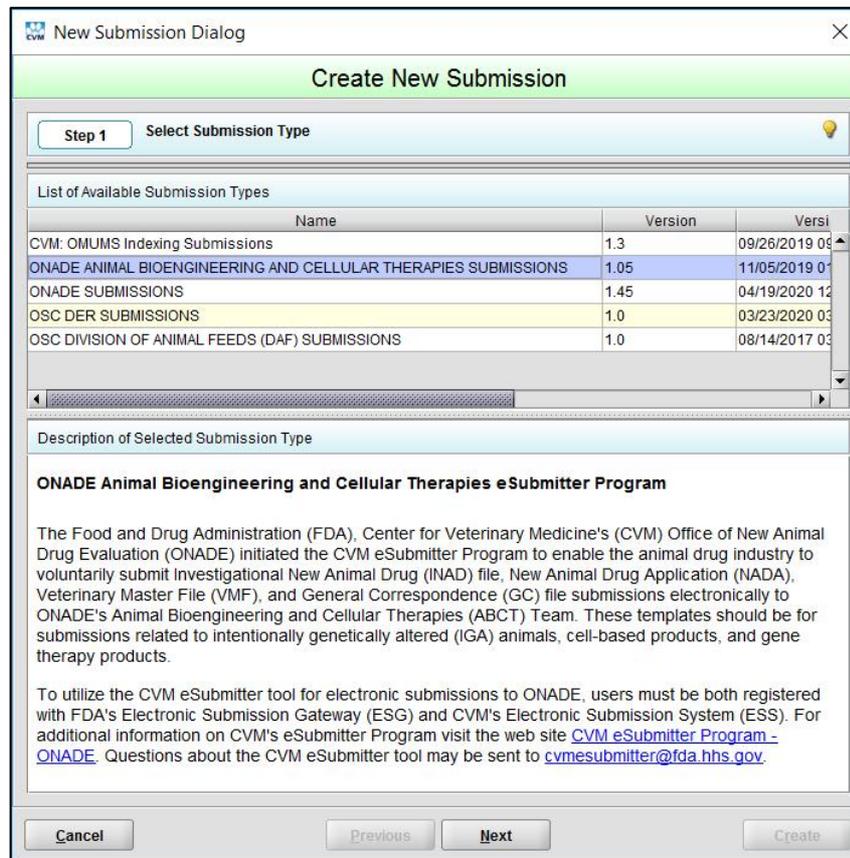
The graphic below shows the relationship between **Document Types**, **Submission Types**, and **Submission Classification Codes**. The **Document Type** is based on the stage of product development. The **Submission Type** and **Submission Classification Code** are based on the type of information that is being submitted.



The next few slides describe how to select the **Document Type**, **Submission Type**, and **Submission Classification Code**.

Creating a Submission for IGAs and ACTPs

When opening CVM eSubmitter, there is a list of available **Submission Types**. Select “ONADE Animal Bioengineering and Cellular Therapies Submissions”.



New Submission Dialog

Create New Submission

Step 1 Select Submission Type

List of Available Submission Types

Name	Version	Version
CVM: OMUMS Indexing Submissions	1.3	09/26/2019 08
ONADE ANIMAL BIOENGINEERING AND CELLULAR THERAPIES SUBMISSIONS	1.05	11/05/2019 01
ONADE SUBMISSIONS	1.45	04/19/2020 12
OSC DER SUBMISSIONS	1.0	03/23/2020 03
OSC DIVISION OF ANIMAL FEEDS (DAF) SUBMISSIONS	1.0	08/14/2017 03

