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1.0 DER Submission – CORE Template

1.1 Node 1.0 Type of submission

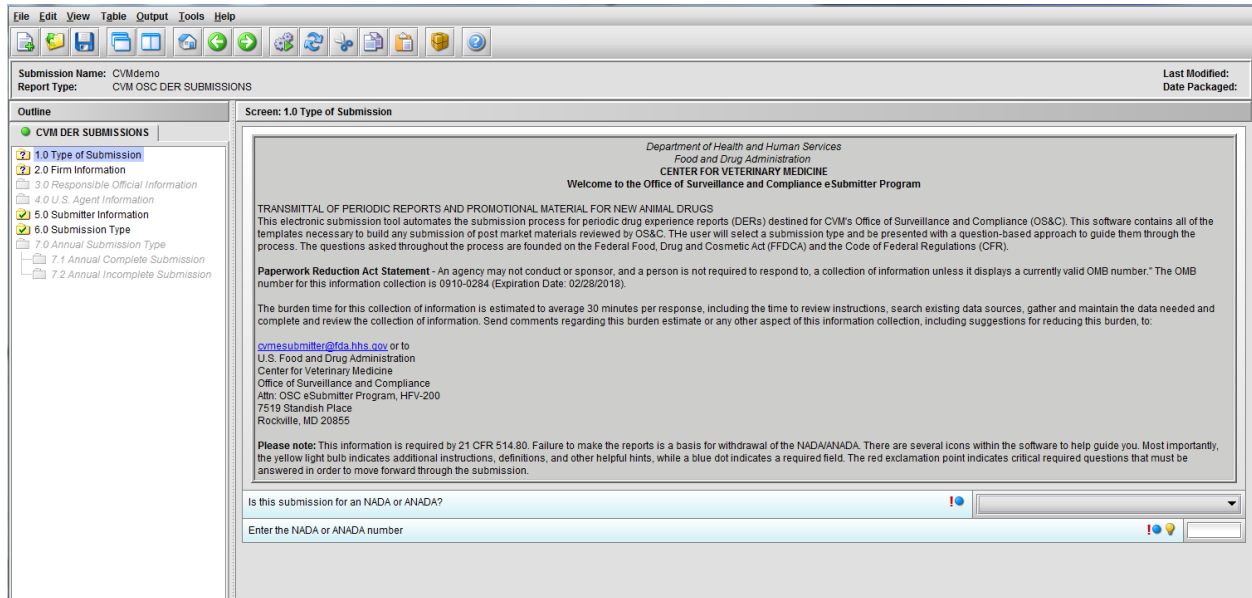


Figure 1.1(a): Initial screen for new submission

