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1.0 DER Submission – CORE Template

1.1 Node 1.0 Type of submission

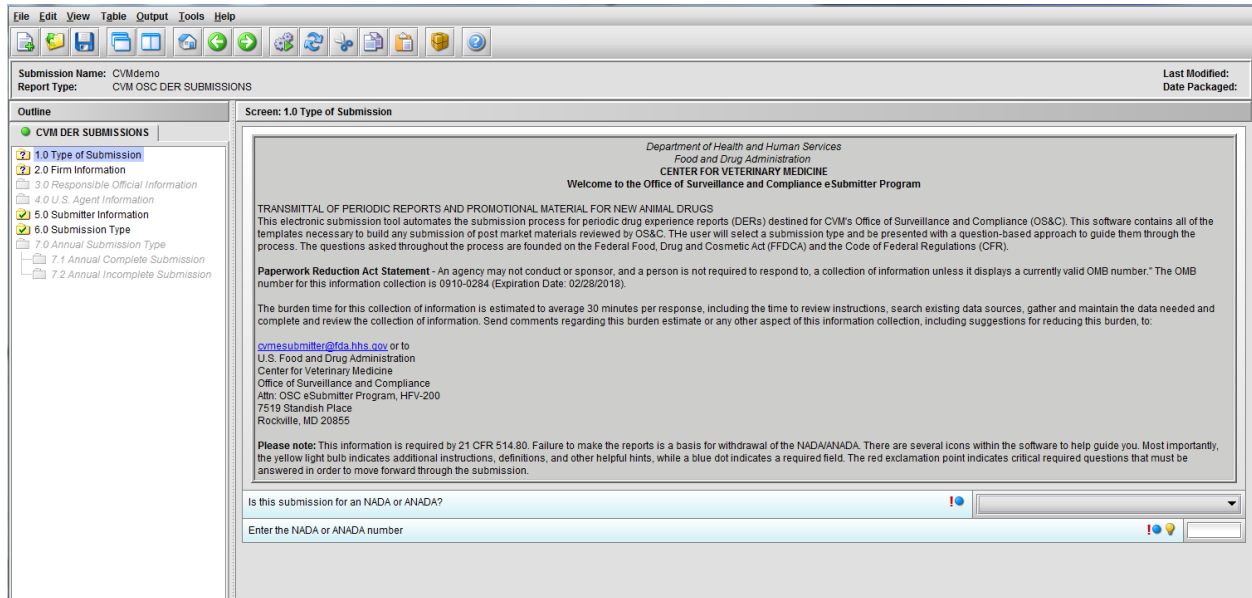


Figure 1.1(a): Initial screen for new submission

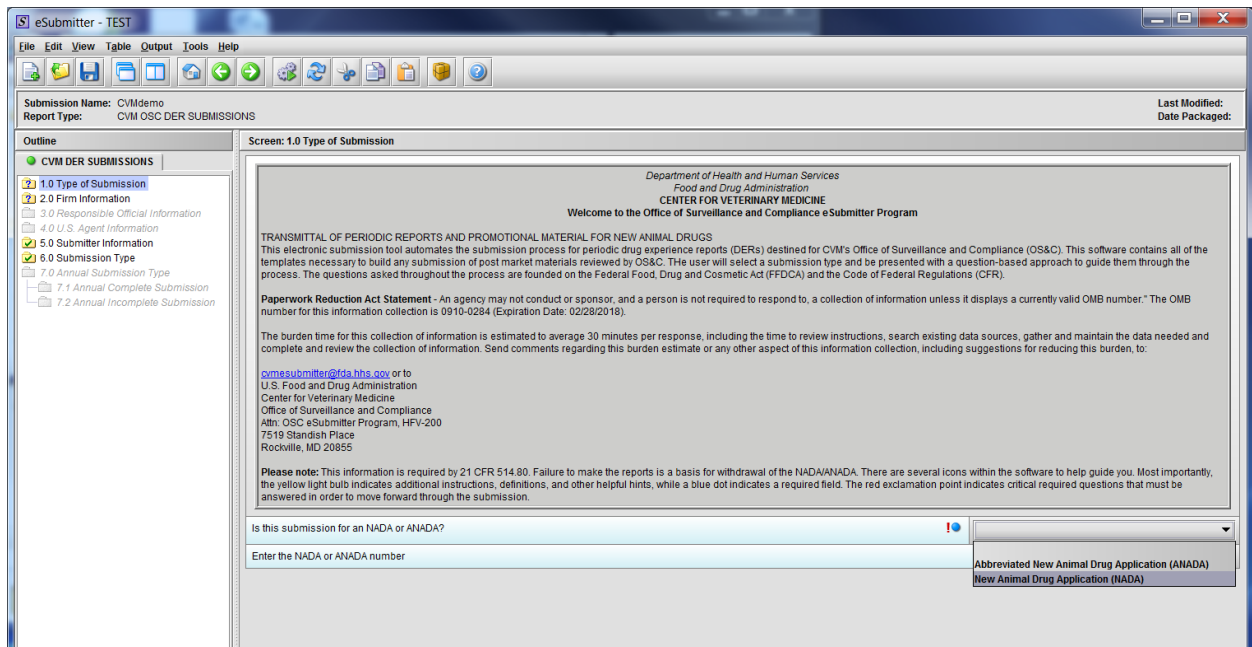


Figure 1.1(b): Drop Down selection for NADA or ANADA

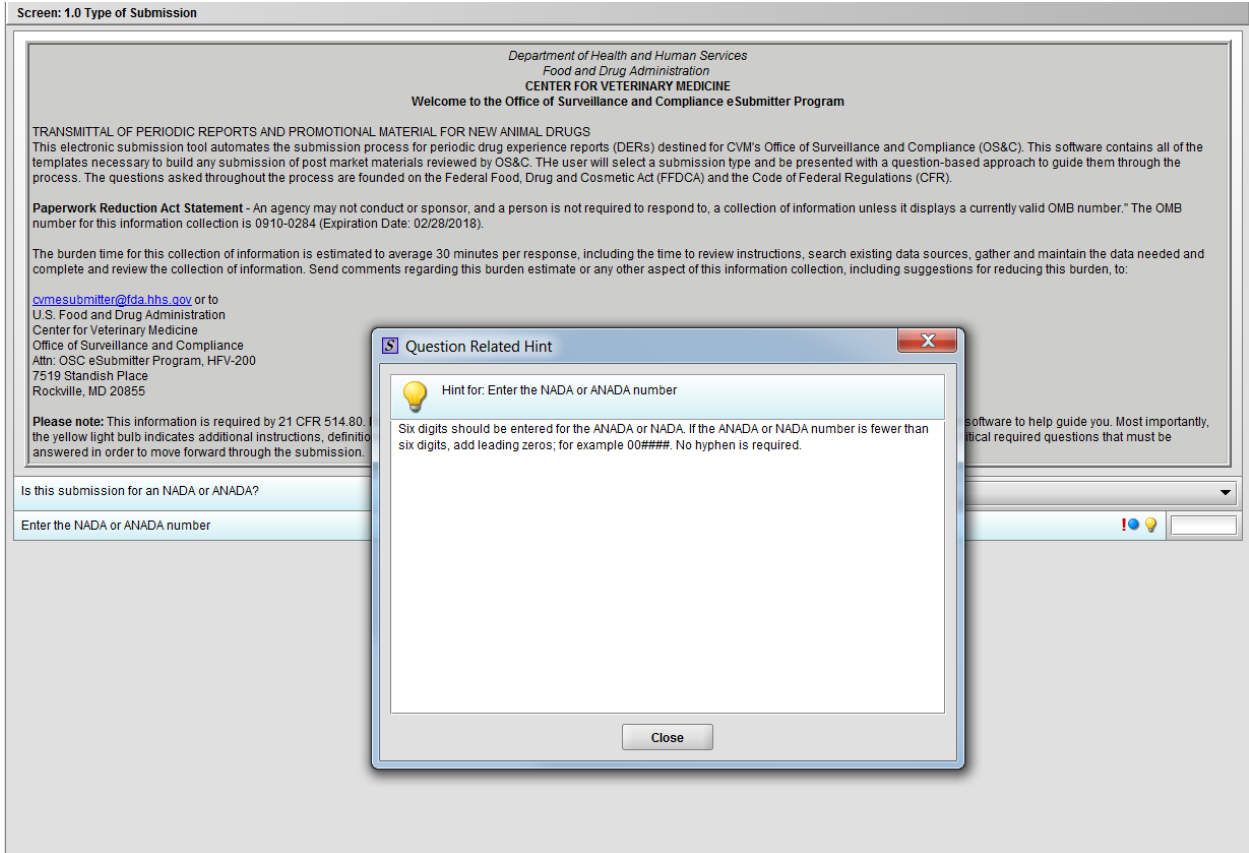


Figure 1.1(c): Hint associated with question 'Enter the NADA or ANADA number'

