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

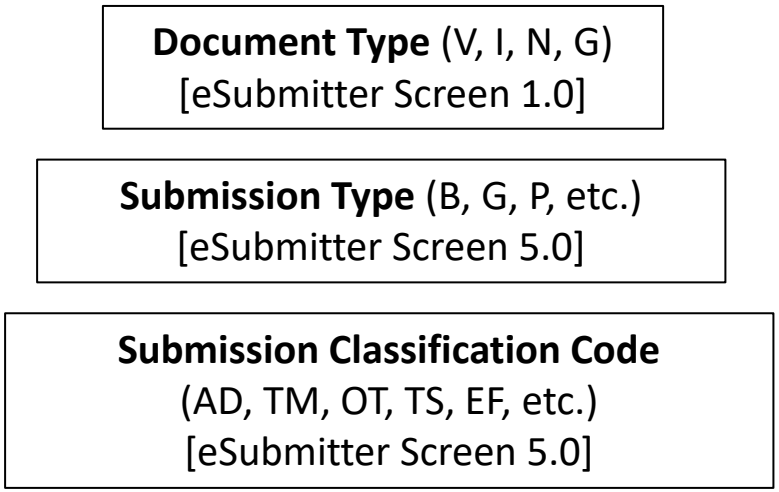
For a basic understanding of CVM eSubmitter, watch the recording of "Webinar 2: How to Use the eSubmitter Tool". The webinar covers how to:

- 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

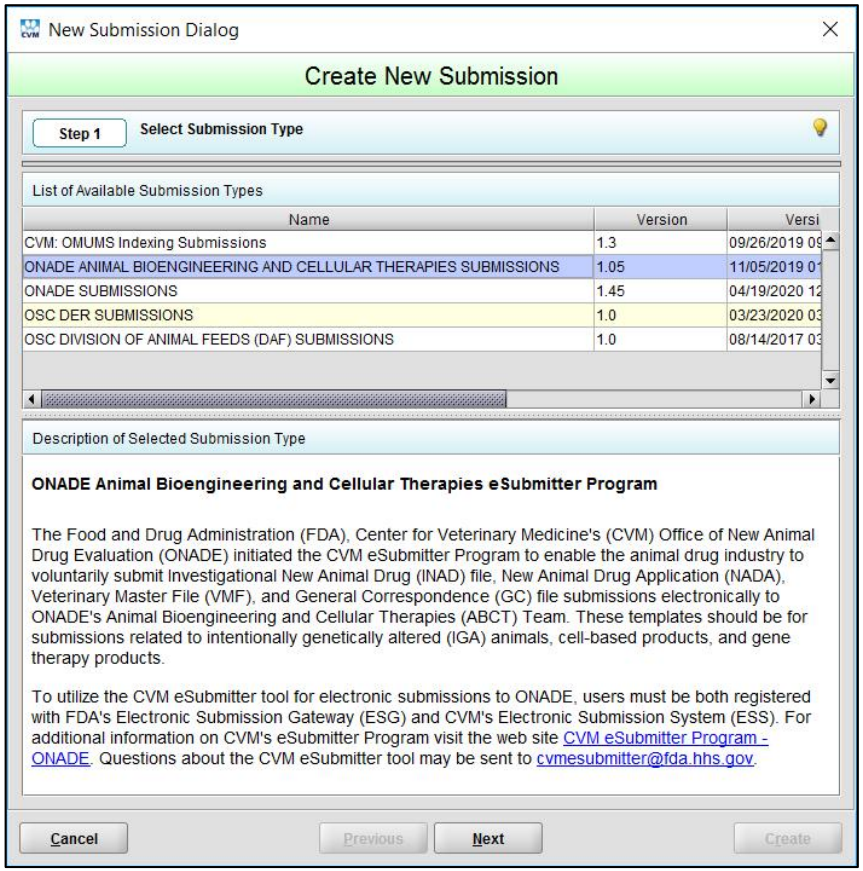
The graphic below shows the relationship between **Document Types**, **Submission Types**, and **Submission Classification Codes**. The **Document Type** is based on the stage of product development. The **Submission Type** and **Submission Classification Code** are based on the type of information that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