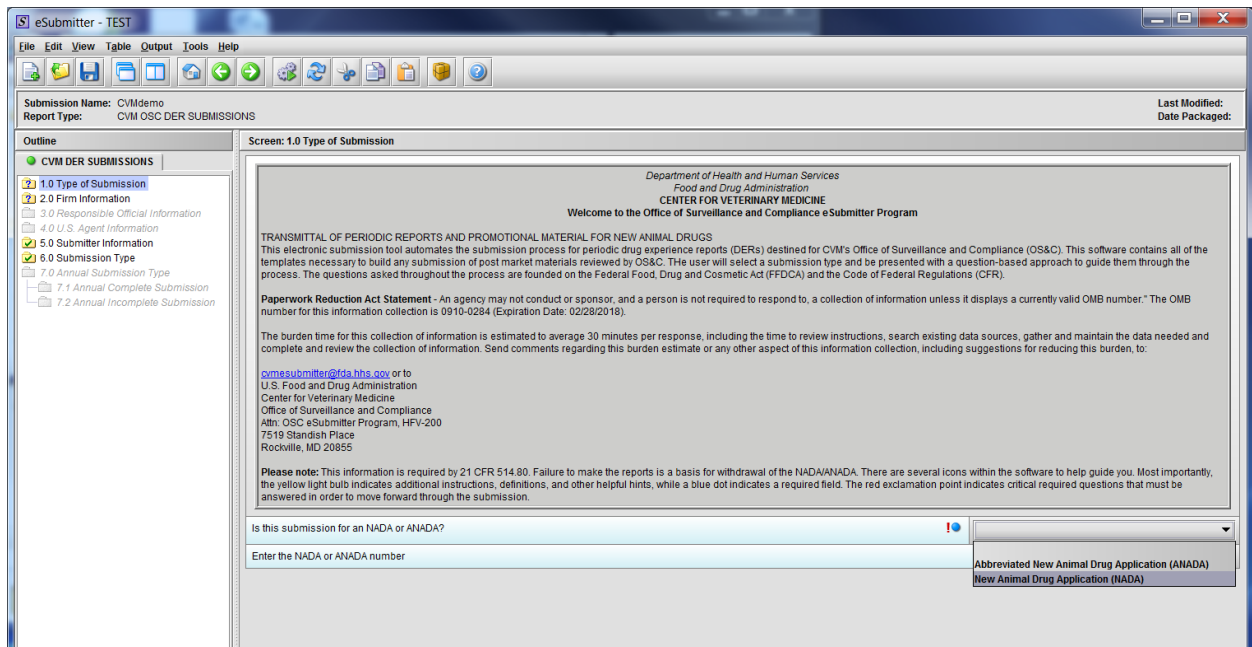


Figure 1.1(b): Drop Down selection for NADA or ANADA

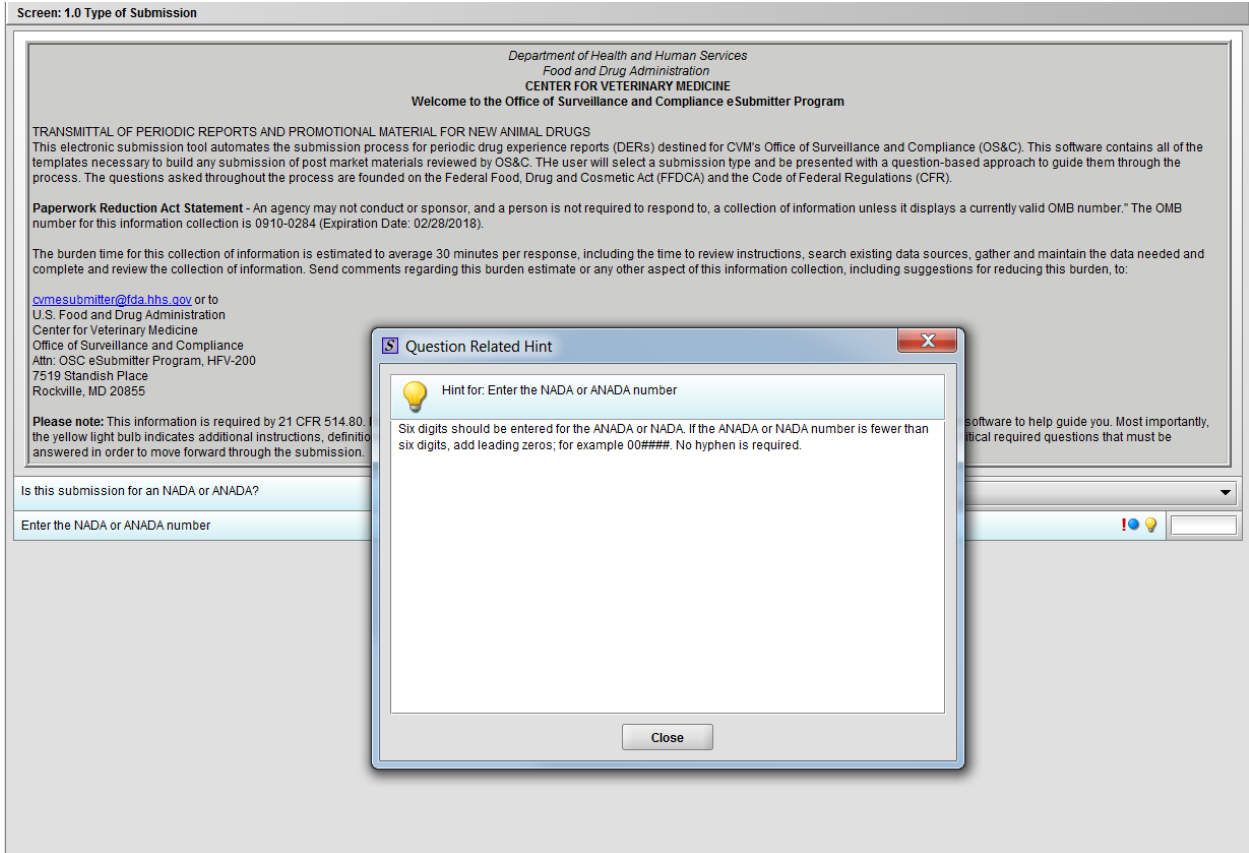


Figure 1.1(c): Hint associated with question 'Enter the NADA or ANADA number'