Description of Selected Submission Type

ONADE Animal Bioengineering and Cellular Therapies eSubmitter Program

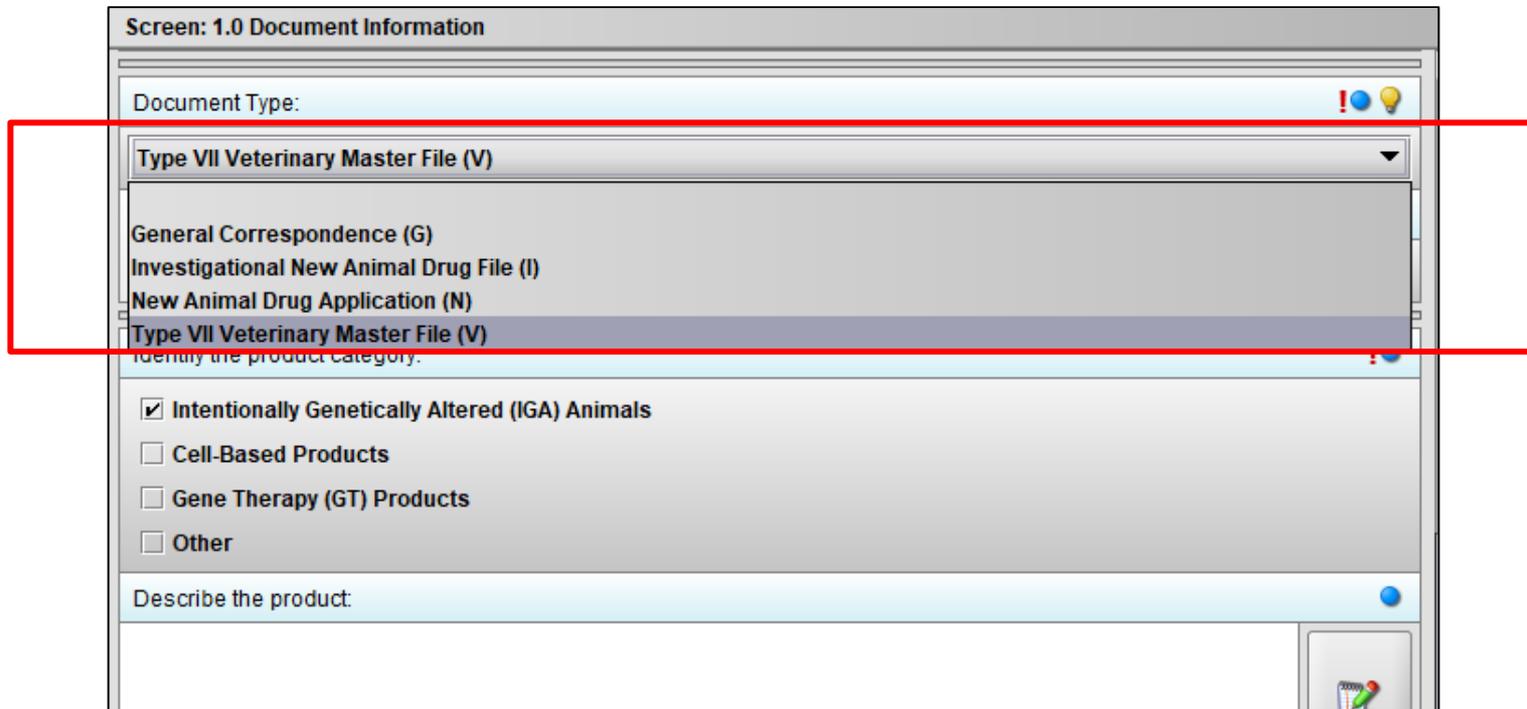
The Food and Drug Administration (FDA), Center for Veterinary Medicine's (CVM) Office of New Animal Drug Evaluation (ONADE) initiated the CVM eSubmitter Program to enable the animal drug industry to voluntarily submit Investigational New Animal Drug (INAD) file, New Animal Drug Application (NADA), Veterinary Master File (VMF), and General Correspondence (GC) file submissions electronically to ONADE's Animal Bioengineering and Cellular Therapies (ABCT) Team. These templates should be for submissions related to intentionally genetically altered (IGA) animals, cell-based products, and gene therapy products.

To utilize the CVM eSubmitter tool for electronic submissions to ONADE, users must be both registered with FDA's Electronic Submission Gateway (ESG) and CVM's Electronic Submission System (ESS). For additional information on CVM's eSubmitter Program visit the web site [CVM eSubmitter Program - ONADE](#). Questions about the CVM eSubmitter tool may be sent to cvmesubmitter@fda.hhs.gov.

Cancel Previous Next Create

Selecting a Document Type in CVM eSubmitter

The first screen is Screen 1.0 Document Information, as shown here. There are four different options for the **Document Type** (highlighted by the red box). The four **Document Type** selections are described in detail on the next slide.