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

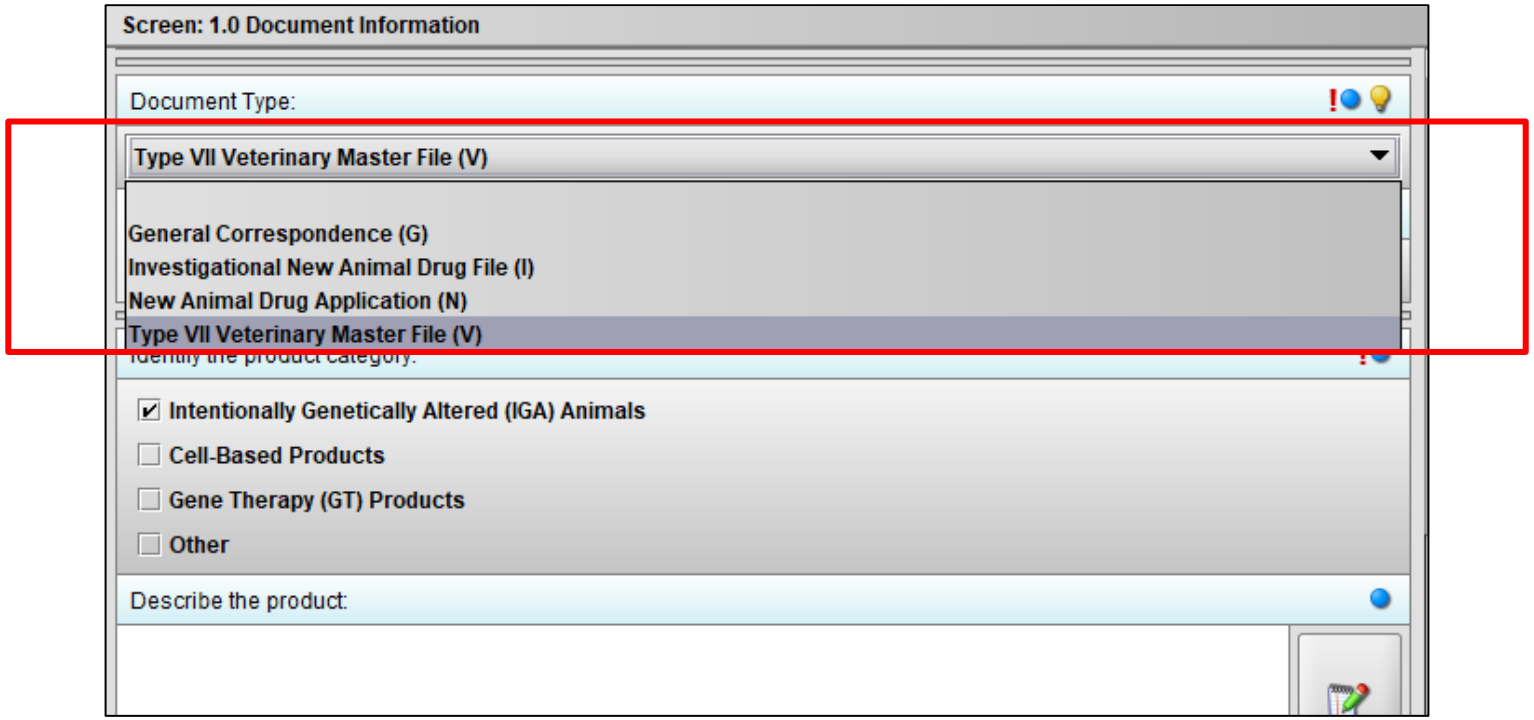
Creating a Submission for IGAs and ACTPs

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



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.