1.2 Node 2.0 Firm Information

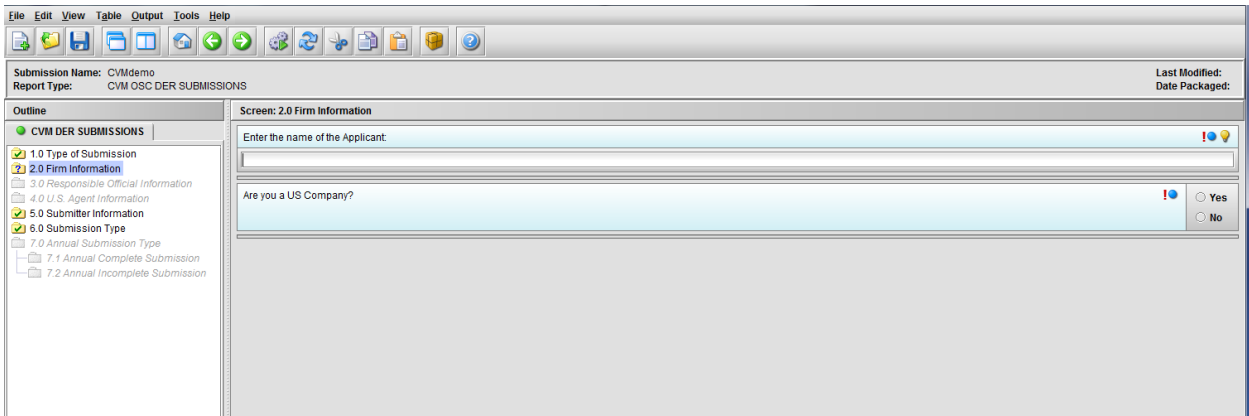


Figure 1.2(a): Firm information screen

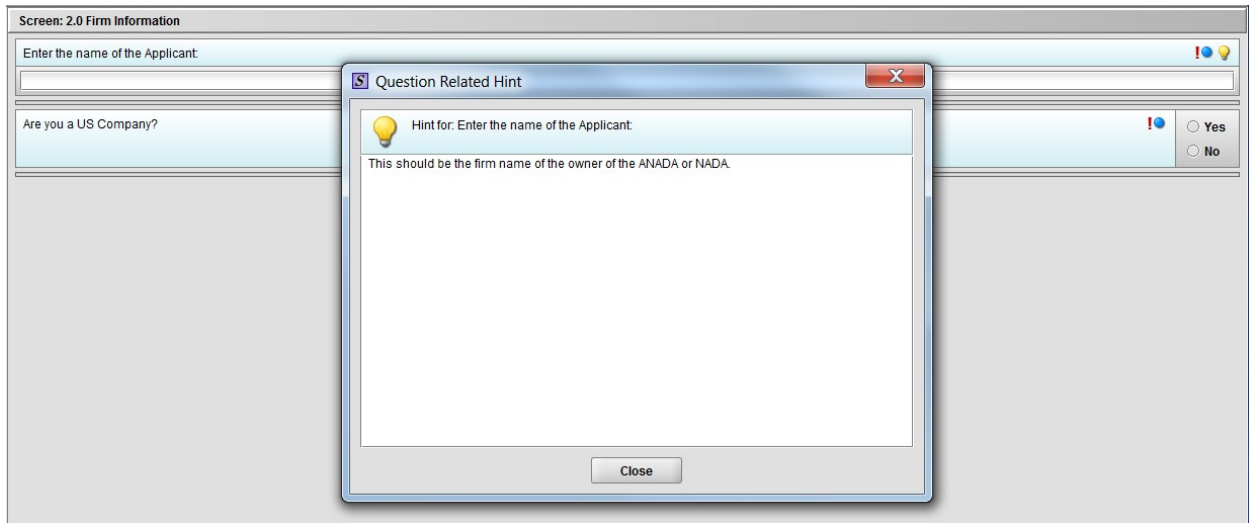


Figure 1.2(b): Hint related to question 'Enter the name of the Applicant'