1.2 Node 2.0 Firm Information

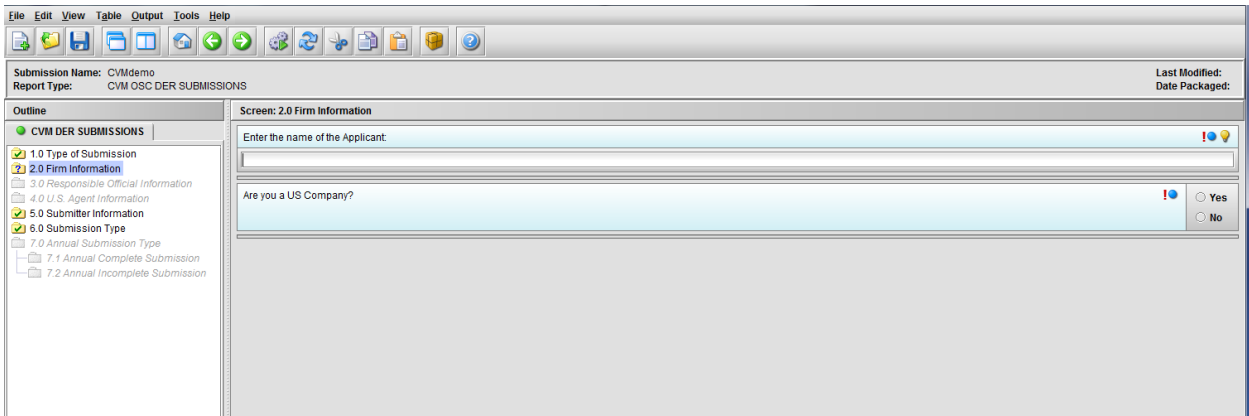


Figure 1.2(a): Firm information screen

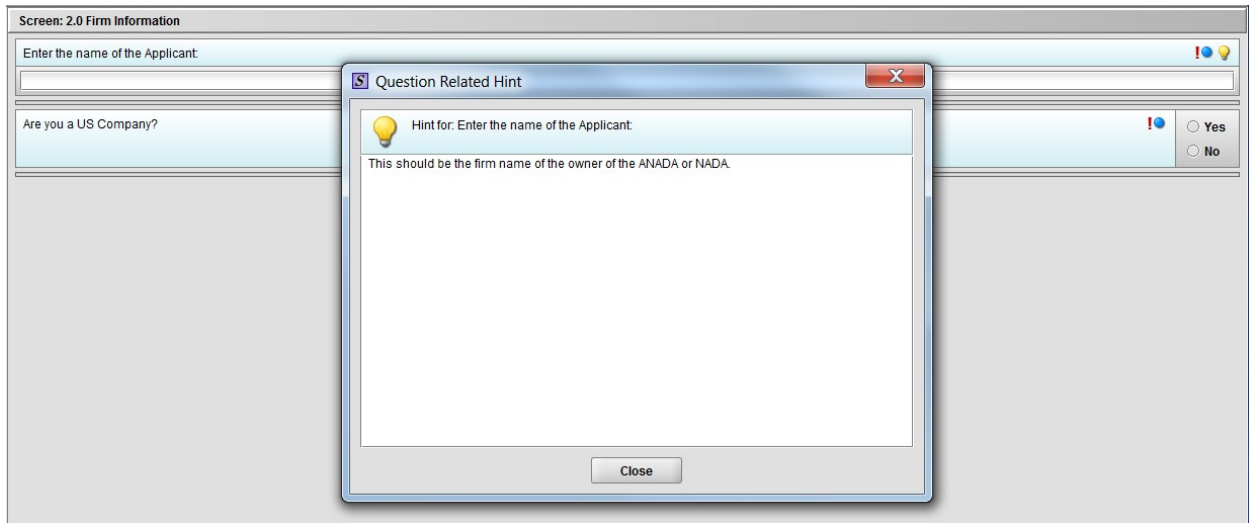


Figure 1.2(b): Hint related to question 'Enter the name of the Applicant'

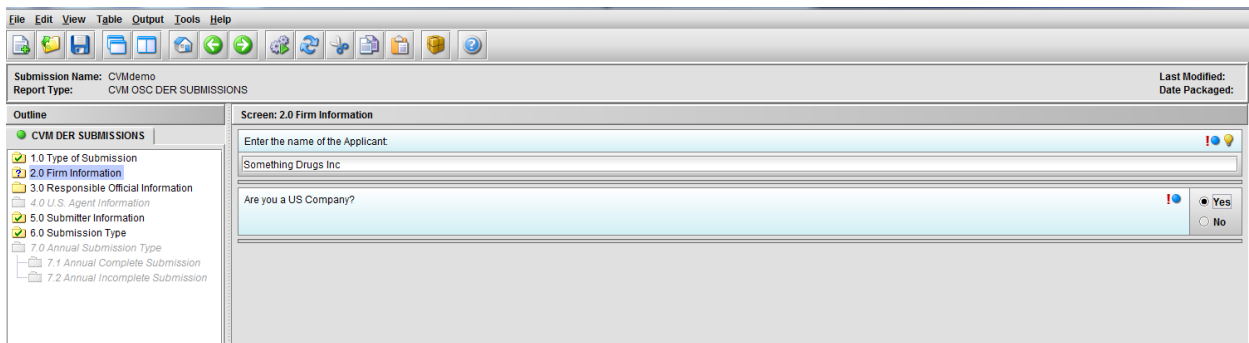


Figure 1.2(c): Selection of 'Yes' to question 'Are you a US Company' enables Node 3.0

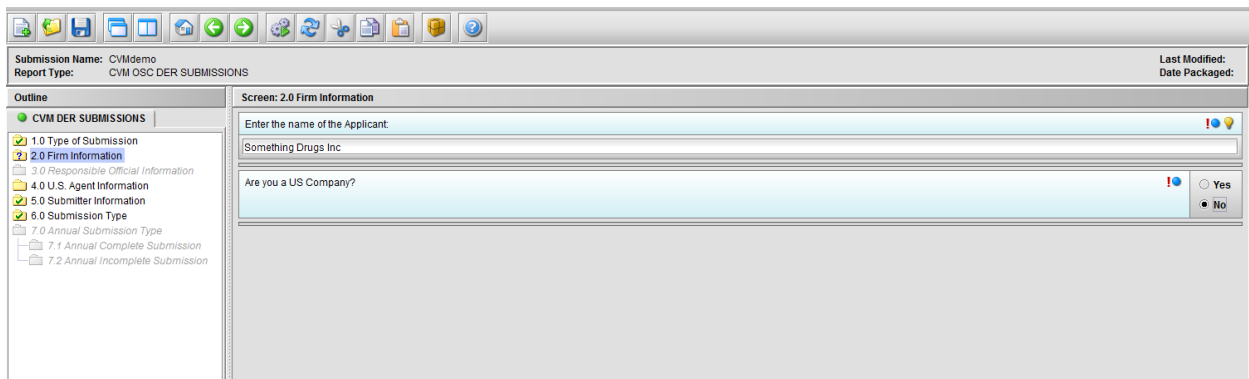


Figure 1.2(d): Selection of 'No' to question 'Are you a US Company' enables Node 4.0

1.3 Node 3.0 Responsible Official Information

The screenshot displays the '3.0 Responsible Official Information' screen within the CVM OSC DER SUBMISSIONS application. The top navigation pane shows a tree view with '3.0 Responsible Official Information' selected. The main area is divided into three sections: 'Contact', 'Address', and 'Phone Numbers'. Each section contains several text input fields with blue circular indicators. The 'Address' section includes a country dropdown menu with 'United States of America' selected. Below these sections are three questions with radio button options for 'Yes' and 'No'. The first question is 'Are you a representative from the Applicant's Firm?' with 'Yes' selected. The second question is 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?'. The third question is 'What date was the Authorization Letter submitted?'. Below the questions is a 'Submit Authorization Letter for Consultant' section with a 'File Attachment' field and a search icon.