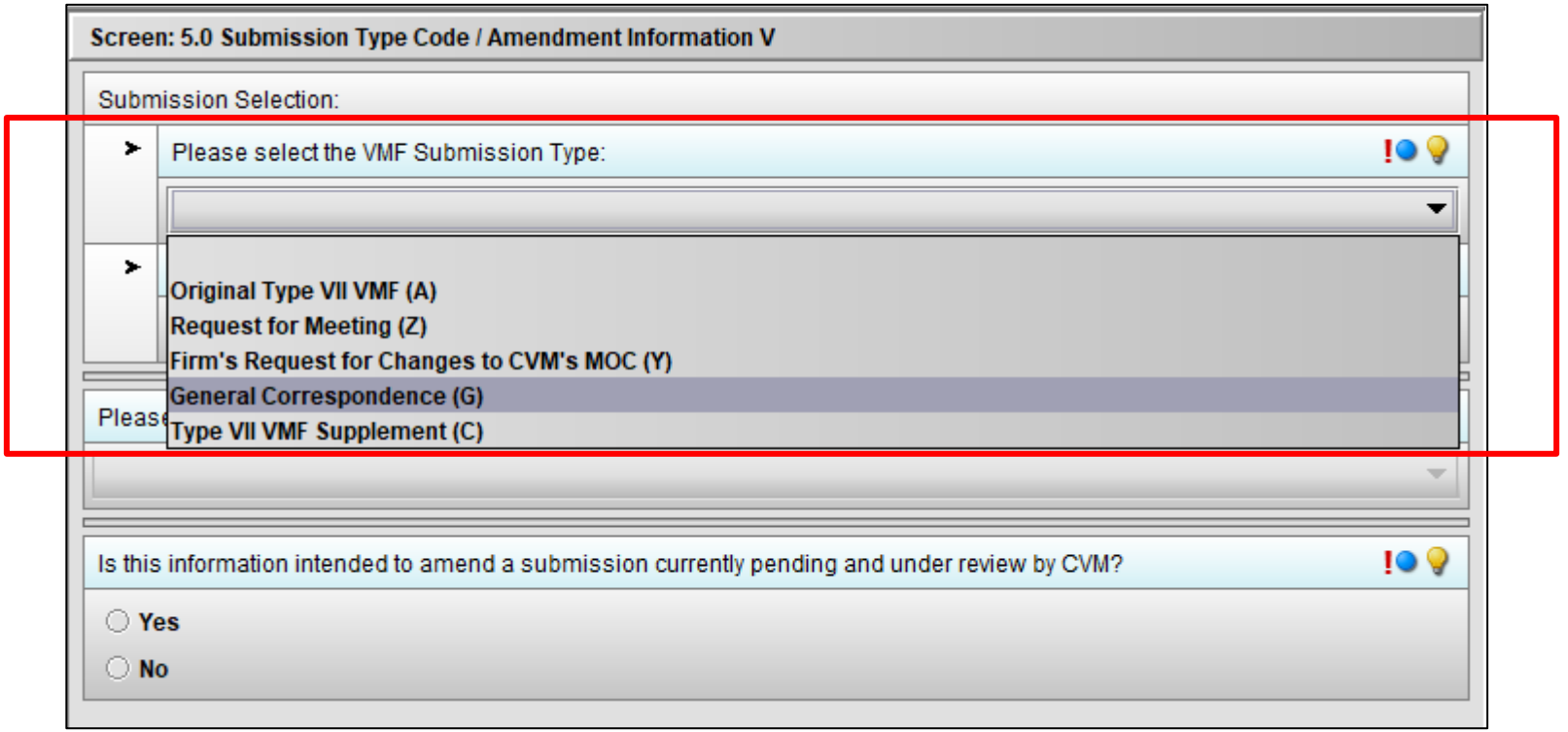
Document Types (cont'd)

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**.

