

CVM's OSC Drug Experience Report (DER) eSubmitter Program

Division of Surveillance
Office of Surveillance and Compliance
FDA, Center for Veterinary Medicine

Introduction

- In July 2017, CVM launched the CVM Drug Experience Reporting (DER) eSubmitter Program
- Type of Submissions Accepted:
 - 21 CFR 514.80, Form FDA 2301
 - Periodic Drug Experience Reports (DERs)
 - Other or Special DERs
 - 21 CFR 514.87, Form FDA 3744
 - Antimicrobial Animal Drug Distribution Reports

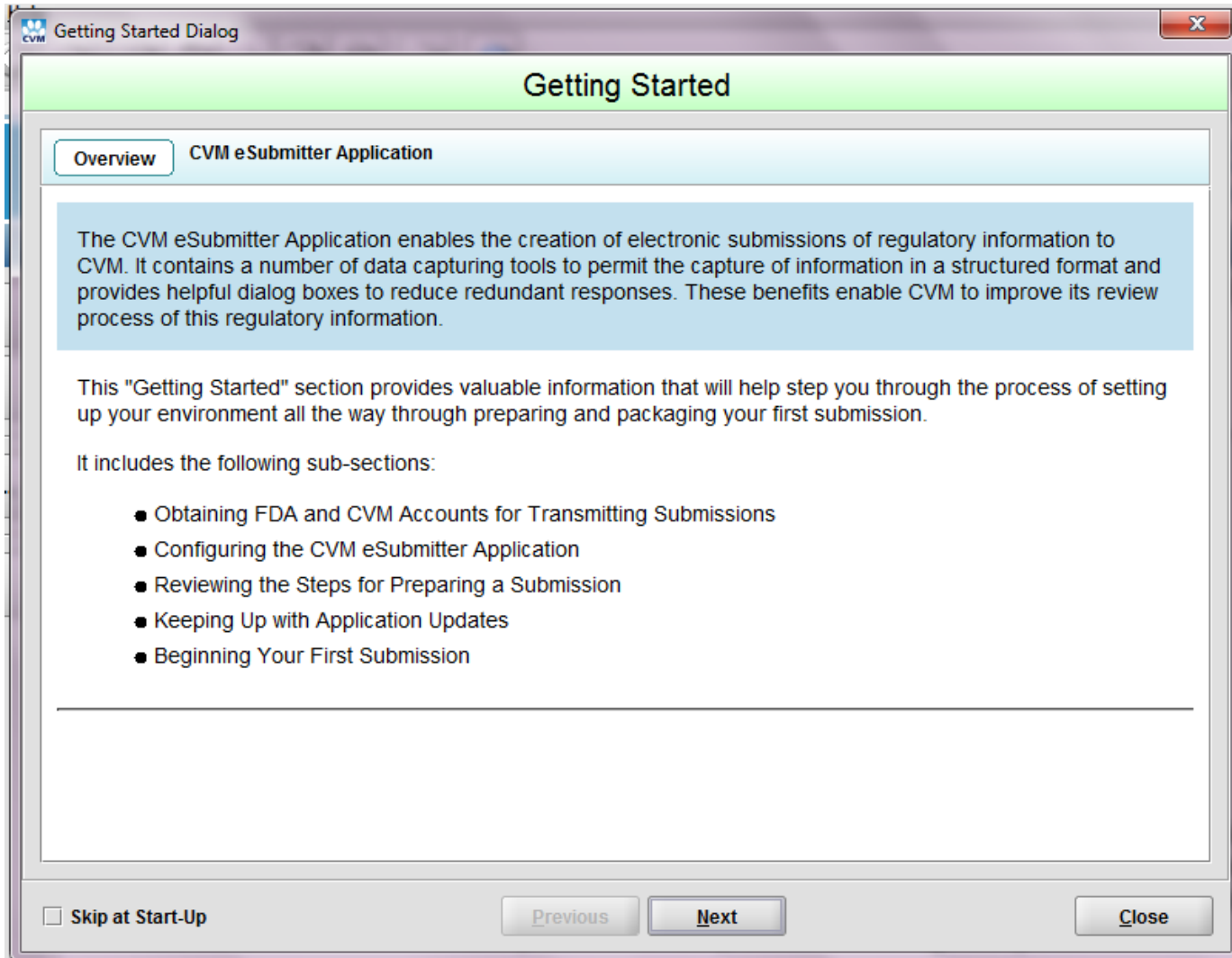
Requirements

- Install CVM eSubmitter Application
 - Launched August 2017
 - Users will not be able to create submissions in FDA eSubmitter as of December 2017
- Register with the FDA Electronic Submissions Gateway (ESG),
- Register with CVM's Electronic Submission System (ESS), and
- Acquire a digital certificate to authenticate your submission and transmit through the FDA ESG.

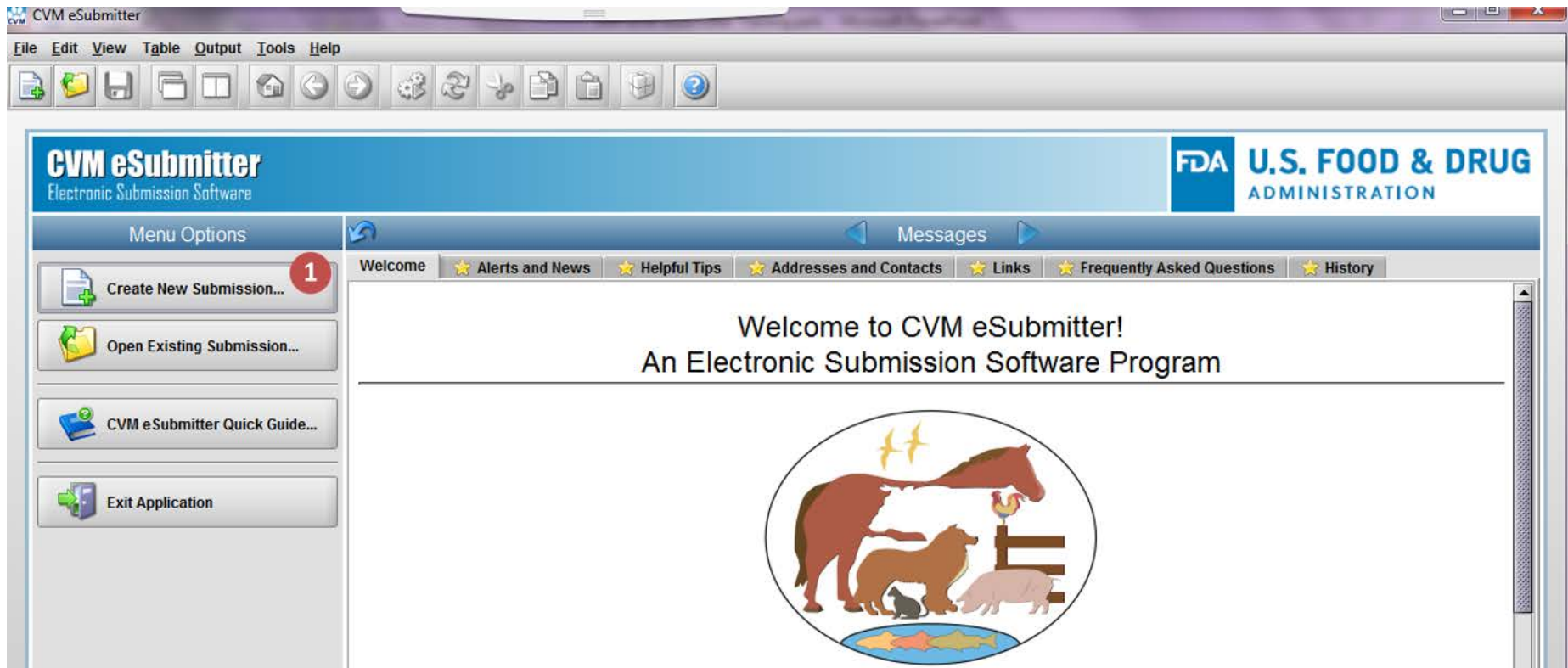
Additional Information is available at:

- Getting Started with eSubmitter:
<https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm404711.htm>
- CVM eSubmitter Resource Center:
<https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm415389.htm>
- In the eSubmitter Application:
 - Getting Started Dialog and Help Menu
 - Resource tabs on the introductory screen
 - CVM eSubmitter Quick Guides