Figure 1.3(a): Responsible Official Information

This close-up screenshot focuses on the bottom section of the form. It shows three questions with radio button options. The first question, 'Are you a representative from the Applicant's Firm?', has the 'Yes' radio button selected. The second question is 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?'. The third question is 'What date was the Authorization Letter submitted?'. Below these questions is a 'Submit Authorization Letter for Consultant' section with a 'File Attachment' field and a search icon.

Figure 1.3(b): Selection of 'Yes' to question 'Are you a representative from the Applicant's Firm' allow user to continue

| | | |
|--|--|--|
| Are you a representative from the Applicant's Firm? | | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official? | | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| What date was the Authorization Letter submitted? | | MM / DD / YY |
| Submit Authorization Letter for Consultant | | |
| File Attachment | <input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Search"/> <input type="button" value="Help"/> | |
| <input type="button" value="Submit"/> | | |

Figure 1.3(c): Selection of 'No' to question 'Are you a representative from the Applicant's Firm' enables question 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?'

| | | |
|--|--|--|
| Phone Numbers | | |
| Telephone number: | <input type="text" value="(703) 333-3333 Ext: 3333"/> | <input type="radio"/> |
| Fax number: | <input type="text"/> | <input type="radio"/> |
| Are you a representative from the Applicant's Firm? | | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official? | | <input checked="" type="radio"/> Yes <input type="radio"/> No |
| What date was the Authorization Letter submitted? | | <input type="radio"/> MM / DD / YY |
| Submit Authorization Letter for Consultant | | |
| File Attachment | <input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Search"/> <input type="button" value="Help"/> | |
| <input type="button" value="Submit"/> | | |

Figure 1.3(d): Selection of 'Yes' to question 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?' enables question 'What date was the Authorization Letter submitted?'

| | | |
|--|--|--|
| Are you a representative from the Applicant's Firm? | | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official? | | <input checked="" type="radio"/> Yes <input type="radio"/> No |
| What date was the Authorization Letter submitted? | | MM / DD / YY |
| Submit Authorization Letter for Consultant | | |
| File Attachment | <input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Search"/> <input type="button" value="Help"/> | |
| <input type="button" value="Submit"/> | | |

Figure 1.3(e): Selection of 'No' to question 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?' enables question 'Submit Authorization Letter submitted?'

1.4 Node 4.0 U.S Agent Information

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/21/2017 03:26:17 PM
Date Packaged:

Outline
CVM DER SUBMISSIONS
1.0 Type of Submission
2.0 Firm Information
3.0 Responsible Official Information
4.0 U.S. Agent Information
5.0 Submitter Information
6.0 Submission Type
7.0 Annual Submission Type
7.1 Annual Complete Submission
7.2 Annual Incomplete Submission

Screen: 4.0 U.S. Agent Information

Please enter U.S. Agent Information

Contact

Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Occupation Title:
Email Address:

Address

Establishment Name:
Division Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:

Phone Numbers

Telephone number:
Fax number:

Are you a representative from the Applicant's Firm? Yes No

Has an authorization letter from the Applicant been provided to CVM that identifies you as the US Agent? Yes No

What date was the Authorization Letter submitted?

Submit Authorization Letter for Consultant

File Attachment

Figure 1.4(a): U.S. Agent Information

Are you a representative from the Applicant's Firm? Yes No

Has an authorization letter from the Applicant been provided to CVM that identifies you as the US Agent? Yes No

What date was the Authorization Letter submitted?

Submit Authorization Letter for Consultant

File Attachment

Figure 1.4(b): Selection of 'Yes' to question 'Are you a representative from the Applicant's Firm' allow user to continue

Are you a representative from the Applicant's Firm? Yes No

Has an authorization letter from the Applicant been provided to CVM that identifies you as the US Agent? Yes No

What date was the Authorization Letter submitted? [disabled]

Submit Authorization Letter for Consultant

File Attachment [upload icon] [remove icon] [search icon] [info icon] [text input]

Figure 1.4(c): Selection of 'No' to question 'Are you a representative from the Applicant's Firm' enables question 'Has an authorization letter from the applicant been provided to CVM that identifies you as the US Agent?'

Are you a representative from the Applicant's Firm? Yes No

Has an authorization letter from the applicant been provided to CVM that identifies you as the US Agent? Yes No

What date was the Authorization Letter submitted? [date field]

Submit Authorization Letter for Consultant

File Attachment [upload icon] [remove icon] [search icon] [info icon] [text input]

Figure 1.4(d): Selection of 'Yes' to question 'Has an authorization letter from the applicant been provided to CVM that identifies you as the US Agent?' enables question 'What date was the Authorization Letter submitted?'

Are you a representative from the Applicant's Firm? Yes No

Has an authorization letter from the applicant been provided to CVM that identifies you as the US Agent? Yes No

What date was the Authorization Letter submitted? [date field]

Submit Authorization Letter for Consultant

File Attachment [upload icon] [remove icon] [search icon] [info icon] [text input]

Figure 1.4(e): Selection of 'No' to question 'Has an authorization letter from the applicant been provided to CVM that identifies you as the Responsible Official?' enables question 'Submit Authorization Letter submitted?'

1.5 Node 5.0 Submitter Information

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|-------------------------|--|-------------------|--|--------------|--|------------|--|-------------------|--|----------------|--|---------------------|--|----------------|--|----------|--|-------------------|--|-------------------|--|-------|--|--------------------------------|--|--------------------------|--|-------------------|----------------|-------------|---------|
| Submission Name: CVMdemo Report Type: CVM OSC DER SUBMISSIONS | Last Modified: 01/21/2017 03:36:17 PM Date Packaged: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Outline <ul style="list-style-type: none">CVM DER SUBMISSIONS<ul style="list-style-type: none">1.0 Type of Submission2.0 Firm Information3.0 Responsible Official Information4.0 U.S. Agent Information5.0 Submitter Information6.0 Submission Type<ul style="list-style-type: none">7.0 Annual Submission Type<ul style="list-style-type: none">7.1 Annual Complete Submission7.2 Annual Incomplete Submission | Screen: 5.0 Submitter Information <p>Is the Submitter the same person as the Responsible Official or US Agent? <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Please Enter Submitter Information</p> <p>Contact</p> <table><tr><td>Title (e.g., Mr., Ms.):</td><td></td></tr><tr><td>First/Given Name:</td><td></td></tr><tr><td>Middle Name:</td><td></td></tr><tr><td>Last Name:</td><td></td></tr><tr><td>Occupation Title:</td><td></td></tr><tr><td>Email Address:</td><td></td></tr></table> <p>Address</p> <table><tr><td>Establishment Name:</td><td></td></tr><tr><td>Division Name:</td><td></td></tr><tr><td>Country:</td><td><input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below)</td></tr><tr><td>Address - Line 1:</td><td></td></tr><tr><td>Address - Line 2:</td><td></td></tr><tr><td>City:</td><td></td></tr><tr><td>State, Province, or Territory:</td><td></td></tr><tr><td>Post Office or Zip Code:</td><td></td></tr></table> <p>Phone Numbers</p> <table><tr><td>Telephone number:</td><td>() - - Ext: -</td></tr><tr><td>Fax number:</td><td>() - -</td></tr></table> | Title (e.g., Mr., Ms.): | | First/Given Name: | | Middle Name: | | Last Name: | | Occupation Title: | | Email Address: | | Establishment Name: | | Division Name: | | Country: | <input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below) | Address - Line 1: | | Address - Line 2: | | City: | | State, Province, or Territory: | | Post Office or Zip Code: | | Telephone number: | () - - Ext: - | Fax number: | () - - |
| Title (e.g., Mr., Ms.): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| First/Given Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Middle Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Last Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Occupation Title: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Email Address: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Establishment Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Division Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Country: | <input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Address - Line 1: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Address - Line 2: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| City: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| State, Province, or Territory: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Post Office or Zip Code: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Telephone number: | () - - Ext: - | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fax number: | () - - | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Figure 1.5(a): Submitter Information. Selection of 'Yes' to question 'Is the Submitter the same person as the Responsible Official or US Agent?' allow user to continue