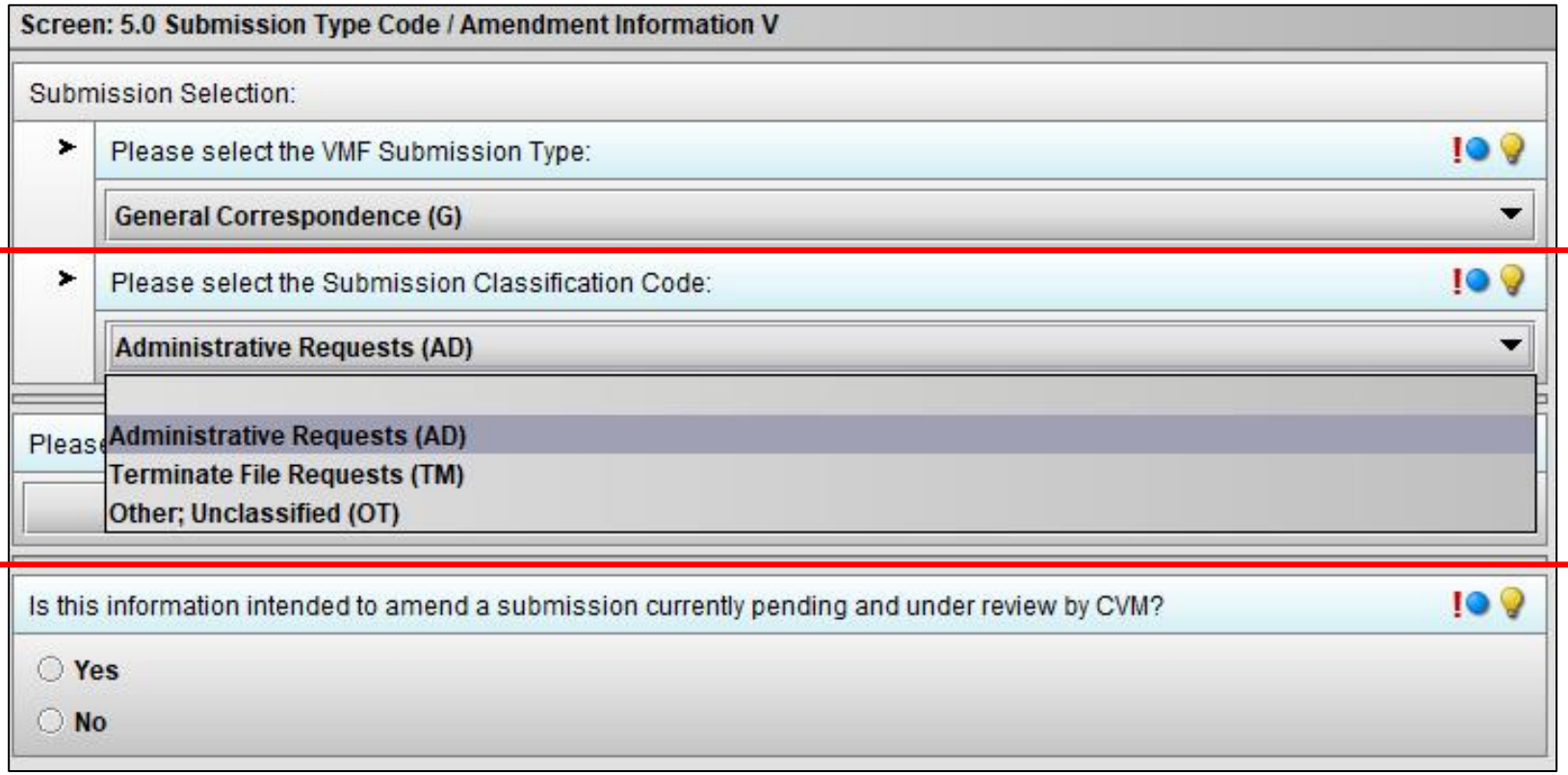
Selecting a Submission Type

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.”