Getting Started

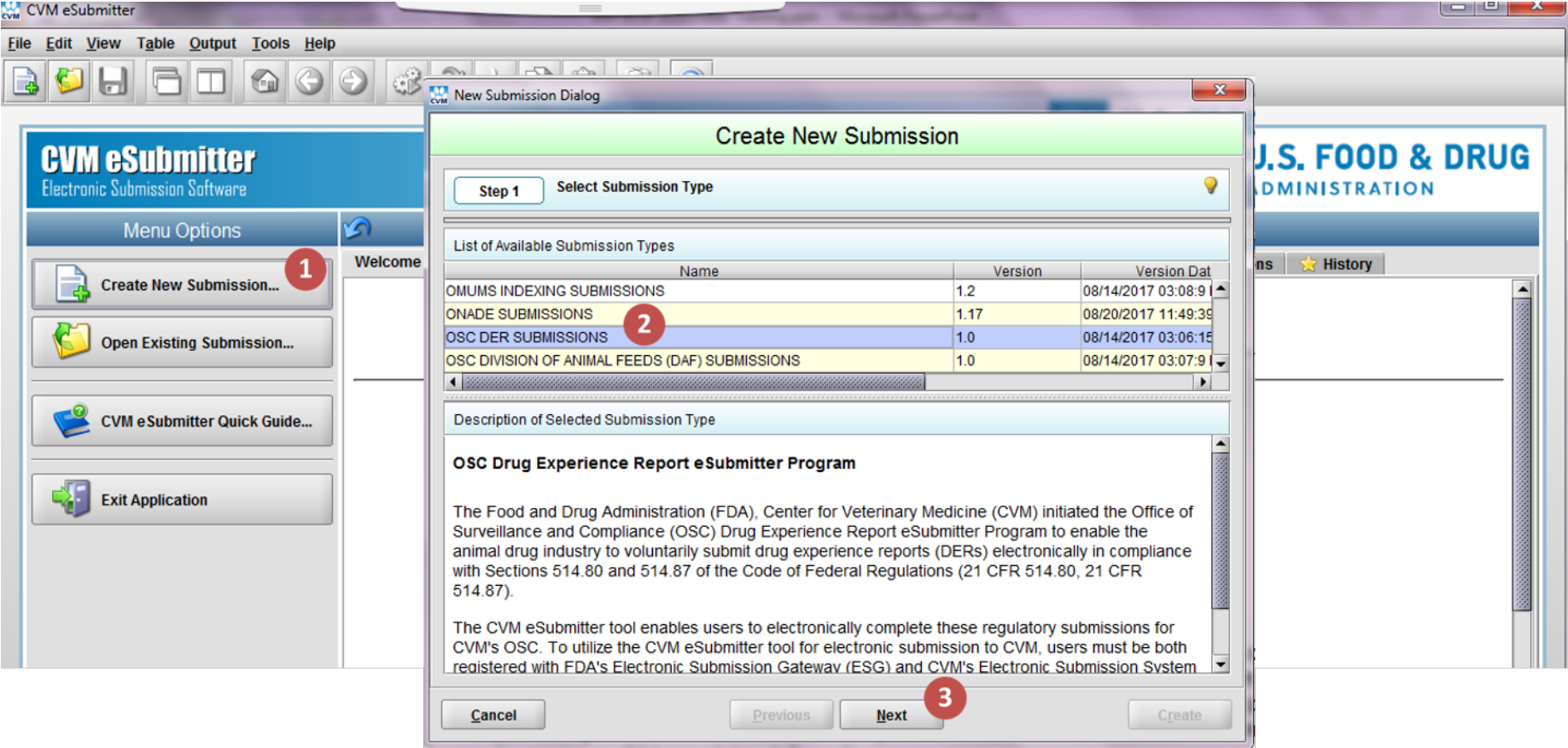


CVM eSubmitter – Creating a Submission



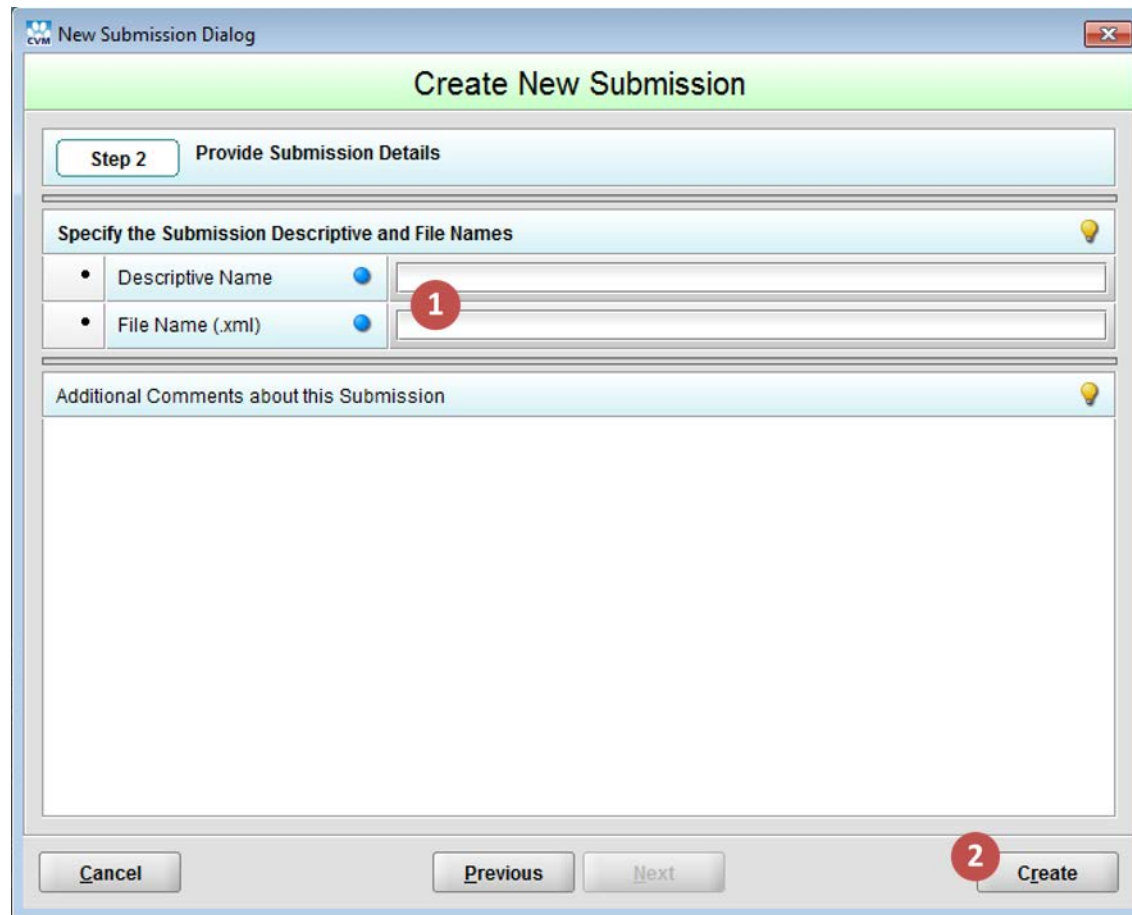
OSC DER eSubmitter Program

Select OSC DER Submissions from dropdown



Submission Creation

Assign a descriptive name and file name to “Create” submission




The screenshot shows a software dialog box titled "New Submission Dialog" with a sub-header "Create New Submission". It is in "Step 2: Provide Submission Details". The main section is "Specify the Submission Descriptive and File Names", which contains two input fields: "Descriptive Name" and "File Name (.xml)". A red circle with the number "1" is positioned over the "File Name (.xml)" field. Below this is a large text area for "Additional Comments about this Submission". At the bottom, there are buttons for "Cancel", "Previous", "Next", and "Create". A red circle with the number "2" is positioned over the "Create" button.

Submission Creation

Core Questions

- Enter (A)NADA information



Is this submission for an NADA or ANADA? 

Enter the NADA or ANADA number  

Blue dot: required field for successful completion of a report

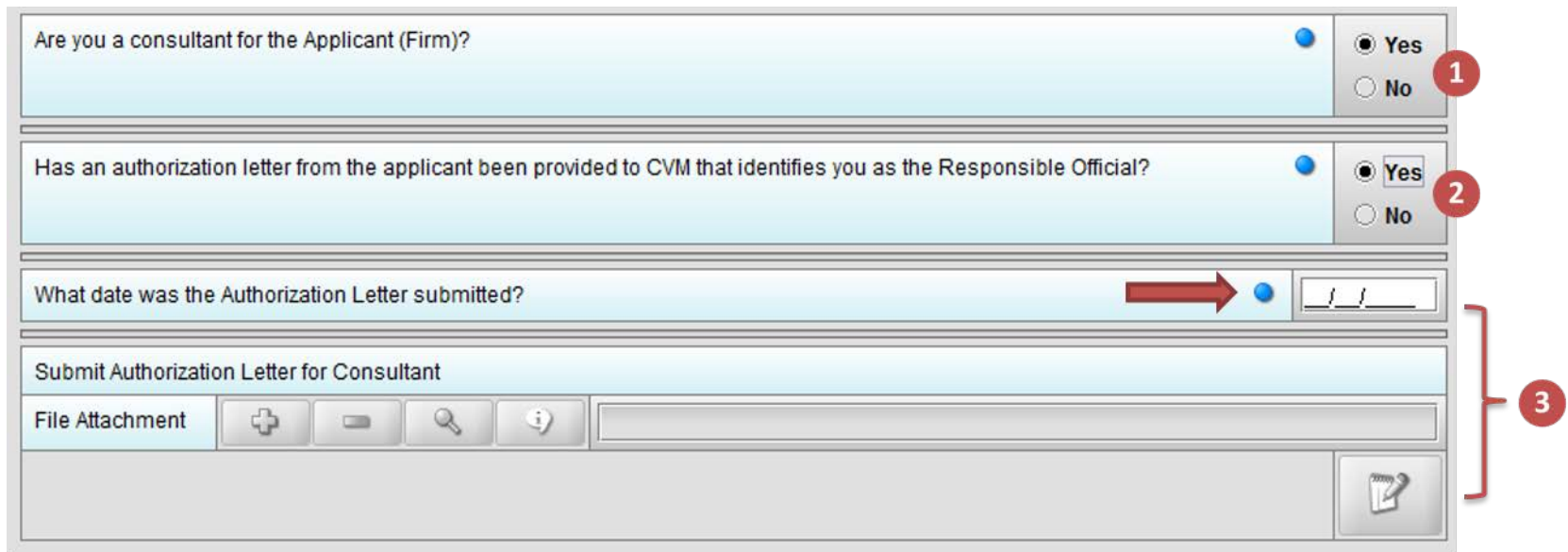
Red exclamation point: critical required questions, must be answered to move forward in the template