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS

Last Modified: 01/21/2017 03:36:17 PM
Date Packaged:

Outline

- CVM DER SUBMISSIONS
 - 1.0 Type of Submission
 - 2.0 Firm Information
 - 3.0 Responsible Official Information
 - 4.0 U.S. Agent Information
 - 5.0 Submitter Information
 - 6.0 Submission Type
 - 7.0 Annual Submission Type
 - 7.1 Annual Complete Submission
 - 7.2 Annual Incomplete Submission

Screen: 5.0 Submitter Information

Is the Submitter the same person as the Responsible Official or US Agent? Yes No

Please Enter Submitter Information

Contact

Title (e.g., Mr., Ms.):

First/Given Name:

Middle Name:

Last Name:

Occupation Title:

Email Address:

Address

Establishment Name:

Division Name:

Country: United States of America Other (select below)

Address - Line 1:

Address - Line 2:

City:

State, Province, or Territory:

Post Office or Zip Code:

Phone Numbers

Telephone number: () - - Ext. -

Fax number: () - -

Figure 1.5(b): Selection of 'No' to question 'Is the Submitter the same person as the Responsible Official or US Agent?' enables the group of questions associated with question 'Please Enter Submitter information.'

1.6 Node 6.0 Submission Type

eSubmitter - TEST

File Edit View Table Output Tools Help

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS

Last Modified: 01/21/2017 03:36:17 PM
Date Packaged:

Outline

- CVM DER SUBMISSIONS
 - 1.0 Type of Submission
 - 2.0 Firm Information
 - 3.0 Responsible Official Information
 - 4.0 U.S. Agent Information
 - 5.0 Submitter Information
 - 6.0 Submission Type
 - 7.0 Annual Submission Type
 - 7.1 Annual Complete Submission
 - 7.2 Annual Incomplete Submission

Screen: 6.0 Submission Type

Select the Submission Type

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

Figure 1.6(a): Submission Type. Drop Down selection for Annual, Semi-Annual or Other/Special Report

1.7 Node 7.0 Annual Submission Type

The screenshot shows the 'CVM DER SUBMISSIONS' interface. The 'Outline' pane on the left has '7.0 Annual Submission Type' selected. The main area displays the 'Screen: 7.0 Annual Submission Type' with the question 'Have all 4 required Semi-Annual (6 months) DERs been submitted?'. The 'Yes' radio button is selected. A red warning banner below the question reads: '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.'

Figure 1.7(a): Annual Submission Type. Selection of 'Annual (Yearly) Periodic Drug Experience Report (DER)' from Node 6.0 enables Node 7.0

This screenshot is identical to Figure 1.7(a), but the 'Yes' radio button is selected, and the 'No' radio button is unselected. The warning banner remains visible.

Figure 1.7(b): Selection of 'Yes' to question 'Have all 4 required Semi-Annual (6 months) DERs been submitted?' enables Node 7.1

This screenshot is identical to Figure 1.7(a), but the 'No' radio button is selected, and the 'Yes' radio button is unselected. The warning banner remains visible.

Figure 1.7(c): Selection of 'No' to question 'Have all 4 required Semi-Annual (6 months) DERs been submitted?' enables Node 7.2

1.7.1 Node 7.1 Annual Complete Submission

Screen: 7.1 Annual Complete Submission

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?

> What is the Report Period for this Annual DER Submission? to

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? Yes
 No
 Not Applicable

Question Related Hint

Hint for: What is the Report Due Date for the Annual DER?

The mm/dd corresponds to the original approval of this NADA or ANADA.

If a petition for change of anniversary date has been submitted and approved by CVM, refer to the approved updated anniversary date.

Annual DERs must be submitted within 60 days of the anniversary date of the approval of the NADA or ANADA.

Close

Figure 1.7.1(a): Hint for question 'What is the Report Due Date for the Annual DER?'

Screen: 7.1 Annual Complete Submission

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?

> What is the Report Period for this Annual DER Submission? to

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? Yes
 No
 Not Applicable

Question Related Hint

Hint for: Is this a combined report?

A combined report consists of multiple NADA or ANADA numbers attached to a single filing.

Close

Figure 1.7.1(b): Hint for question 'Is this a combined report?'

***NOTE: There are three (3) option in the figure above. The 'Not Applicable' option is only there for demonstrative purpose only. It will be removed after selection of Annual Template choice.

1.7.2 Node 7.2 Annual Incomplete Submission

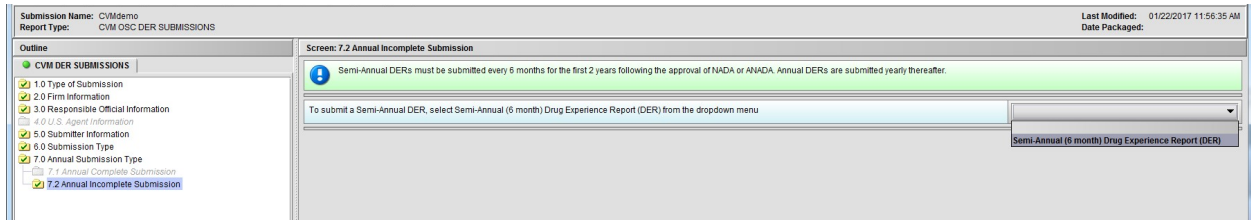


Figure 1.7.2(a): Drop Down navigates to Semi-Annual Template

2.0 DER Submission – Semi-Annual Template

2.1 Node 1.0 Submission Selection – Semi-Annual (6 months) DER

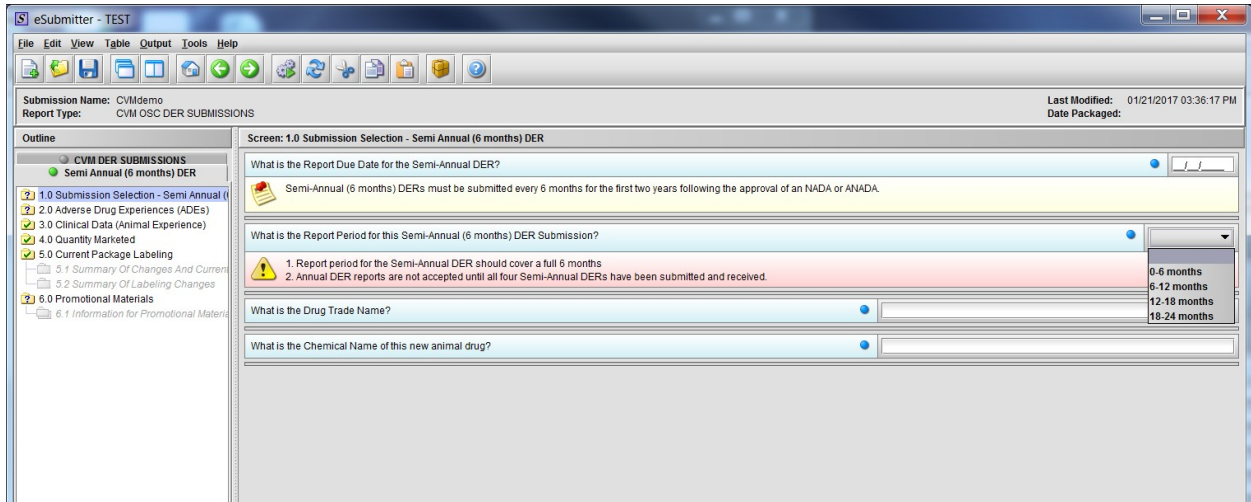


Figure 2.1(a): Submission Selection – Semi-Annual (6 months) DER. Drop Down selection for question 'What is the Report Period for this Semi-Annual (6 months) DER Submission?'