Selecting the Submission Classification Code

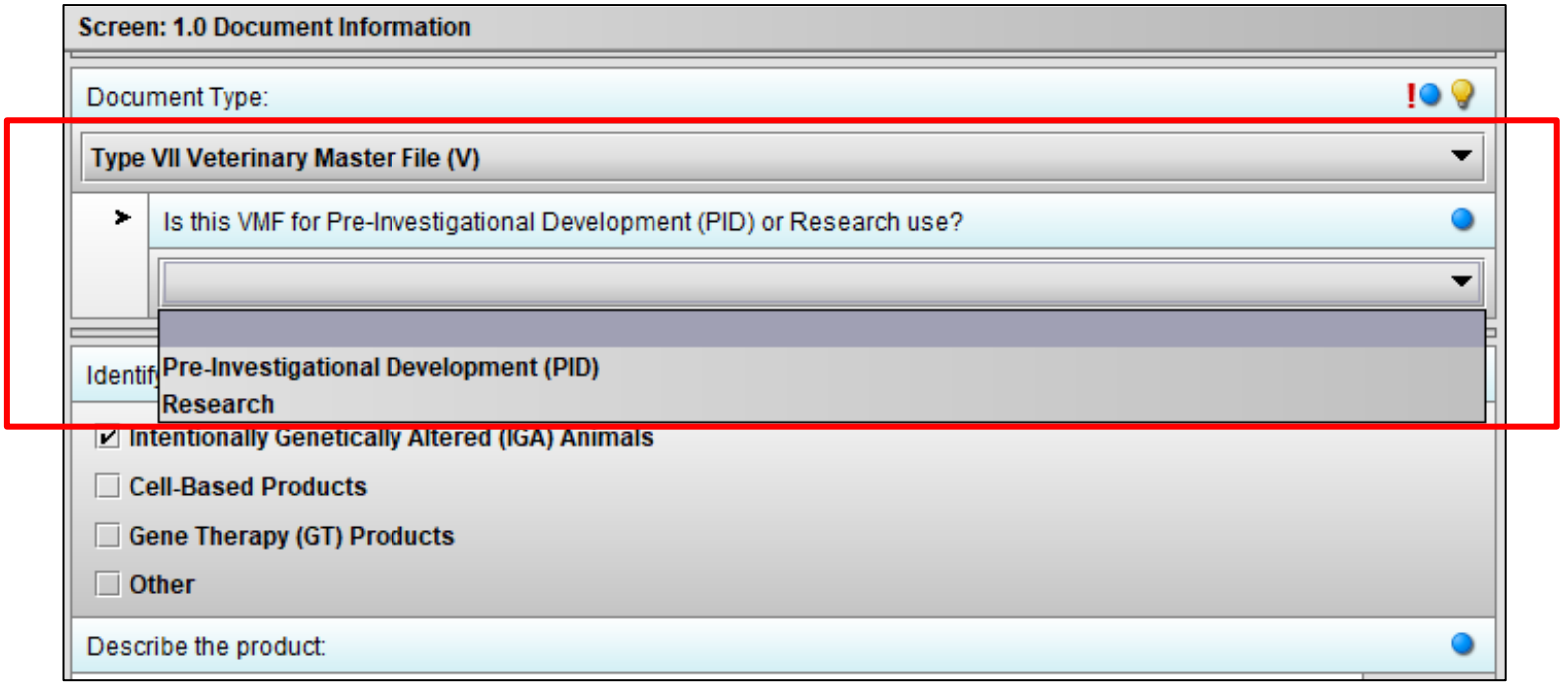
Next, select a **Submission Classification Code (SCC)**. For this image, the **SCC** selected is “Administrative Requests” or “AD” (highlighted by the red box).