Light bulb: additional instructions, definitions and other helpful hints

Firm Information

Core Questions continued

- Enter Firm Name/US Company?
 - US Agent or Responsible Official
 - Submitter Contact Information (if different than Responsible Official)
- Authorization Letter



Are you a consultant for the Applicant (Firm)? Yes No 1

Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official? Yes No 2

What date was the Authorization Letter submitted? 3

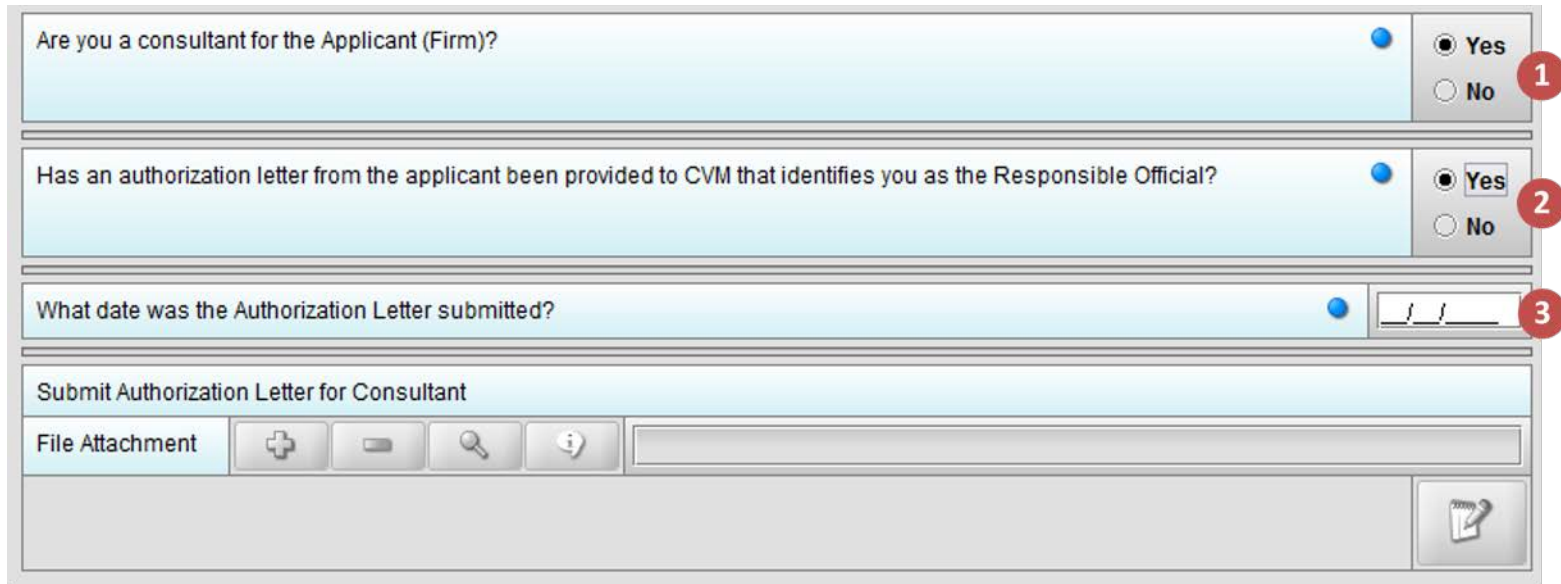
Submit Authorization Letter for Consultant

File Attachment

Firm Information

Core Questions continued

- Enter Firm Name/US Company?
 - US Agent or Responsible Official
 - Submitter Contact Information (if different than Responsible Official)
- Authorization Letter (Previously provided)



The screenshot shows a web form with four main sections. The first section asks 'Are you a consultant for the Applicant (Firm)?' with radio buttons for 'Yes' and 'No', and a red circle with the number '1' next to the 'Yes' option. The second section asks 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?' with radio buttons for 'Yes' and 'No', and a red circle with the number '2' next to the 'Yes' option. The third section asks 'What date was the Authorization Letter submitted?' with a date input field and a red circle with the number '3' next to it. The fourth section is titled 'Submit Authorization Letter for Consultant' and contains a 'File Attachment' area with a plus sign, a minus sign, a search icon, and an information icon, followed by a text input field and a document icon button.

Firm Information

Core Questions continued





- Authorization Letter (attachment)
 - To provide a file attachment, select the green plus sign
 - DER eSubmitter templates currently only accept PDF file attachments

Are you a consultant for the Applicant (Firm)? Yes No 1

Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official? Yes No 2

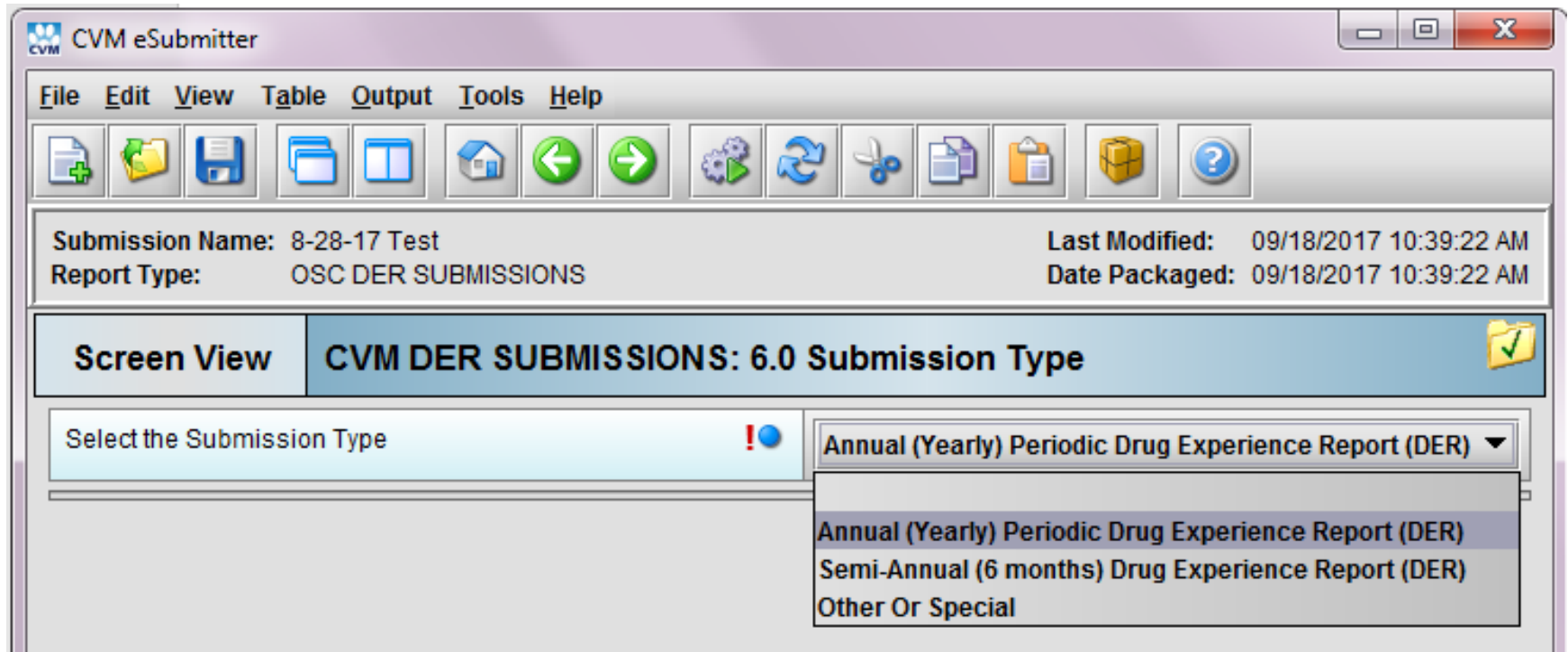
What date was the Authorization Letter submitted?