2.2 Node 2.0 Adverse Drug Experiences (ADEs)

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

ADVERSE DRUG EXPERIENCES

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

- What is the total number of reports being submitted?
- How many product defects are being submitted?
- How many complaints affecting animals are being submitted?
- How many animals reacted?

Summary of Increased Frequency of Adverse Drug Experiences

| Title | Name | Date | Size | Path |
|-------|------|------|------|------|
|-------|------|------|------|------|

0 items in the list

Figure 2.2(a): Adverse Drug Experiences (ADEs). Selection of 'Yes' to question 'Do you have information regarding Adverse Drug Experiences to submit?' enables question 'Type of Information to Report'.

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/21/2017 03:56:17 PM
Date Package:

Outline

- CVM DER SUBMISSIONS
- Semi Annual (6 months) DER
- 1.0 Submission Selection - Semi Annual (6 months) DER
- 2.0 Adverse Drug Experiences (ADEs)
- 3.0 Clinical Data (Animal Experience)
- 4.0 Quantity Marketed
- 5.0 Current Package Labeling
 - 5.1 Summary of Changes And Current Package Labeling
 - 5.2 Summary Of Labeling Changes
- 6.0 Promotional Materials
 - 6.1 Information for Promotional Materials

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

ADVERSE DRUG EXPERIENCES

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

- What is the total number of reports being submitted?
- How many product defects are being submitted?
- How many complaints affecting animals are being submitted?
- How many animals reacted?

Summary of Increased Frequency of Adverse Drug Experiences

| Title | Name | Date | Size | Path |
|-------|------|------|------|------|
|-------|------|------|------|------|

0 items in the list

Question Related Hint

Hint for: Summary of Increased Frequency of Adverse Drug Experiences


Summary report of increased Adverse Drug Experience: Provide a summary of the number of ADEs recorded for this reporting period. Provide a comparison of numbers of ADEs for this reporting period compared to the last or previous reporting periods. Also provide comment on reports of ADEs that are considered serious.

Close

Figure 2.2(b): Hint for question 'Summary of Increased Frequency of Adverse Drug Experiences'


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>

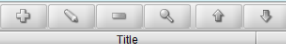
Type of Information to Report Adverse Drug Experience Reports associated with this periodic DER were submitted electronically
 Summary of Increased Frequency of Adverse Drug Experiences

ADVERSE DRUG EXPERIENCES

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

- What is the total number of reports being submitted?
- How many product defects are being submitted?
- How many complaints affecting animals are being submitted?
- How many animals reacted?

Summary of Increased Frequency of Adverse Drug Experiences 


 0 items in the list

| Title | Name | Date | Size | Path |
|-------|------|------|------|------|
| | | | | |

Figure 2.2(c): Selection of 'Adverse Drug Experience Reports.....' from question 'Type of Information to Report' enables the following four (4) questions: 'What is the total number of reports being submitted?', 'How many product defects are being submitted?', 'How many complaints affecting animals are being submitted?' and 'How many animals reacted?'.


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

ADVERSE DRUG EXPERIENCES

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

- What is the total number of reports being submitted?
- How many product defects are being submitted?
- How many complaints affecting animals are being submitted?
- How many animals reacted?

Summary of Increased Frequency of Adverse Drug Experiences 

 0 items in the list


| Title | Name | Date | Size | Path |
|-------|------|------|------|------|
| | | | | |

Figure 2.2(d): Selection of 'Summary of Increased Frequency.....' from question 'Type of Information to Report' enables the question 'Summary of Increased Frequency of Adverse Drug Experiences'

*** Note: Selection to question 'Type of Information to Report' can be either or both.


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/Animal/Veterinary/SafetyHealth/ReportaProblem/ucm212682.htm>

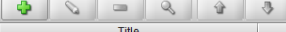
Type of Information to Report Adverse Drug Experience Reports associated with this periodic DER were submitted electronically
 Summary of Increased Frequency of Adverse Drug Experiences

ADVERSE DRUG EXPERIENCES

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

- What is the total number of reports being submitted?
- How many product defects are being submitted?
- How many complaints affecting animals are being submitted?
- How many animals reacted?

Summary of Increased Frequency of Adverse Drug Experiences


 0 items in the list

| Title | Name | Date | Size | Path |
|-------|------|------|------|------|
| | | | | |

Figure 2.2(e): Selection of 'Summary of Increased Frequency.....' from question 'Type of Information to Report' enables the question 'Summary of Increased Frequency of Adverse Drug Experiences'


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/Animal/Veterinary/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

ADVERSE DRUG EXPERIENCES

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

- What is the total number of reports being submitted?
- How many product defects are being submitted?
- How many complaints affecting animals are being submitted?
- How many animals reacted?

Summary of Increased Frequency of Adverse Drug Experiences

 0 items in the list

| Title | Name | Date | Size | Path |
|-------|------|------|------|------|
| | | | | |

Figure 2.2(f): Selection of 'No' to question 'Do you have information regarding Adverse Drug Experiences to submit?' navigates to next Node.

Node 3.0 Clinical Data (Animal Experience)

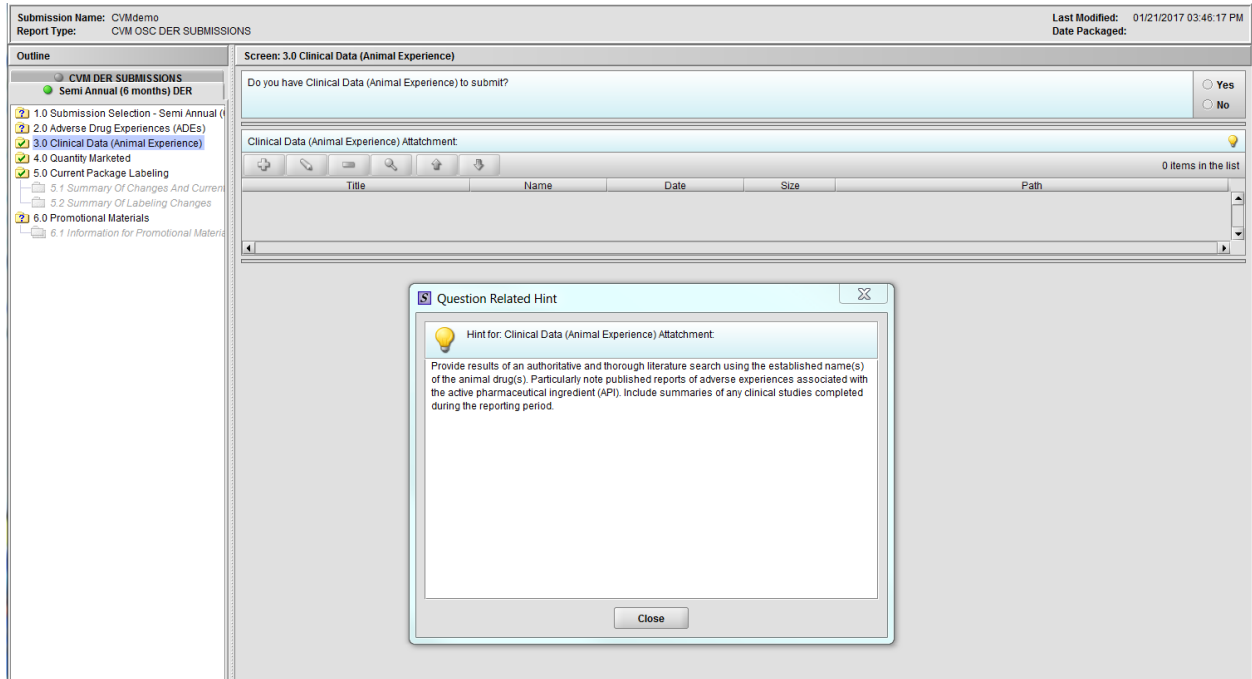


Figure 2.3(a): Clinical Data (Animal Experience). Hint for question 'Clinical Data (Animal Experience) Attachment'.