Document Types

There are four **Document Types**² in CVM eSubmitter:

- 1. Investigational New Animal Drug (INAD; I):** to submit information for the phased review process for an approval (for more information on phased review, see GFI #132 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-132-administrative-applications-and-phased-review-process>).
- 2. New Animal Drug Application (NADA; N):** to request approval for a new product or to submit information to an established NADA for an approved product.

² For questions regarding the appropriate **Document Type**, please contact the Project Manager or the ONADE Project Management Team at CVM_PM_Biotech@fda.hhs.gov.

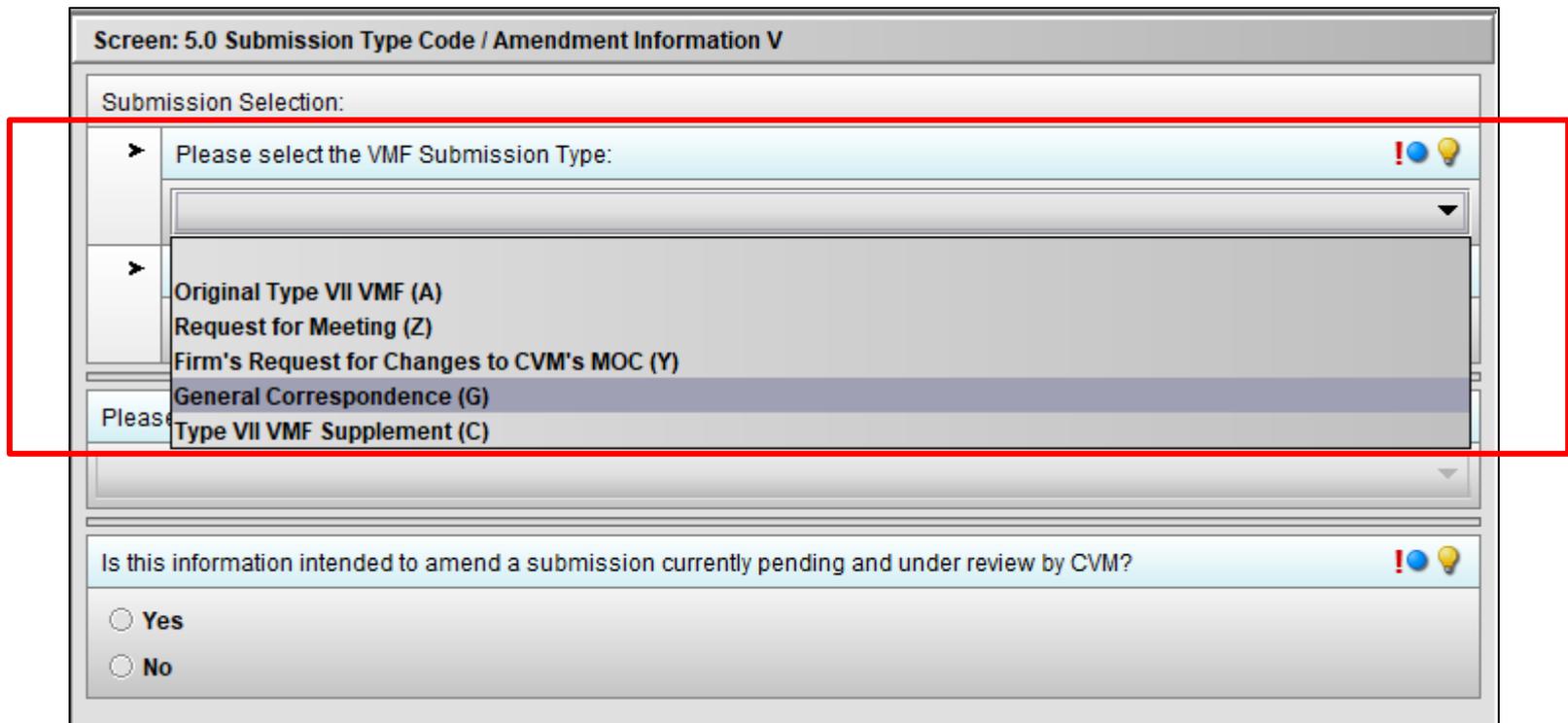
Document Types (cont'd)

3. **Type VII Veterinary Master File (VMF; V):** to provide the following information:
 - Pre-Investigational Development (PID): the early stages of product development that typically take place prior to determining the precise product and indication that will be the subject of an NADA. PID usually takes place prior to the establishment of an INAD.
 - Products that are not intended to go through the NADA approval pathway, such as products used only for research.