Submit Authorization Letter for Consultant

File Attachment  3   



Submission Selection

Annual, Semi-Annual, Other or Special







Annual DER

- Confirm all Semi-Annual Reports have been submitted

Have all 4 required Semi-Annual (6 months) DERs been submitted?		<input checked="" type="radio"/> Yes <input type="radio"/> No
 CAUTION: If all 4 Semi-Annual DERs have not been submitted and received by CVM, then the annual DER will not be accepted and processed by CVM.		








- Enter Report Due Date and Reporting Period


What is the Report Due Date for the Annual DER?	 	<input type="text" value="__/__/__"/>
▶ What is the Report Period for this Annual DER Submission?		<input type="text" value="__/__/__"/> to <input type="text" value="__/__/__"/>
▶  WARNING: Report period for the Annual DER should cover a full 12 months. Make sure Annual DERs for all prior reporting periods have been submitted to avoid delinquent reporting.		

Note: State in the Comments section at the end of the report if the Report Period is more or less than 12 months

Combined Annual DER

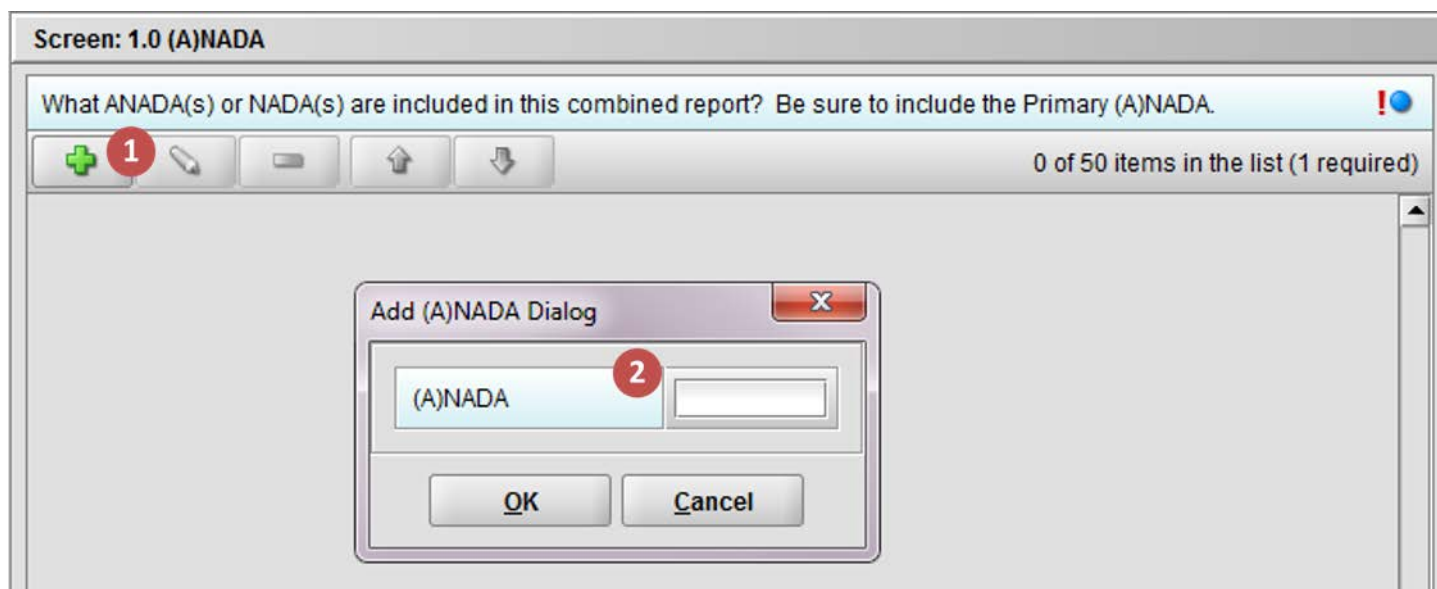
Combined report question is equivalent to Box 7 on the Form FDA 2301

 CAUTION: If all 4 Semi-Annual DERs have not been submitted and received by CVM, then the annual DER will not be accepted and processed by CVM.	
What is the Report Due Date for the Annual DER?	  <input type="text" value="01/01/2018"/>
▶ What is the Report Period for this Annual DER Submission?	 <input type="text" value="01/01/2017"/> to <input type="text" value="12/31/2017"/>
▶  WARNING:	Report period for the Annual DER should cover a full 12 months. Make sure Annual DERs for all prior reporting periods have been submitted to avoid delinquent reporting.
Is this a combined report?	  <input checked="" type="radio"/> Yes <input type="radio"/> No

 Hint for: Is this a combined report?
A combined report consists of multiple NADA or ANADA numbers attached to a single filing (21 CFR 514.80(c)).

Combined Annual DER

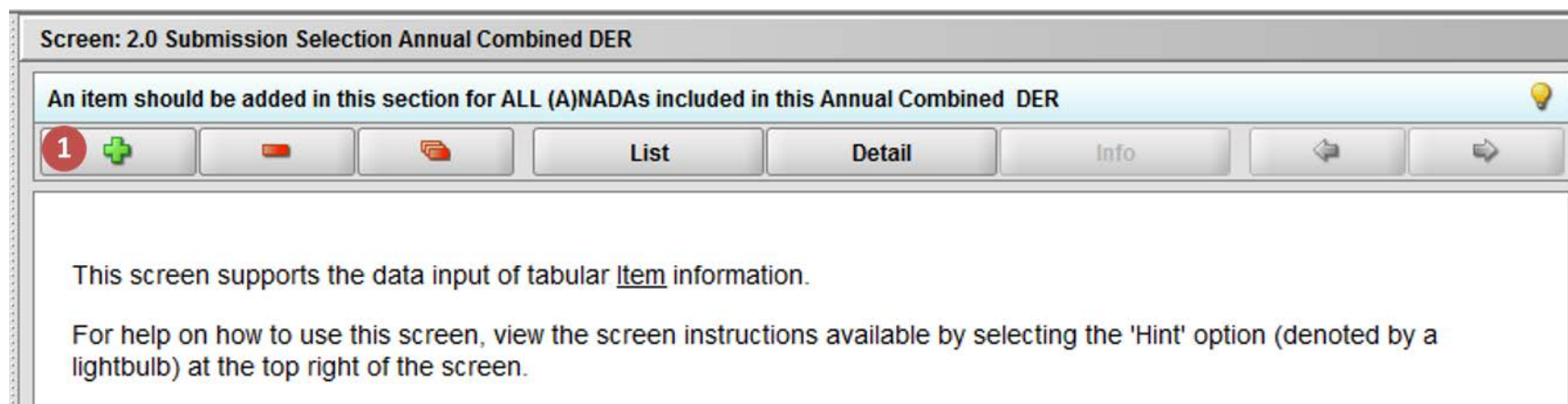
- Enter all (A)NADAs, including the primary (A)NADA



Note: Repeat steps 1 & 2 as needed to add additional (A)NADAs to the list

Combined Annual DER – Proprietary Name and Chemical Name

- Combined Reports use tabular data entry screens
- Provide proprietary and chemical names for ALL (A)NADAs included in a combined report



*Note: **Info** view displays guidance information describing the options available*

Combined Annual DER – Proprietary Name and Chemical Name

Screen: 2.0 Submission Selection Annual Combined DER

An item should be added in this section for ALL (A)NADAs included in this Annual Combined DER

List **Detail** **Info**

Item: 1

The (A)NADAs in the following dropdown list are sorted in numerical order.

What ANADA(s) or NADA(s) are included in this combined report? **2**


What is the Proprietary Name? **3**




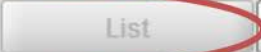




What is the Chemical Name of this new animal drug?

*Note: **Detail** view displays the individual questions for data entry*

Combined Annual DER – Proprietary Name and Chemical Name


Screen: 2.0 Submission Selection Annual Combined DER

An item should be added in this section for ALL (A)NADAs included in this Annual Combined DER 



>	Item	Additional A/NADA (s)	What is the Proprietary Name?	What is the Chemical Name of this new animal drug?
	1	141001	Drug A	ingredient A
	2	200001	Drug A + Drug B	ingredient A, ingredient B
▶	3	200002	Drug A + Drug C	ingredient A, ingredient C

Note:


- **List** view displays a list referencing all items included
- Additional instructions for the tabular screen are available in the hint 
- In the other sections of a combined report (e.g. clinical data, current package labeling):
 - Provide information for at least the primary (A)NADA
 - Quantity Marketed questions must be answered for all (A)NADAs


Annual DER – Proprietary Name and Chemical Name

The remainder of this demonstration is for an **Annual DER** (non-combined)

Is this a combined report?   Yes No

Screen: 1.0 Submission Selection - Annual DER

What is the Proprietary Name? 