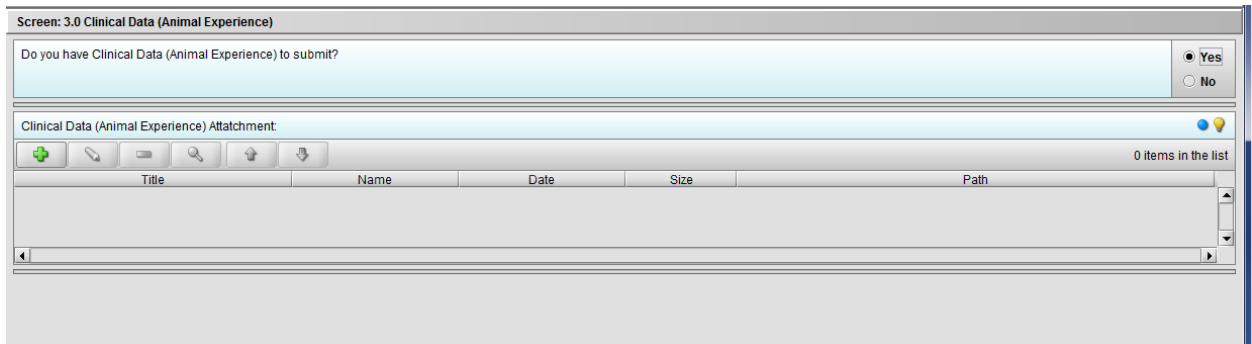


Figure 2.3(b): Selection of 'Yes' to question 'Do you have Clinical Data (Animal Experience) to submit?' enables question 'Clinical Data (Animal Experience) Attachment'.

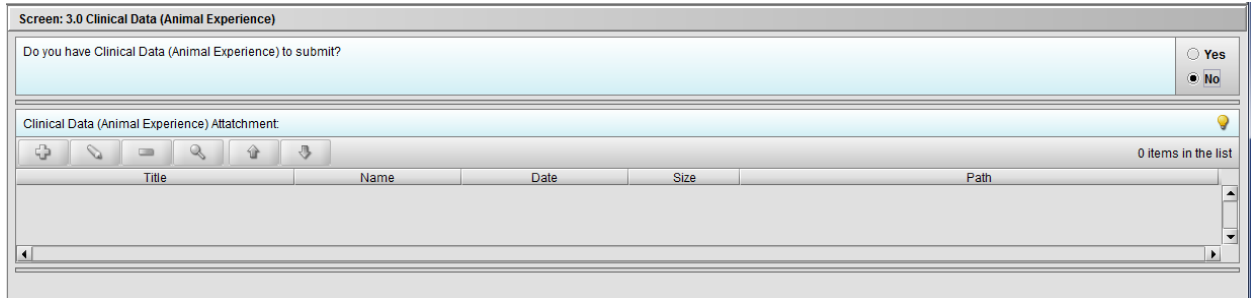


Figure 2.3(c): Selection of 'No' to question 'Do you have Clinical Data (Animal Experience) to submit?' navigates to next Node.

2.3 Node 4.0 Quantity Marketed

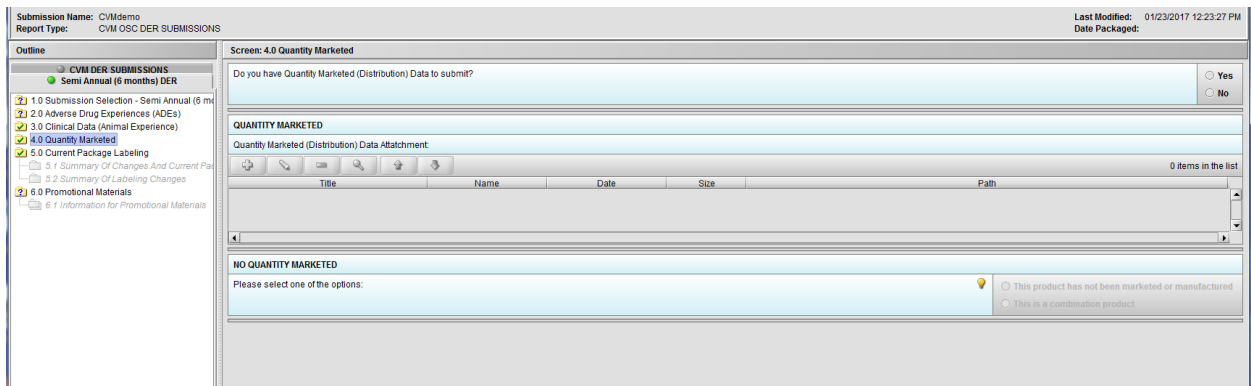


Figure 2.4(a): Quantity Marketed

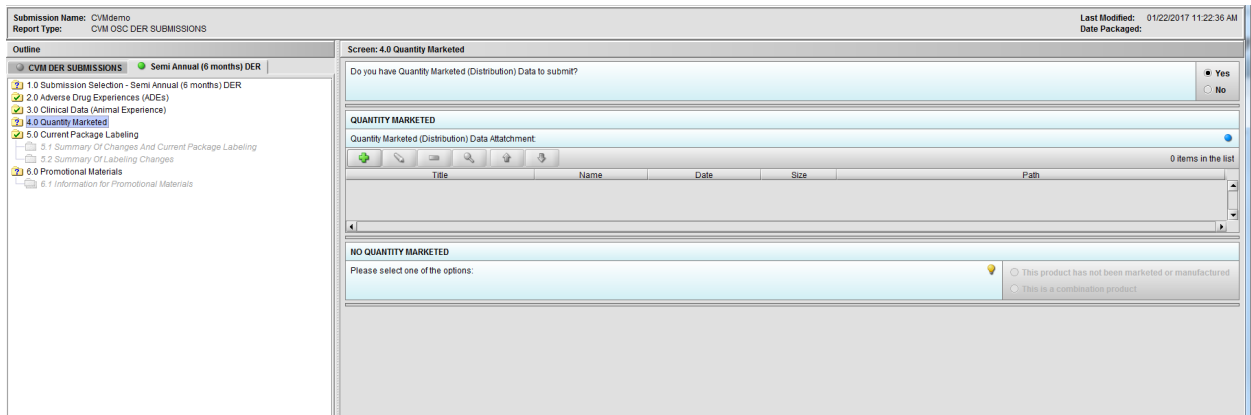


Figure 2.4(b): Selection of 'Yes' to question 'Do you have Quantity Marketed (Distribution) Data to submit?' enables question 'Quantity Marketed (Distribution) Data Attachment:'.