4. **General Correspondence (GC; G):** to discuss one or two high-level questions that are not specific to a VMF, INAD, or NADA with CVM. The **GC Document Type** is rarely used and should not be confused with a “G” **Submission Type**.

Selecting a Submission Type

In Screen 5.0 of CVM eSubmitter, as shown here, select the **Submission Type** (highlighted in the red box). For this image, the **Submission Type** selected is “General Correspondence” or “G.”



Screen: 5.0 Submission Type Code / Amendment Information V

Submission Selection:

➤ Please select the VMF Submission Type: !💡

➤

- Original Type VII VMF (A)
- Request for Meeting (Z)
- Firm's Request for Changes to CVM's MOC (Y)
- General Correspondence (G)**
- Type VII VMF Supplement (C)

Please

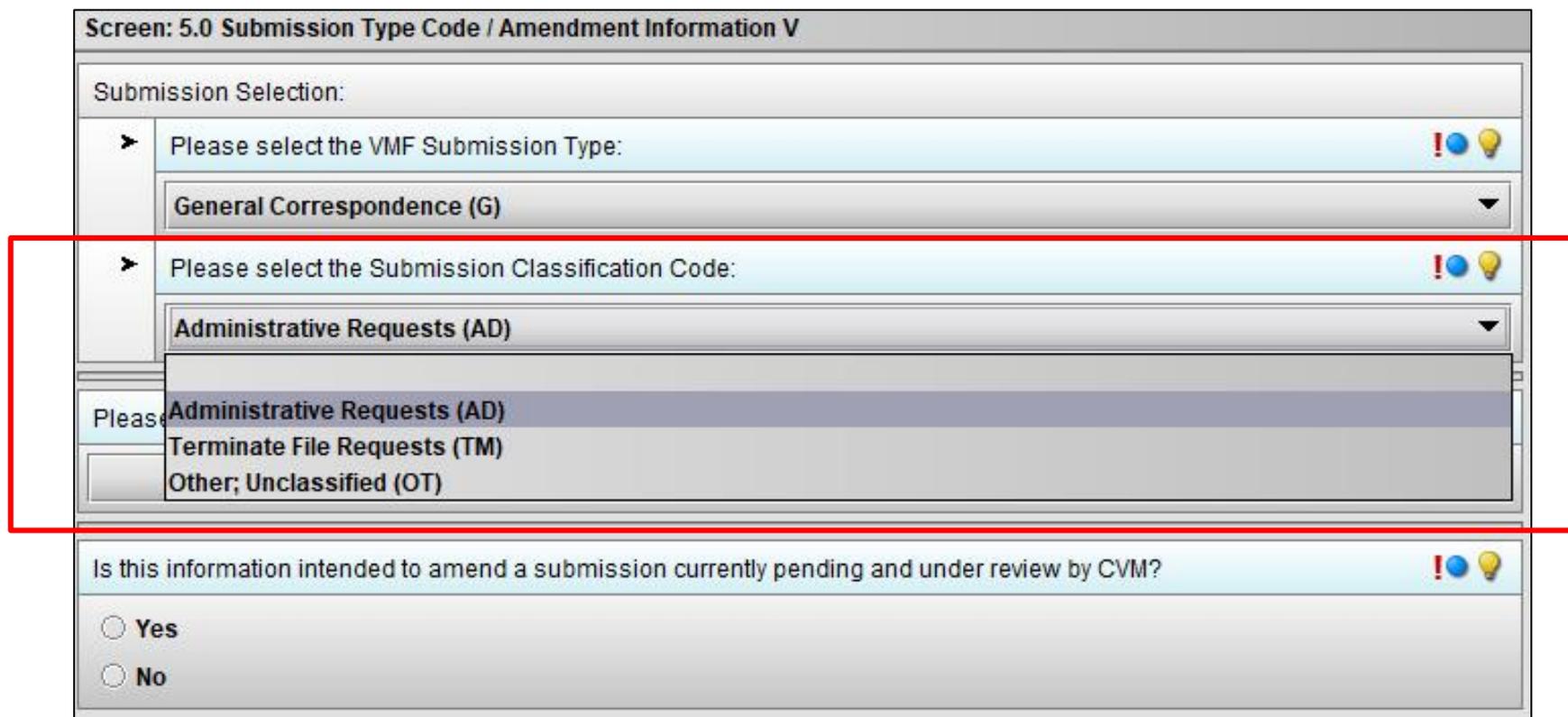
Is this information intended to amend a submission currently pending and under review by CVM? !💡