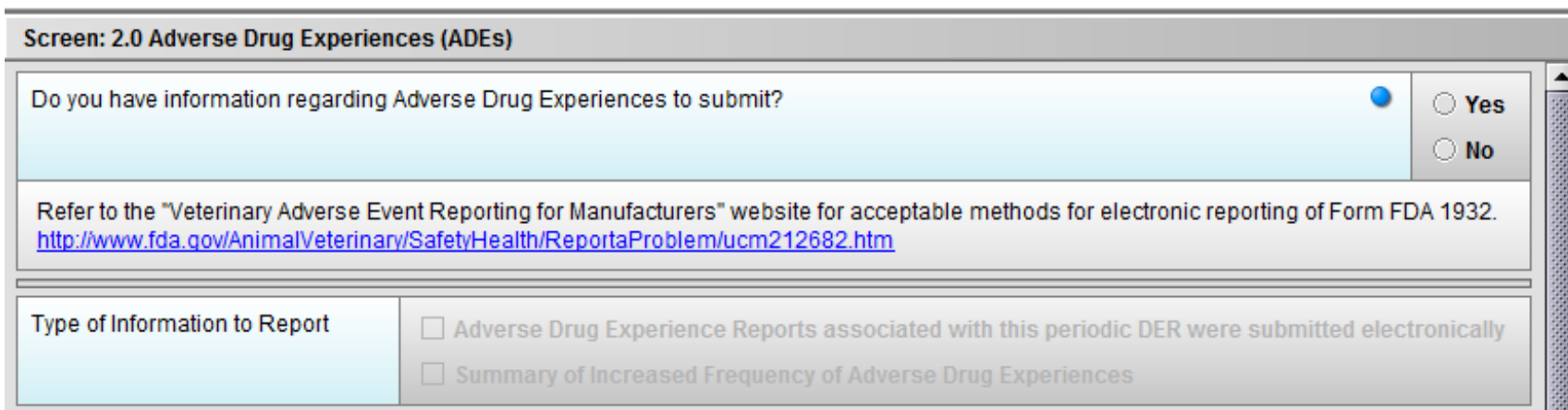
What is the Chemical Name of this new animal drug? 

Annual DER – ADE Information

NOTE: Adverse Drug Experience Reports (ADEs) on Form FDA 1932 are not to be submitted in eSubmitter

Refer to the Veterinary Adverse Event Reporting for Manufacturers website for acceptable methods for electronic reporting of ADEs:

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm212682.htm>



Screen: 2.0 Adverse Drug Experiences (ADEs)

Do you have information regarding Adverse Drug Experiences to submit? Yes No

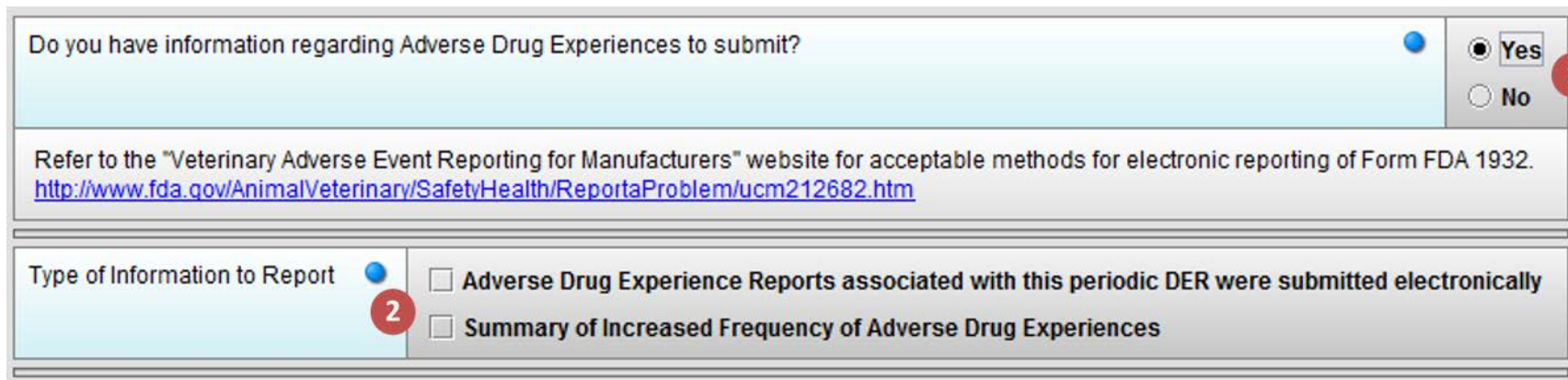
Refer to the "Veterinary Adverse Event Reporting for Manufacturers" website for acceptable methods for electronic reporting of Form FDA 1932.
<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm212682.htm>

Type of Information to Report

- Adverse Drug Experience Reports associated with this periodic DER were submitted electronically
- Summary of Increased Frequency of Adverse Drug Experiences

Annual DER – ADE Information

- Type of information to report:
 - Select one or both options as necessary
 - Data entry sections will be enabled or disabled based on selection(s)



Do you have information regarding Adverse Drug Experiences to submit? Yes No 1

Refer to the "Veterinary Adverse Event Reporting for Manufacturers" website for acceptable methods for electronic reporting of Form FDA 1932.
<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm212682.htm>

Type of Information to Report 2

Adverse Drug Experience Reports associated with this periodic DER were submitted electronically

Summary of Increased Frequency of Adverse Drug Experiences

Annual DER – ADE Information

Select the first option to provide information regarding ADEs that were submitted electronically

Screen: 2.0 Adverse Drug Experiences (ADEs)

Do you have information regarding Adverse Drug Experiences to submit? Yes No **1**

Refer to the "Veterinary Adverse Event Reporting for Manufacturers" website for acceptable methods for electronic reporting of Form FDA 1932.
<http://www.fda.gov/Animal/Veterinary/Safety/Health/ReportaProblem/ucm212682.htm>

Type of Information to Report **2**

Adverse Drug Experience Reports associated with this periodic DER were submitted electronically

Summary of Increased Frequency of Adverse Drug Experiences

ADVERSE DRUG EXPERIENCES

For the periodic Adverse Drug Experience reports submitted electronically, answer the following questions

• What was the total number of reports submitted electronically?	<input type="text"/>	3
• How many product defects were submitted electronically?	<input type="text"/>	
• How many complaints affecting animals were submitted electronically?	<input type="text"/>	
• How many animals reacted?	<input type="text"/>	

Annual DER – ADE Summary

Select the second option to upload a Summary of Increased Frequency of ADEs (PDF attachment(s))

Screen: 2.0 Adverse Drug Experiences (ADEs)

Do you have information regarding Adverse Drug Experiences to submit? Yes No 1

Refer to the "Veterinary Adverse Event Reporting for Manufacturers" website for acceptable methods for electronic reporting of Form FDA 1932.
<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm212682.htm>

Type of Information to Report 2

Adverse Drug Experience Reports associated with this periodic DER were submitted electronically

Summary of Increased Frequency of Adverse Drug Experiences

Summary of Increased Frequency of Adverse Drug Experiences: 🔍 ⚡

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

3 0 items in the list

Title	Name	Date	Size
-------	------	------	------

Annual DER – Clinical Data

Screen: 3.0 Clinical Data (Animal Experience)

Do you have Clinical Data (Animal Experience) to submit? Yes No 1

Clinical Data (Animal Experience) Attachment: 2

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

0 items in the list

Title	Name	Date	Size
-------	------	------	------

Question Related Hint

Hint for: Clinical Data (Animal Experience) Attachment:

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

Provide results of an authoritative and thorough literature search using the established name(s) of the animal drug(s). Particularly note published reports of adverse experiences associated with the active pharmaceutical ingredient (API). Include summaries of any clinical studies completed during the reporting period.







Annual DER – Clinical Data

Screen: 3.0 Clinical Data (Animal Experience)

Do you have Clinical Data (Animal Experience) to submit? Yes No

Clinical Data (Animal Experience) Attachment:

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

      0 items in the list

Title	Name	Date	Size
-------	------	------	------

Please review the specifications for file attachments in the [FDA eSubmitter User Manual](#).

Annual DER – Quantity Marketed

Screen: 4.0 Quantity Marketed

Do you have Quantity Marketed (Distribution) Data to submit? Yes No 1

QUANTITY MARKETED

How are you submitting your Quantity Marketed Data? Distribution data under 514.80(i)(A) Distribution data under 514.80(i)(B) using Form FDA 3744

Quantity Marketed (Distribution) Data Attachment:

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

0 items in the list

Title	Name	Date	Size
-------	------	------	------

Please review the specifications for file attachments in the [FDA eSubmitter User Manual](#).