Examples

Example 1: Selecting a VMF Document Type

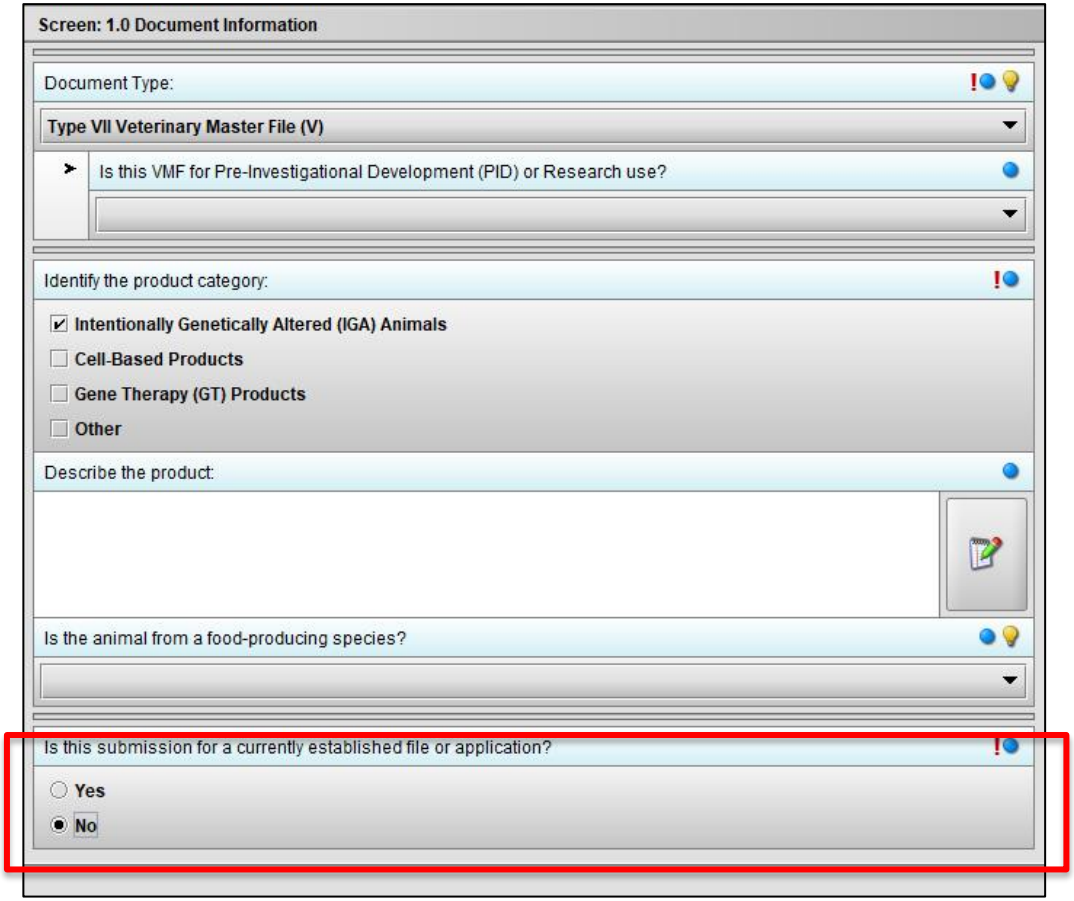
After selecting VMF in Screen 1.0 of CVM eSubmitter, there is a second question asking, “Is this VMF for Pre-Investigational Development (PID) or Research use?” (see the red box). Select “PID” when in the early stages of research or when commercialization is the end goal. Select “Research” when the goal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



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.

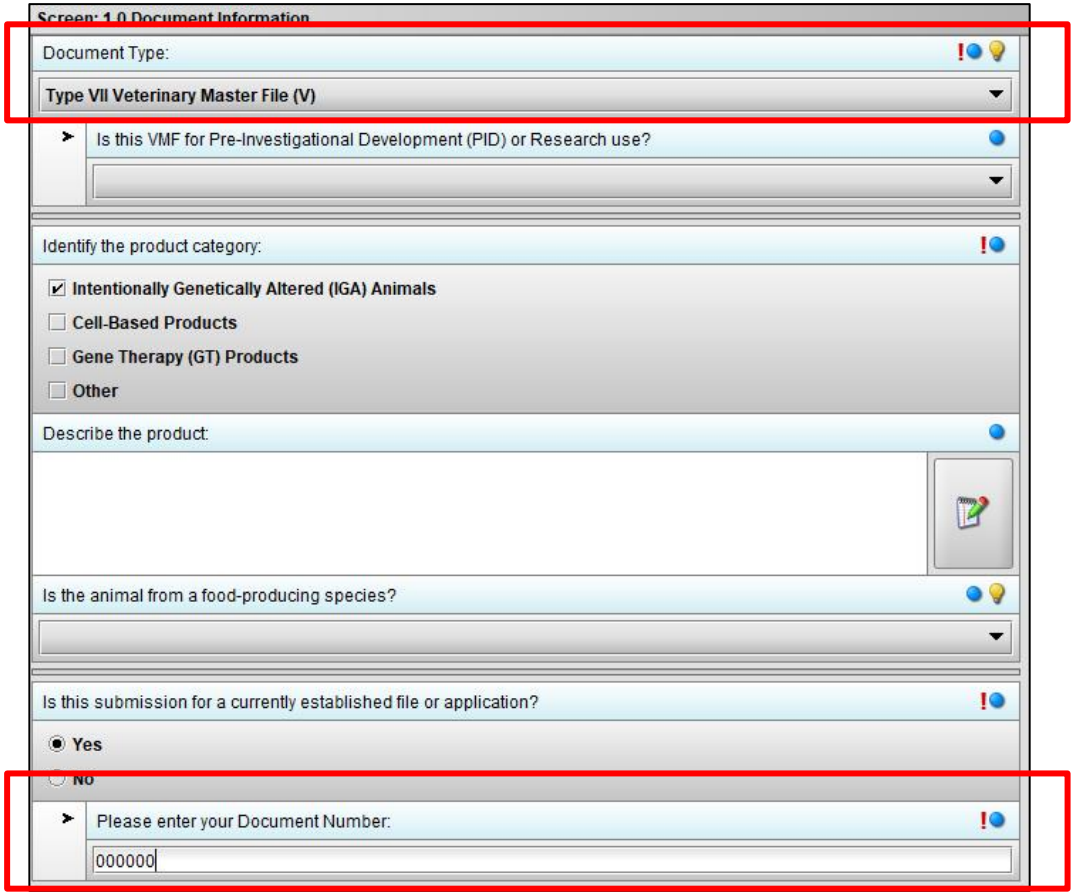
This document number will be included in the submission receipt (.zip file). Open the zip file to see the attachment with the document number.