Yes

No

Selecting the Submission Classification Code

Next, select a **Submission Classification Code (SCC)**. For this image, the SCC selected is “Administrative Requests” or “AD” (highlighted by the red box).



Screen: 5.0 Submission Type Code / Amendment Information V

Submission Selection:

▶ Please select the VMF Submission Type: ! ?

General Correspondence (G) ▼

▶ Please select the Submission Classification Code: ! ?

Administrative Requests (AD) ▼

Administrative Requests (AD)

Terminate File Requests (TM)

Other; Unclassified (OT)

Is this information intended to amend a submission currently pending and under review by CVM? ! ?

Yes

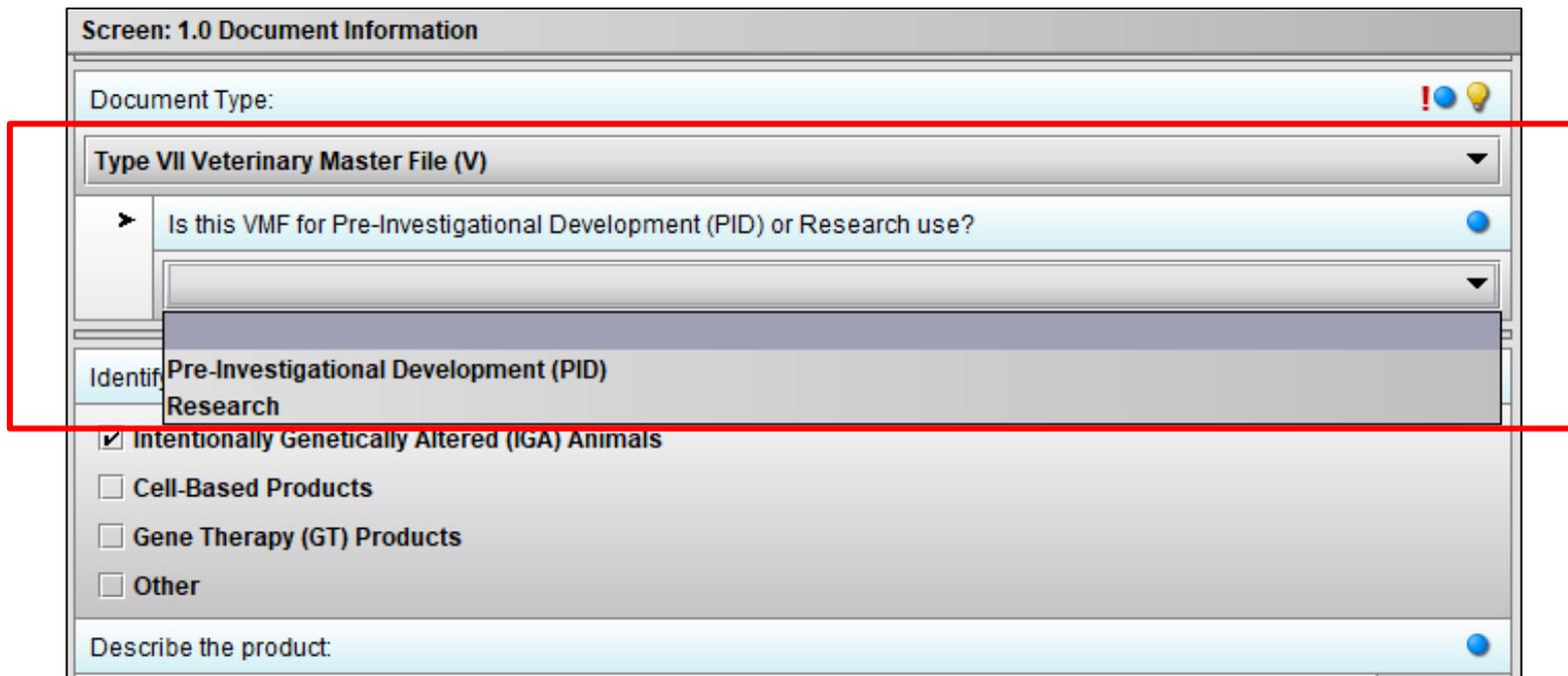
No



Examples

Example 1: Selecting a VMF Document Type