NO QUANTITY MARKETED

Please select one of the options: This product has not been marketed or manufactured This is a combination product (e.g. ADAA)

Annual DER – Quantity Marketed With Sales



2 options for reporting if the product was marketed

1. Previous DER QM reporting method (Form FDA 2301)
2. QM on Form FDA 3744 (**only if a petition has been submitted and approved**)

Screen: 4.0 Quantity Marketed

Do you have Quantity Marketed (Distribution) Data to submit? Yes No **1**

QUANTITY MARKETED

How are you submitting your Quantity Marketed Data? Distribution data under 514.80(i)(A) **2** Distribution data under 514.80(i)(B) using Form FDA 3744

Quantity Marketed (Distribution) Data Attachment:

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

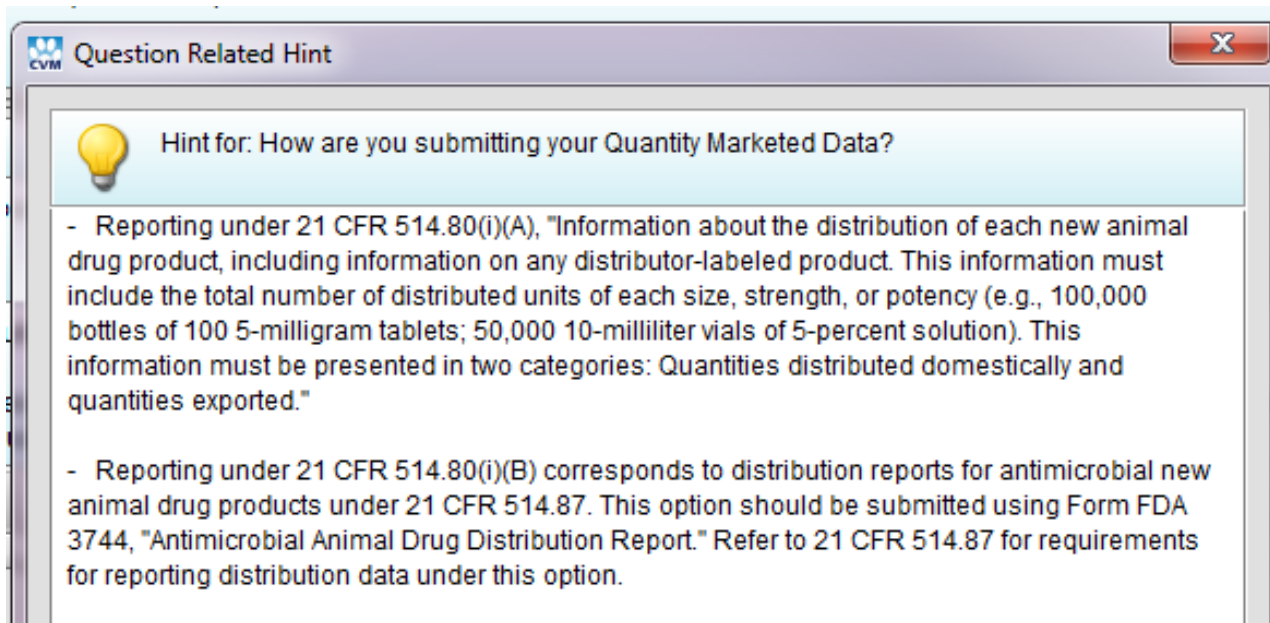
3 0 items in the list

Title	Name	Date	Size
-------	------	------	------

Annual DER – Quantity Marketed With Sales



Reminder: Refer to the hints for additional information



The most recent version of Form FDA 3744 is available at:

<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM219560.pdf>

Annual DER – Quantity Marketed No Sales



2 options for reporting if the product was not marketed

Screen: 4.0 Quantity Marketed

Do you have Quantity Marketed (Distribution) Data to submit? Yes No

1

NO QUANTITY MARKETED

Please select one of the options:

This product has not been marketed or manufactured

This is a combination product (e.g. ADAA)

2

Question Related Hint

Hint for: Please select one of the options:

Combination products include combinations of new animal drugs when the active ingredients or drugs intended for use in the combination have previously been separately approved (e.g. ADAA combinations)

Note: This refers to the streamlined approval process established by the Animal Drug Availability Act of 1996 (ADAA). See 21 CFR 514.4(c).

Annual DER – Labeling

Screen: 5.0 Current Package Labeling

Do you have Current Package Labeling to submit? ● ● Yes No

1

Summary of Labeling Changes

- Select a) “no changes” certification, b) write in, or c) attach a summary

Screen: 5.1 Current Package Labeling and Summary of Labeling Changes

I certify that no changes have been made to the labeling. a

Summary of Labeling Changes:

If you have information you would like to provide, you may include it using the memo field below. To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

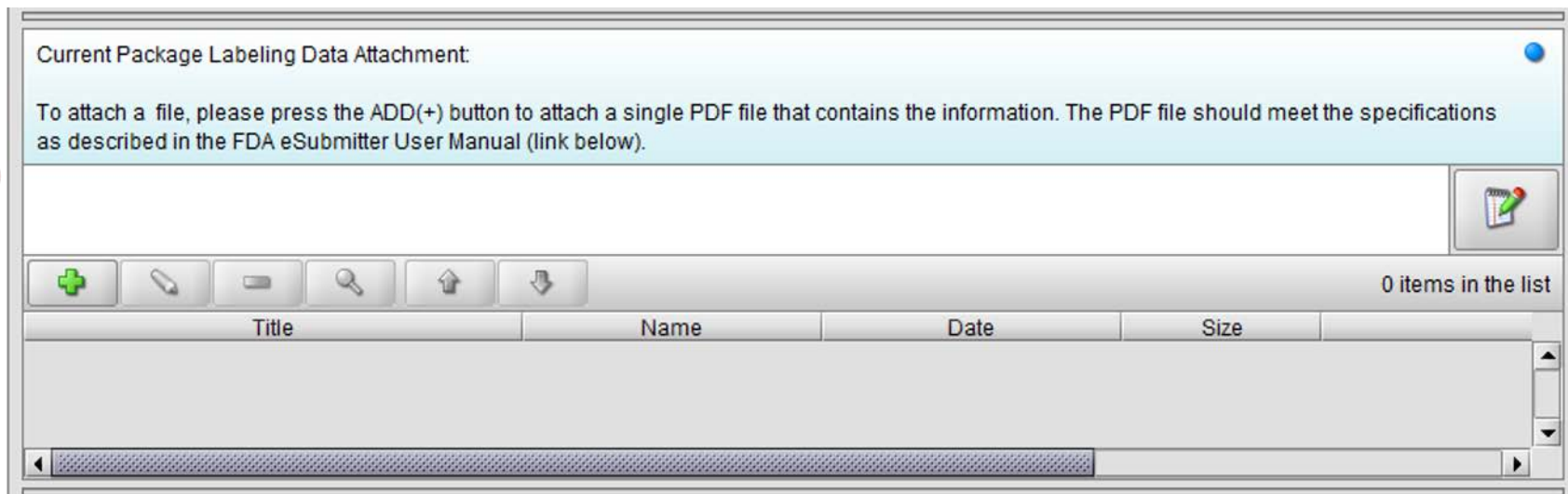
b c

0 items in the list

Title	Name	Date	Size
-------	------	------	------

2

Annual DER – Labeling



- Allows for multiple attachments (PDF)
- Provide appropriate descriptive name and file name on each attachment

Annual DER – Labeling


Screen: 5.0 Current Package Labeling


Do you have Current Package Labeling to submit?  

Yes 1


No







Screen: 5.2 Summary of Labeling Changes

 For products that have not been marketed or manufactured, or combination products, where Current Package Labeling is unavailable, provide a statement as to why Current Package Labeling is not being submitted.

Why is current package labeling not being provided? 

If you have information you would like to provide, you may include it using the memo field below. To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).



0 items in the list


Title	Name	Date	Size
-------	------	------	------

Annual DER – Promotional Materials

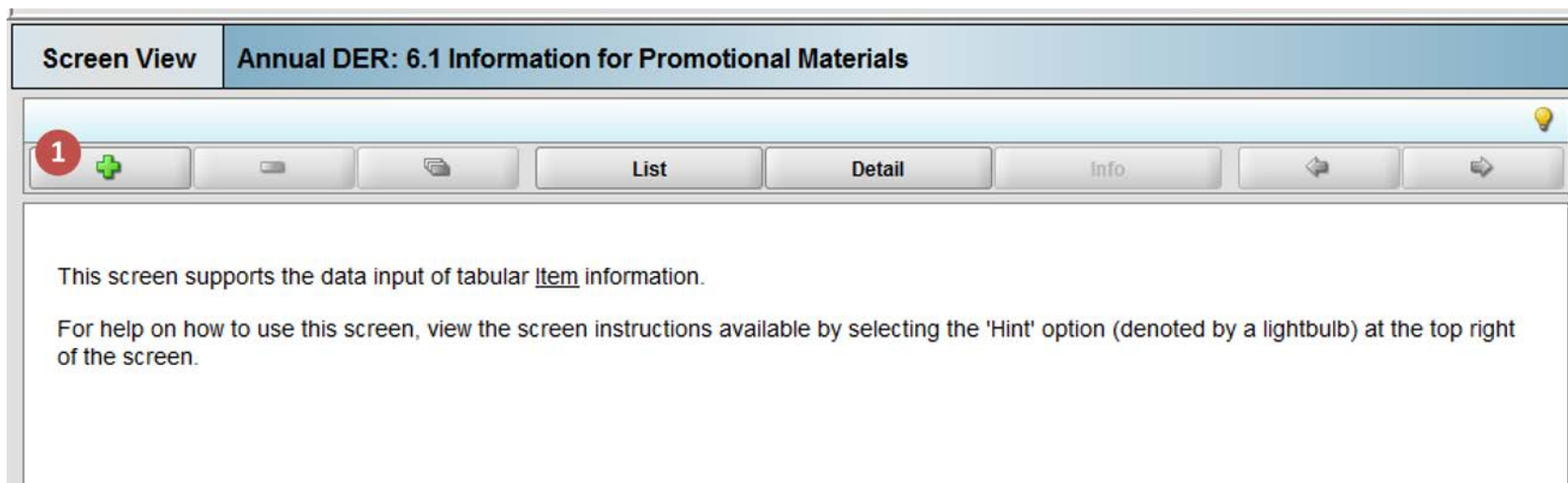
- DER eSubmitter program currently only accepts PDFs
- Other file types would need to be submitted by mail as a follow-up, or the whole submission should be sent in paper copy