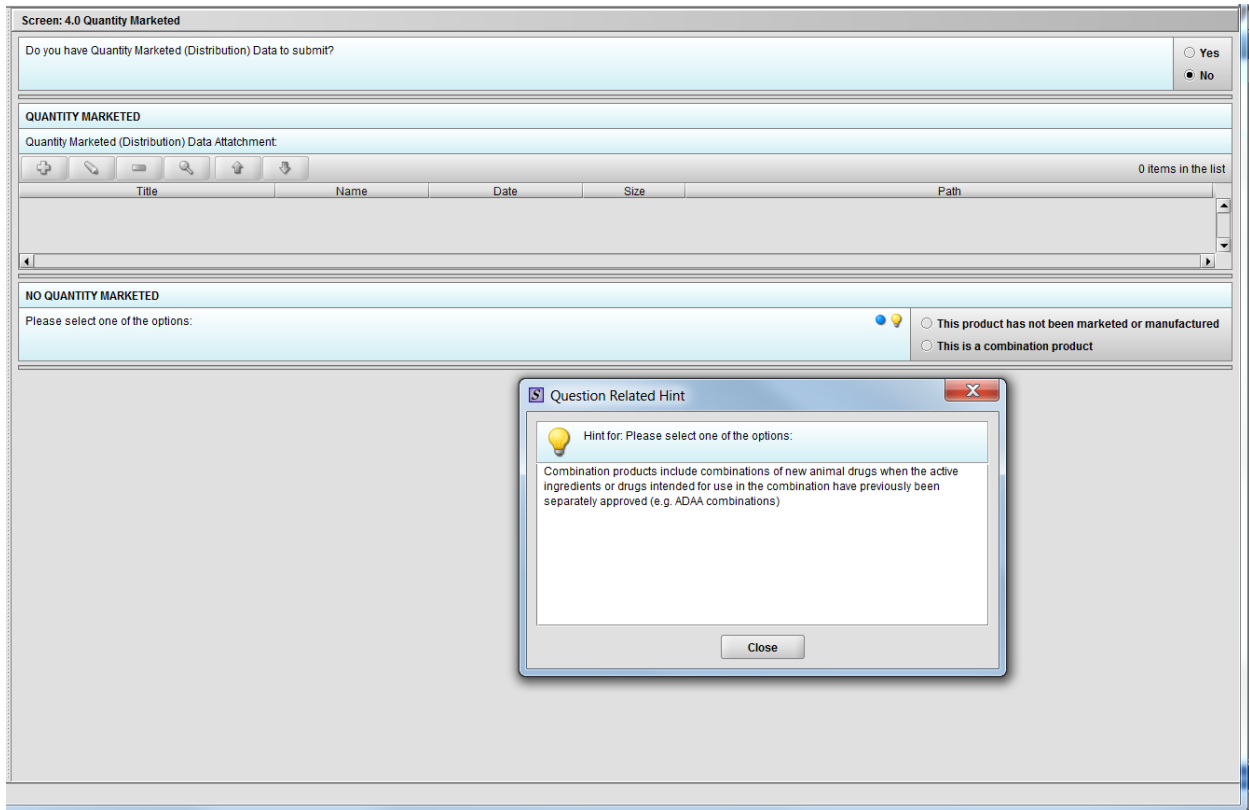


Figure 2.4(c): Selection of 'No' to question 'Do you have Quantity Marketed (Distribution) Data to submit?' navigates to next Node. Hint to question 'Quantity Marketed (Distribution) Data Attachment:'

2.4 Node 5.0 Current Package Labeling

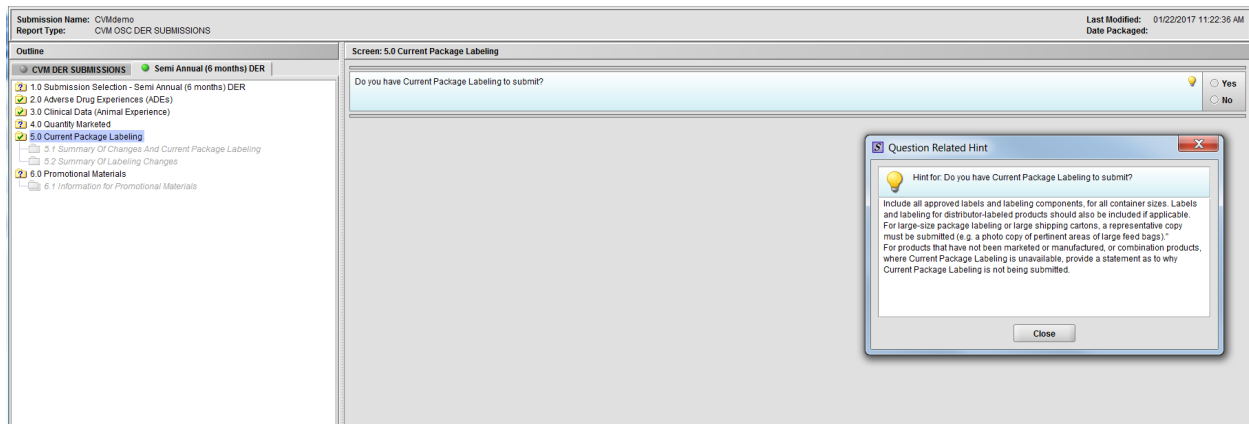


Figure 2.5(a): Current Package Labeling. Hint for question 'Do you have Current Package Labeling to submit?'

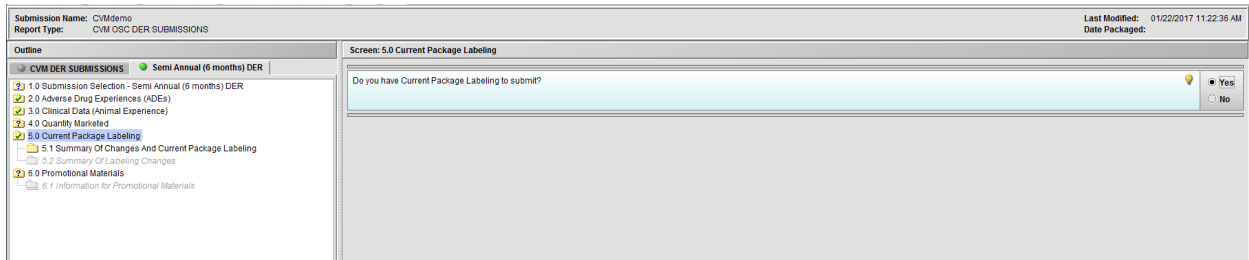


Figure 2.5(b): Selection of 'Yes' to question 'Do you have Current Package Labeling to submit?' enables Node 5.1

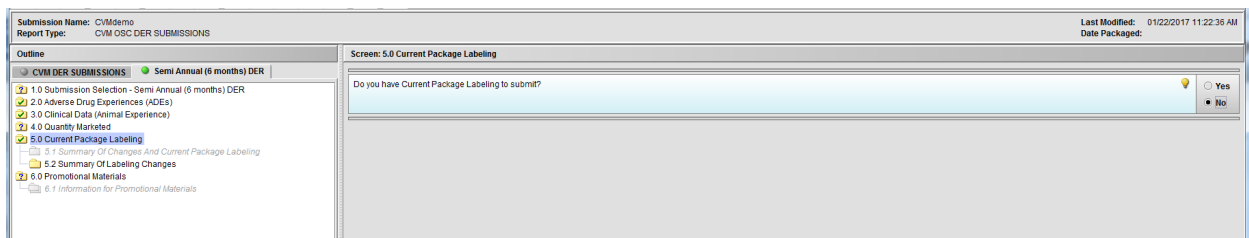


Figure 2.5(c): Selection of 'No' to question 'Do you have Current Package Labeling to submit?' enables Node 5.2