After selecting VMF in Screen 1.0 of CVM eSubmitter, there is a second question asking, “Is this VMF for Pre-Investigational Development (PID) or Research use?” (see the red box). Select “PID” when in the early stages of research or when commercialization is the end goal. Select “Research” when the goal is simply to conduct research (i.e., not pursuing an approval).



Screen: 1.0 Document Information

Document Type: ! ?

Type VII Veterinary Master File (V)

Is this VMF for Pre-Investigational Development (PID) or Research use? ?

Identif Pre-Investigational Development (PID)
Research

Intentionally Genetically Altered (IGA) Animals

Cell-Based Products

Gene Therapy (GT) Products

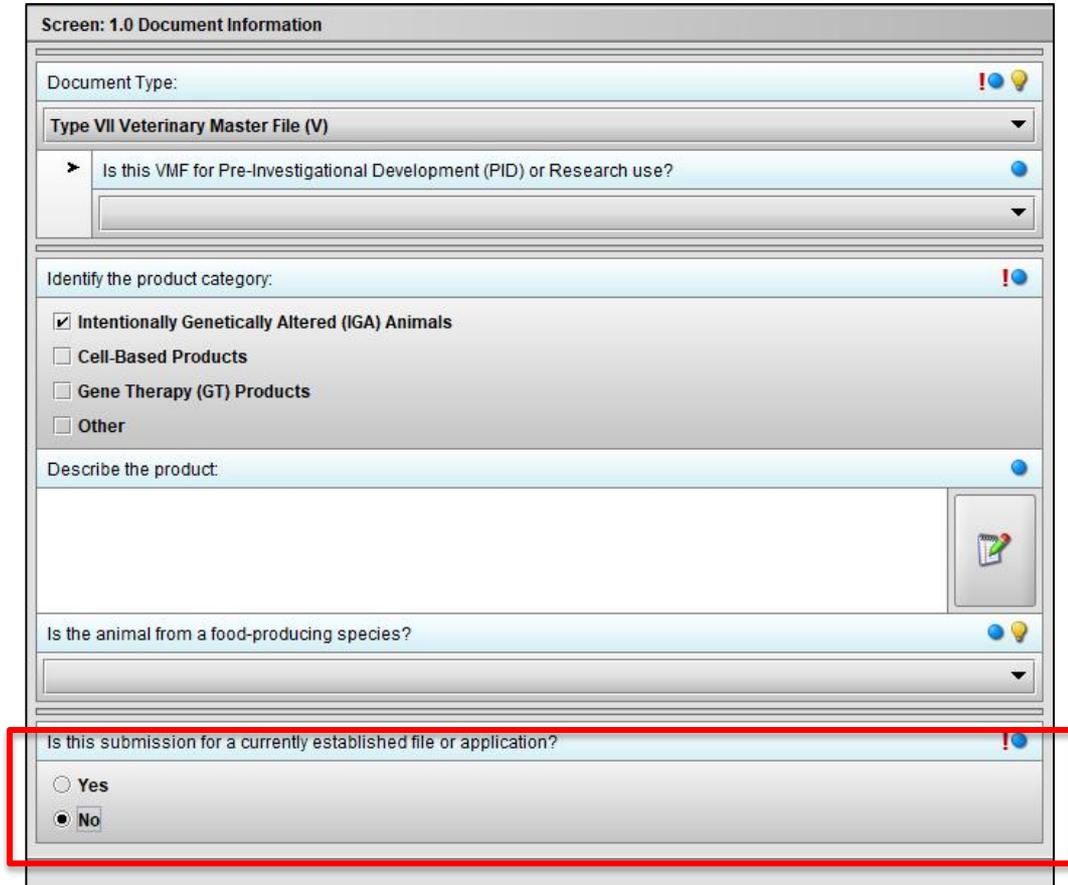
Other

Describe the product: ?