Screen: 6.0 Promotional Materials

Do you have Promotional Materials (Mailing Piece and/or Advertising Materials) to submit? Yes No

 If the Promotional Material is only available in an unsupported file type, submit by mail with completed Form FDA 2301 and cover letter referencing this Annual DER submission (include date of submission and reporting period) to:
Food and Drug Administration
Center for Veterinary Medicine
Document Control Unit (HFV-199)
7500 Standish Place
Rockville, MD 20855

Annual DER – Promotional Materials



If you have promotional materials to provide, for each item:

- Enter all the information required on 2301
- Additional box for web link has been provided (optional)

Annual DER – Promotional Materials



Screen: 6.1 Information for Promotional Materials

Item: 1

Date of Issuance

Type of Material

Identification Code (Code No., etc.)

Web Link

Promotional Materials Attachment:

To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link below).

3 0 items in the list

Title	Name	Date	Size
-------	------	------	------







Annual DER – Comments

- Anything that would be included in a cover letters now can be provided in the Comments Section
- Allows 1 PDF file upload

Screen: 7.0 Comments

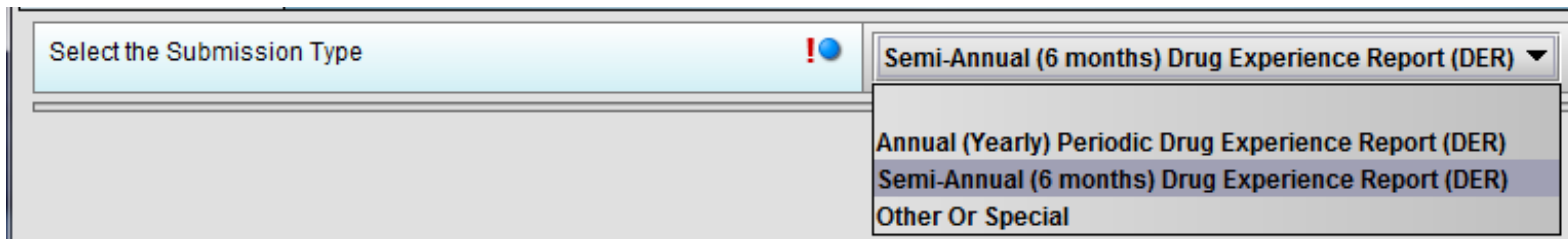
Please review the specifications for the file attachments in the [FDA eSubmitter User Manual](#).

If you have additional comments that you would like to include in this submission, you may provide them using the memo field below or attach a PDF file using the attachment feature. To attach a file, please press the ADD(+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the FDA eSubmitter User Manual (link above).

File Attachment					<input type="text"/>
Details					

Semi-Annual DER

- Very similar to the Annual DER Template, with a few exceptions:
 - Reporting Period will include a selection of the months: 0-6, 6-12, 12-18, 18-24
 - No option for Combined Reporting
 - No option to submit Quantity Marketed using the Form FDA 3744



Select the Submission Type !


Semi-Annual (6 months) Drug Experience Report (DER) ▼

- Annual (Yearly) Periodic Drug Experience Report (DER)
- Semi-Annual (6 months) Drug Experience Report (DER)
- Other Or Special

Special DERs

- Select “Other Or Special”
 - Scroll for all options
- Follow the templates

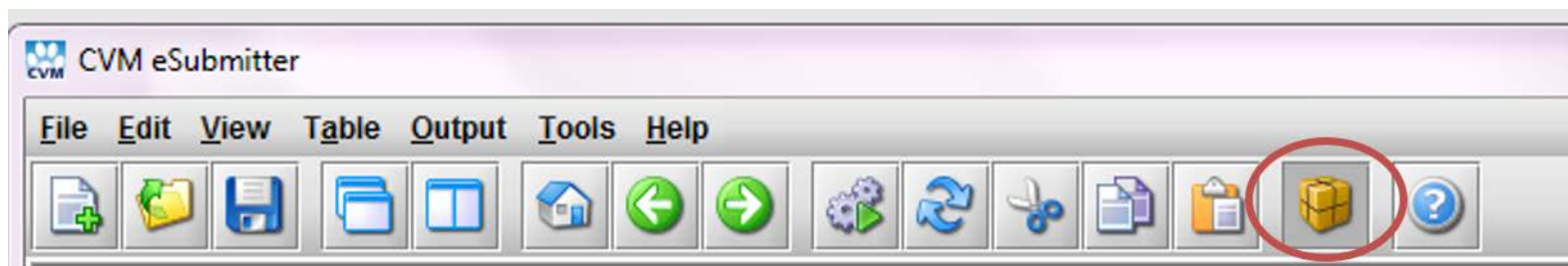
Screen: 8.0 Submission Selection - Other DER

What type of report are you submitting? 

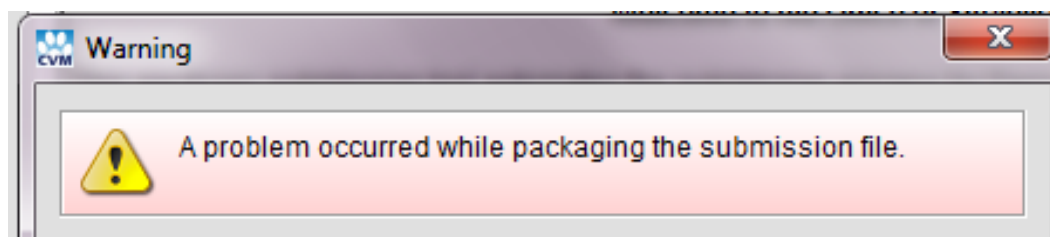
- Promotional or Advertising Materials Submission
- New Distributor (Distributor's Statement)
- Follow Up or Amendment
- Revised Labeling
- Petition to Change Anniversary Date
- Request for Meeting
- Response to Letter from CVM
- Advertising and Promotion Complaint
- General Correspondence
- Antimicrobial Animal Drug Distribution Report (Form FDA 3744)