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 number[3] 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.



[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.

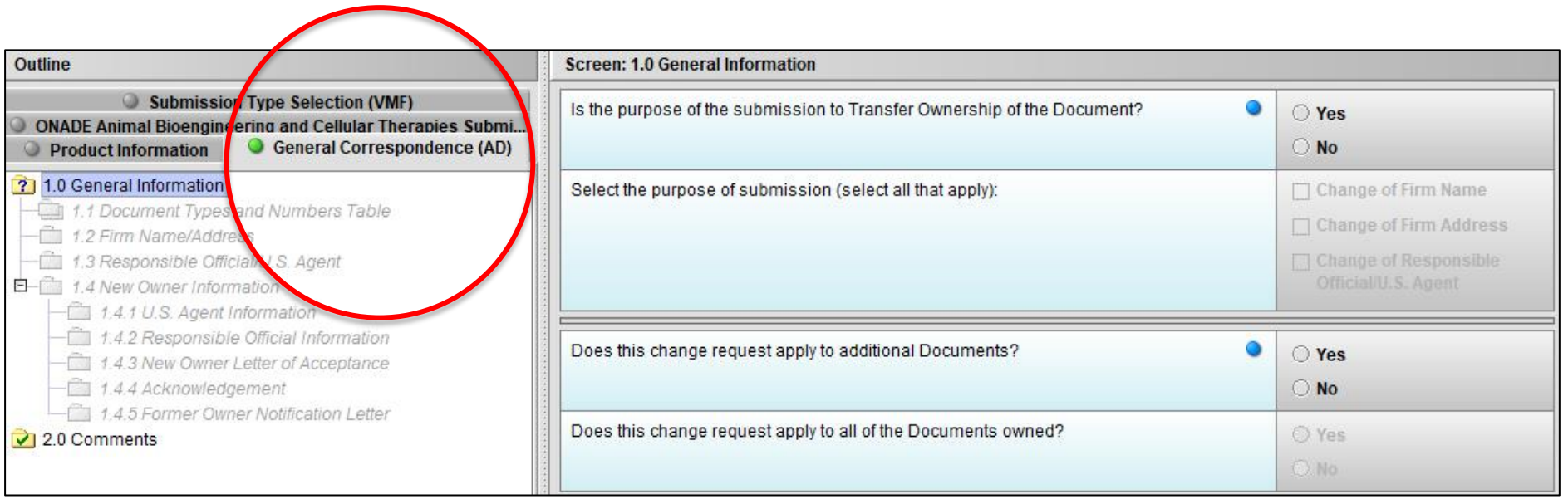
Example 2: Submission Classification Codes (SCCs)

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:	• Transfer ownership • Change firm address • Change firm name • Change Responsible Official/ U.S. Agent	• Terminate a file	• 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).



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 revew 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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