2.4.1 Node 5.1 Summary of Changes and Current Package Labeling

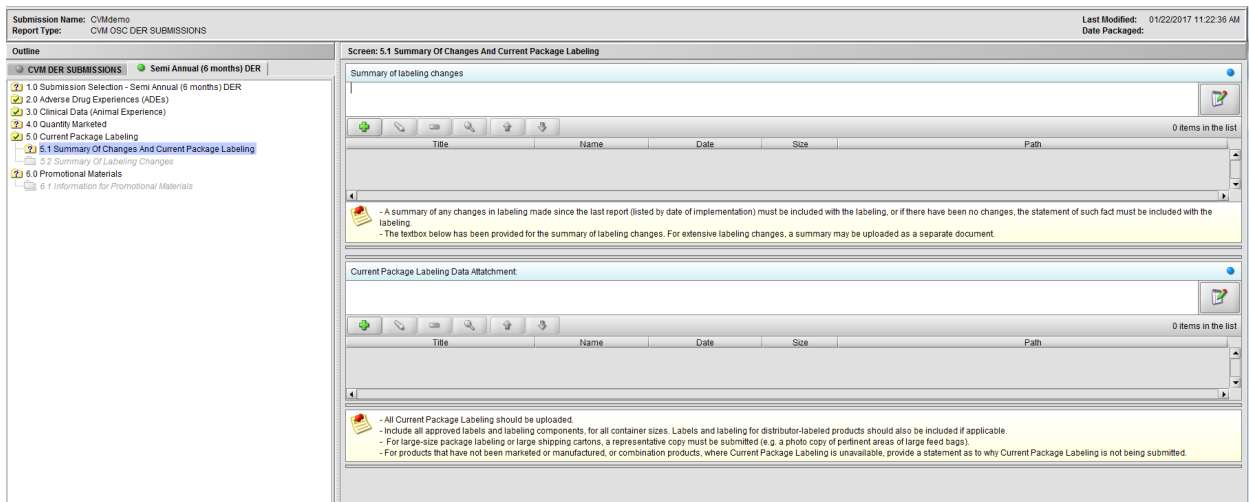


Figure 2.5.1(a): Summary Of Changes And Current Package Labeling

2.4.2 Node 5.2 Summary pf Labeling Changes

Figure 2.5.2(a): Summary Of Changes And Current Package Labeling

2.5 Node 6.0 Promotional Materials

Figure 2.6(a): Promotional Materials

Figure 2.6(b): Selection of 'Yes' to question 'Do you have Promotional Materials (Mailing Piece and/or Advertising Materials) to submit?' enables Node 6.1

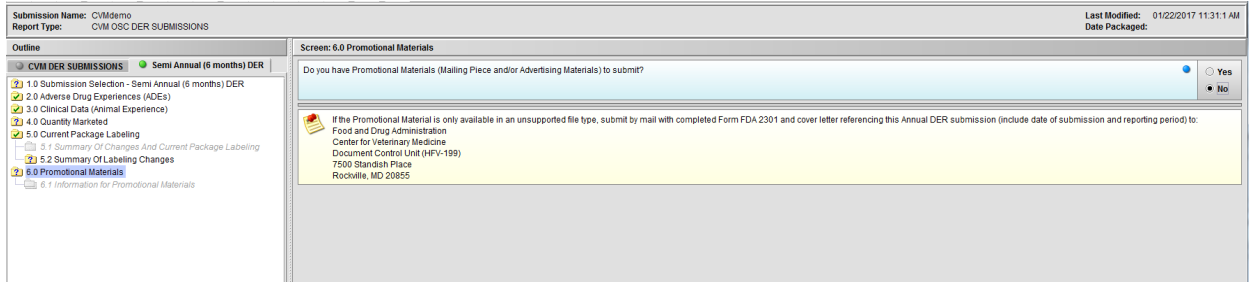


Figure 2.6(c): Selection of 'No' to question 'Do you have Promotional Materials (Mailing Piece and/or Advertising Materials) to submit?' completes the submission questions

2.5.1 Node 6.1 Information for Promotional Material

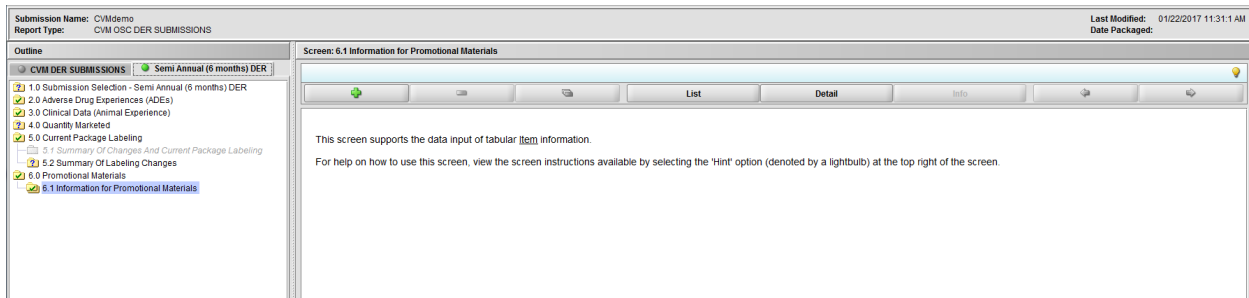


Figure 2.6.1(a): Information for Promotional Materials

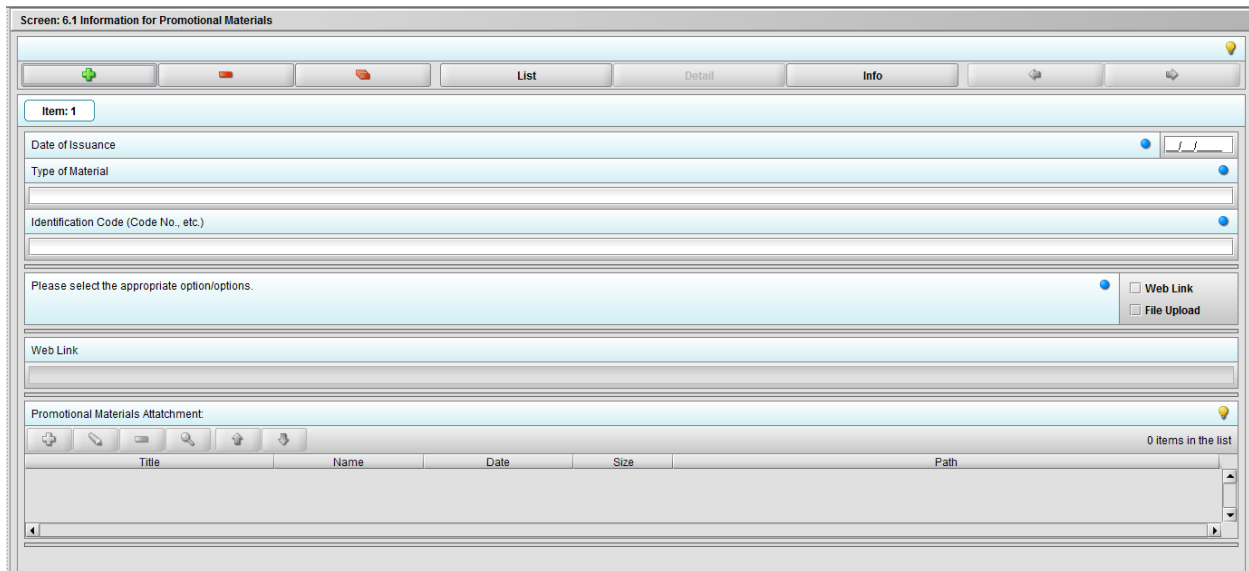


Figure 2.6.1(b): Clicking the '+' navigates to the questions associated with Promotional Materials.

Screen: 6.1 Information for Promotional Materials

Item: 1

Date of Issuance

Type of Material

Identification Code (Code No., etc.)

Please select the appropriate option/options.

Web Link
 File Upload

Web Link

Promotional Materials Attachment:

| Title | Name | Date | Size | Path |
|---------------------|------|------|------|------|
| 0 items in the list | | | | |

Figure 2.6.1(c): Selecting 'Web link' on question 'Please select the appropriate option/options.' enables question 'Web link'.

Screen: 6.1 Information for Promotional Materials

Item: 1

Date of Issuance

Type of Material

Identification Code (Code No., etc.)

Please select the appropriate option/options.

Web Link
 File Upload

Web Link

Promotional Materials Attachment:

| Title | Name | Date | Size | Path |
|---------------------|------|------|------|------|
| 0 items in the list | | | | |

Figure 2.6.1(c): Selecting 'File Upload' on question 'Please select the appropriate option/options.' enables question 'Promotional materials Attachment'.

*** Note: Selection to question 'Please select the appropriate option/options.' can be either or both.

Screen: 6.1 Information for Promotional Materials

Item: 1

Date of Issuance

Type of Material

Identification Code (Code No., etc.)

Please select the appropriate option/options. Web Link File Upload

Web Link

Promotional Materials Attachment

| Title | Name | Date | Size | Path |
|---------------------|------|------|------|------|
| 0 items in the list | | | | |

Figure 2.6.1(c): Selecting 'File Upload' on question 'Please select the appropriate option/options.' enables question 'Promotional materials Attachment'.