Example 1: VMF, established files question

To request a new file or application, select “no” (red circle) for the question “Is this submission for a currently established file or application” and a document number will be assigned upon receipt of the submission.

This document number will be included in the submission receipt (.zip file). Open the zip file to see the attachment with the document number.



Screen: 1.0 Document Information

Document Type: ! ?

Type VII Veterinary Master File (V)

Is this VMF for Pre-Investigational Development (PID) or Research use? ?

Identify the product category: ! ?

Intentionally Genetically Altered (IGA) Animals

Cell-Based Products

Gene Therapy (GT) Products

Other

Describe the product: ?

Is the animal from a food-producing species? ? !

Is this submission for a currently established file or application? ! ?

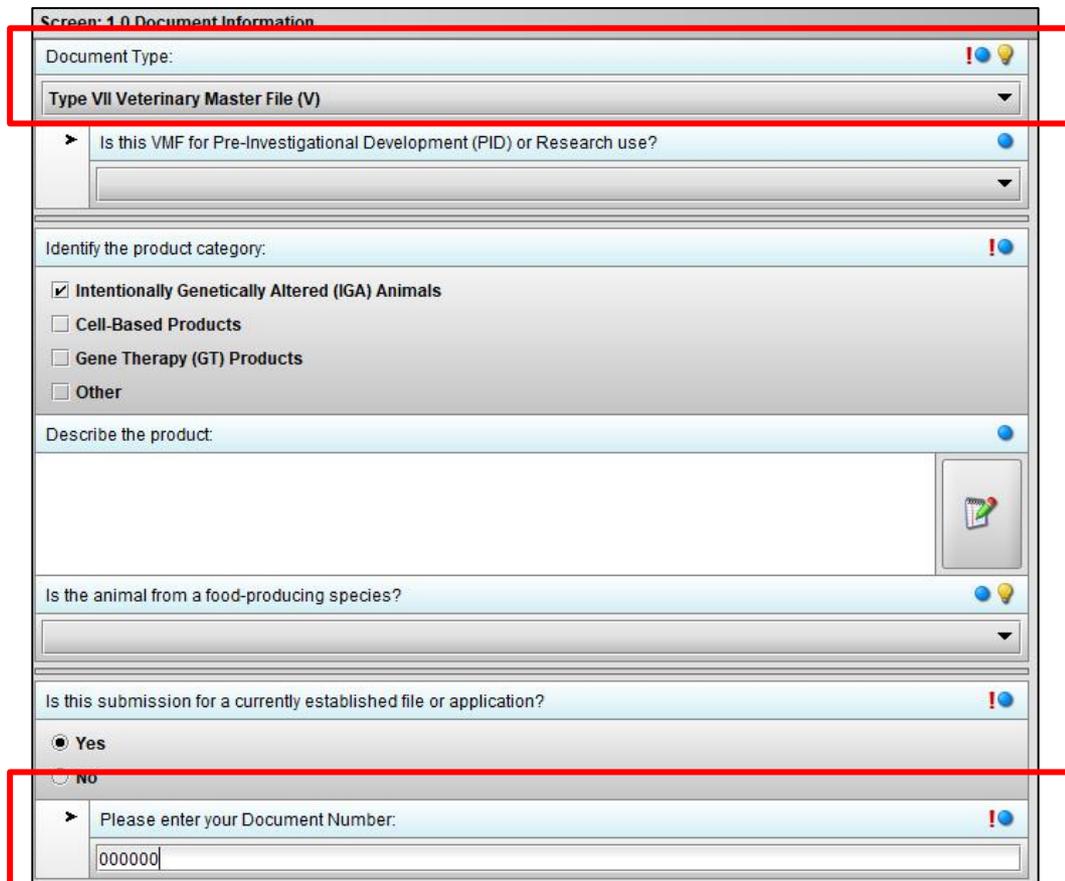
Yes

No

Example 1: VMF, document type and number

Next, select whether the file has already been established. For established files, the **Document Type** selected (top red box) must match the **Document Type** that the document number³ is assigned to (bottom red box).