Packaging the Report

- Complete the eSubmitter process by packaging the report

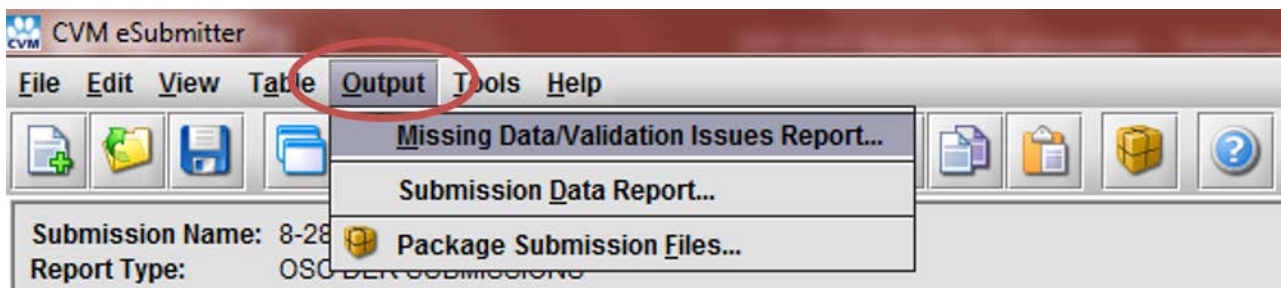


- Errors in a submission will be identified when packaging



Missing Data Report

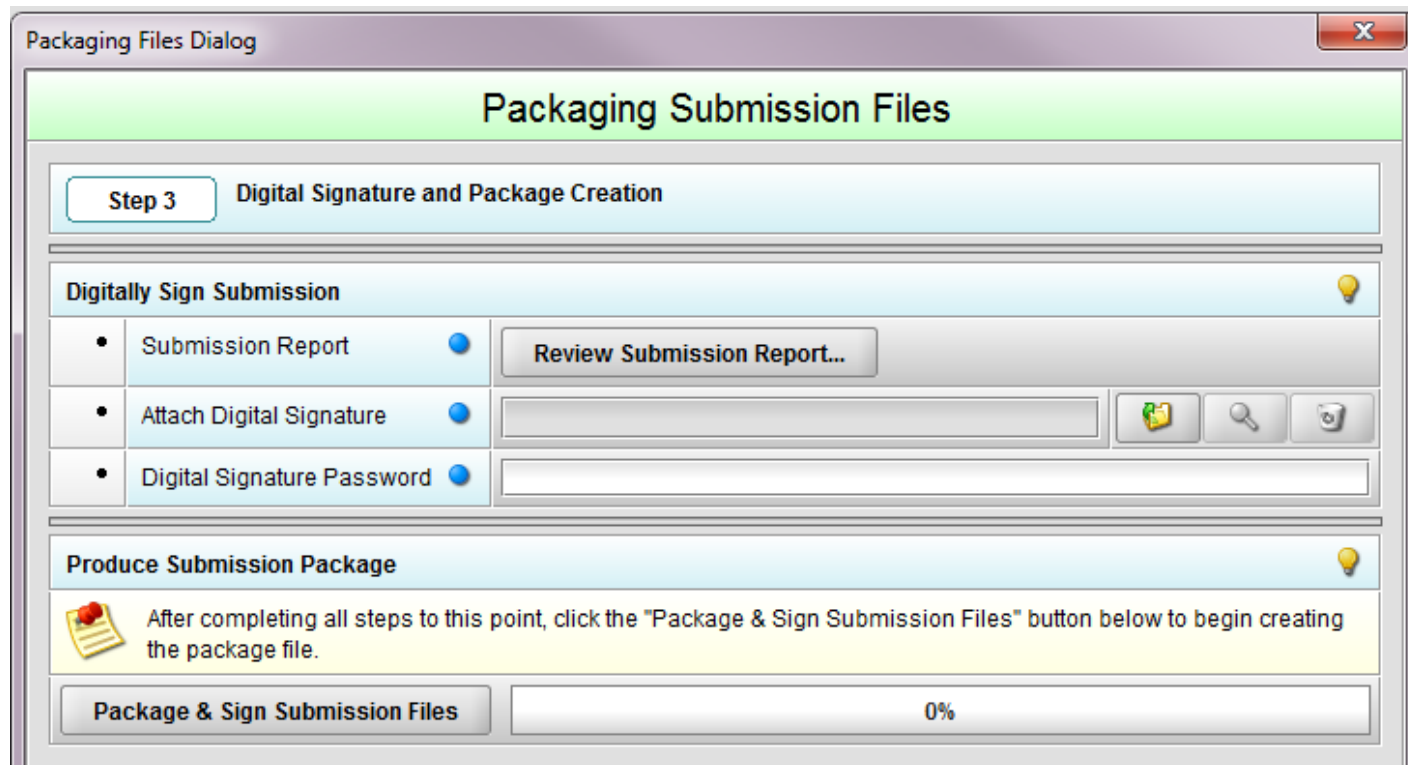
- Review errors in the Missing Data Report
 - Can be accessed through the Warning prompt or the Output Menu



- The Missing Data Report will open in a browser window

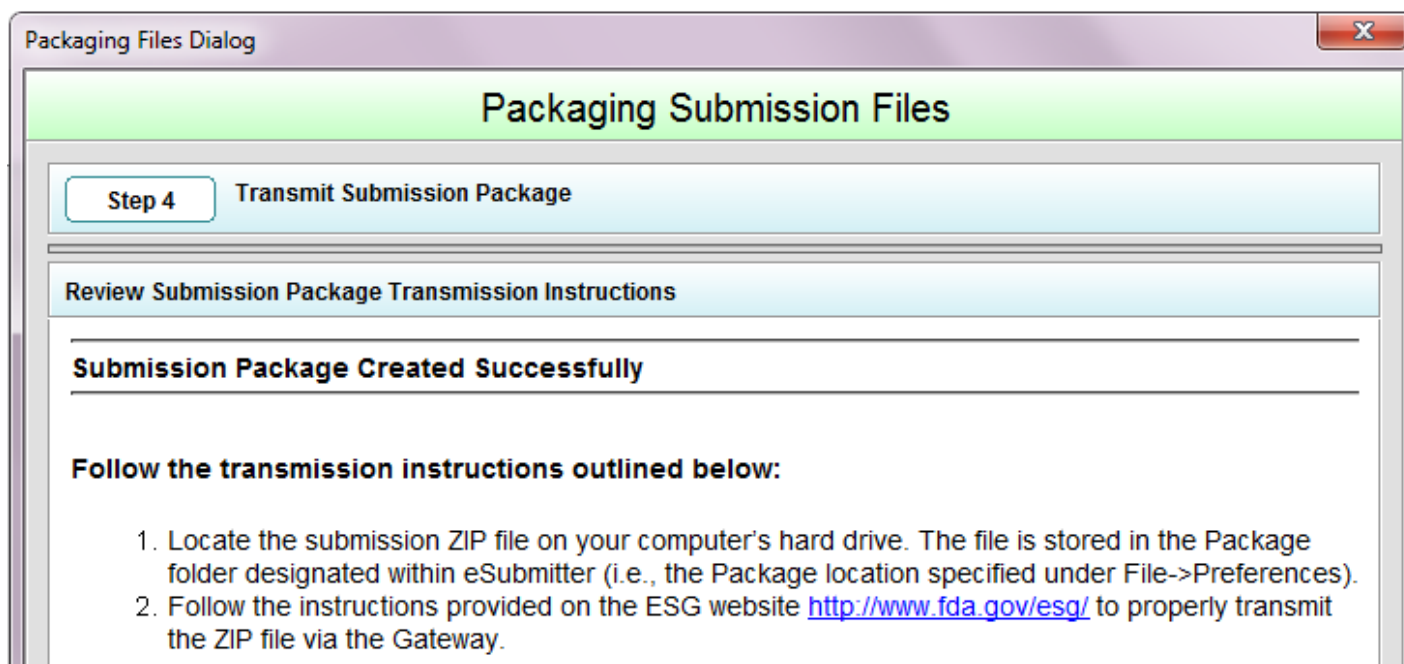
Packaging the Report

1. Confirm Package File Name and Output Location
2. Verify file attachments
3. Review submission report, digitally sign, and package the submission



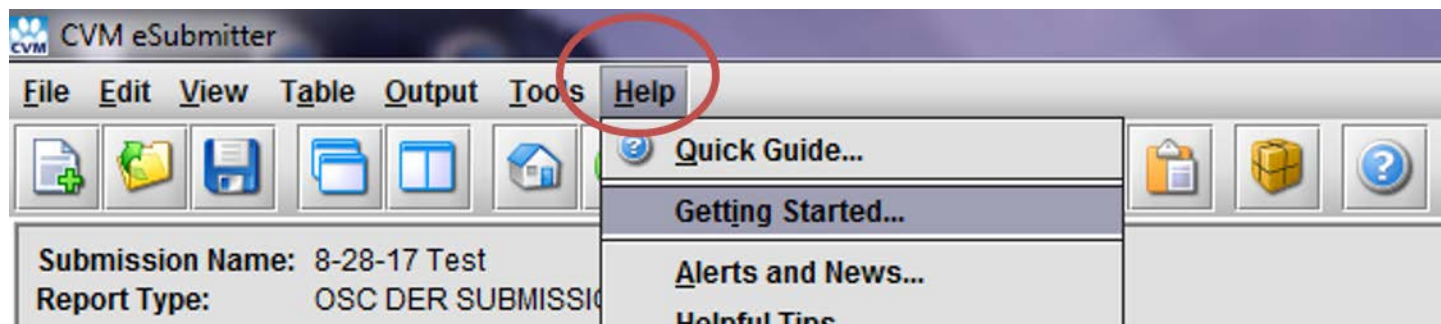
Completing the Report

Once complete, the final dialog will contain instructions for transmitting the submission package to CVM



Help on Packaging the Report

- For helpful tips and instructions see the following documents:
 - *CVM eSubmitter Adobe Digital Signature Quick Guide*
 - *CVM eSubmitter Packaging Quick Guide*
 - *CVM eSubmitter Frequently Asked Questions*
- Accessed through links in the Help Menu (Quick Guide or Getting Started Dialog), or the Manual subfolder of the CVM eSubmitter application



Transmitting the Submission

- Submit your report using the Electronic Submission Gateway (WebTrader)
- 2 Acknowledgment notifications upon acceptance
- Notifications for non-acceptance
 - Invalid (A)NADA
 - QM question not answered for all NADAs in a combined report
 - Unsupported file types (only PDF at this time)
 - Not all Semi-Annuals have been received
 - CVM's system can not accept DERs more than 60 days before due date



Questions?

Questions can be sent to cvmesubmitter@fda.hhs.gov

Additional information regarding the
OSC DER eSubmitter Program is available at:
<https://www.fda.gov/forindustry/fdaesubmitter/ucm226814.htm>