For example, if “VMF” is selected for the **Document Type** but the document number is associated with an INAD **Document Type**, then the submission will be rejected.



Screen: 1.0 Document Information

Document Type: ! ?
 Type VII Veterinary Master File (V)

Is this VMF for Pre-Investigational Development (PID) or Research use?

Identify the product category: ! ?
 Intentionally Genetically Altered (IGA) Animals
 Cell-Based Products
 Gene Therapy (GT) Products
 Other

Describe the product: ?

Is the animal from a food-producing species? ! ?

Is this submission for a currently established file or application? ! ?
 Yes
 No

Please enter your Document Number: ! ?
 000000

³ If you do not know your six-digit document number, then please contact the ONADE Project Management Team at CVM_PM_Biotech@fda.hhs.gov.

Example 2: Submission Classification Codes (SCCs)



Specific **SCC** options are associated with each **Submission Type**. For example, there are three available **SCC** options on Screen 5.0 under the General Correspondence “G” **Submission Type**.

Option (SCC):	Administrative requests (AD)	Terminate file request (TM)	Other; unclassified (OT)
Used to:	<ul style="list-style-type: none"> • Transfer ownership • Change firm address • Change firm name • Change Responsible Official/ U.S. Agent 	<ul style="list-style-type: none"> • Terminate a file 	<ul style="list-style-type: none"> • Request participation in the Veterinary Innovation Program • Request permission to share file • Submit information related to an adverse event • Request review of the proprietary name • Submit DABCT annual reports (for INADs and VMFs)

Example 2: SSC Selection - continued

In this example, the **Document Type** selected is “VMF”, the **Submission Type** selected is “General Correspondence” or “G,” and the **SCC** selected is “administrative requests” or “AD”. The general information specific to this submission is entered in a new tab (highlighted by the red circle).

The screenshot shows the FDA submission software interface. On the left is the 'Outline' pane, and on the right is the 'Screen: 1.0 General Information' pane. A red circle highlights the '1.0 General Information' tab in the Outline pane.

Outline:

- Submission Type Selection (VMF)
- ONADE Animal Bioengineering and Cellular Therapies Submi...
- Product Information
 - General Correspondence (AD)
- 1.0 General Information** (highlighted)
- 1.1 Document Types and Numbers Table
- 1.2 Firm Name/Address
- 1.3 Responsible Official/ U.S. Agent
- 1.4 New Owner Information
 - 1.4.1 U.S. Agent Information
 - 1.4.2 Responsible Official Information
 - 1.4.3 New Owner Letter of Acceptance
 - 1.4.4 Acknowledgement
 - 1.4.5 Former Owner Notification Letter
- 2.0 Comments

Screen: 1.0 General Information:

Is the purpose of the submission to Transfer Ownership of the Document? Yes No

Select the purpose of submission (select all that apply):

- Change of Firm Name
- Change of Firm Address
- Change of Responsible Official/ U.S. Agent

Does this change request apply to additional Documents? Yes No

Does this change request apply to all of the Documents owned? Yes No

Example 3: Difference between Document Type “GC” and Submission Type “G”

Both the **Document Type** “GC” and a **Submission Type** “G” refer to “general correspondence”. The difference between them is:

- The **Document Type** “G” or “GC” is a file used for discussions that occur when there is no other file (INAD, NADA, or VMF) associated with the product.
 - Developers use this **Document Type** if they have one or two high-level questions that they would like to discuss with CVM.
 - This **Document Type** is rarely used and should not be confused with a “G” **Submission Type**.
- A **Submission Type** “G” is used for general correspondences to a file (VMF, INAD, NADA, or GC)
 - Developers use this **Submission Type** to submit administrative or general information or to request termination of the file.



Questions?

For general questions about the review process for IGAs and ACTPs, contact the ONADE Project Management team at CVM_PM_Biotech@fda.hhs.gov

For specific questions about eSubmitter, contact the eSubmitter help desk at cvmesubmitter@fda.hhs.gov

For all other general animal product-related inquiries, contact AskCVM@fda.hhs.gov