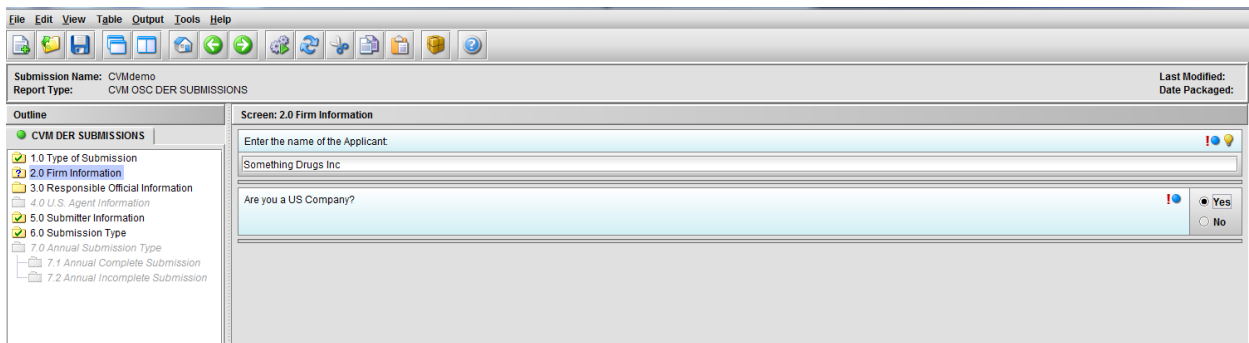


Figure 1.2(c): Selection of 'Yes' to question 'Are you a US Company' enables Node 3.0

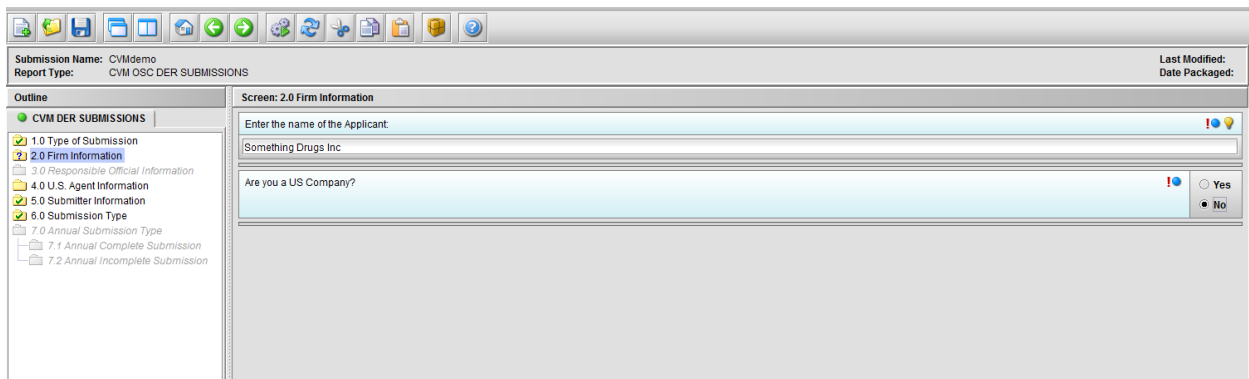


Figure 1.2(d): Selection of 'No' to question 'Are you a US Company' enables Node 4.0

1.3 Node 3.0 Responsible Official Information

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: 3.0 Responsible Official Information
Please enter Responsible Official 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:

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 Responsible Official? Yes No
What date was the Authorization Letter submitted?
Submit Authorization Letter for Consultant
File Attachment

Figure 1.3(a): Responsible Official Information

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

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?		____/____/____
Submit Authorization Letter for Consultant		
File Attachment	<input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Find"/> <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"/> ____/____/____
Submit Authorization Letter for Consultant		
File Attachment	<input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Find"/> <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?		____/____/____
Submit Authorization Letter for Consultant		
File Attachment	<input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Find"/> <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? [Date field]

Submit Authorization Letter for Consultant

File Attachment [Add] [Remove] [Search] [Info] [Text field]

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 [Add] [Remove] [Search] [Info] [Text field]

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 [Add] [Remove] [Search] [Info] [Text field]

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		Last Modified: 01/21/2017 03:36:17 PM																																							
Report Type: CVM OSC DER SUBMISSIONS		Date Packaged:																																							
Outline	Screen: 5.0 Submitter Information																																								
<ul style="list-style-type: none"><input checked="" type="checkbox"/> CVM DER SUBMISSIONS<input checked="" type="checkbox"/> 1.0 Type of Submission<input checked="" type="checkbox"/> 2.0 Firm Information<input checked="" type="checkbox"/> 3.0 Responsible Official Information<input type="checkbox"/> 4.0 U.S. Agent Information<input checked="" type="checkbox"/> 5.0 Submitter Information<input checked="" type="checkbox"/> 6.0 Submission Type<input type="checkbox"/> 7.0 Annual Submission Type<input type="checkbox"/> 7.1 Annual Complete Submission<input type="checkbox"/> 7.2 Annual Incomplete Submission	<p>Is the Submitter the same person as the Responsible Official or US Agent? <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <hr/> <p>Please Enter Submitter Information</p> <table border="1"><tr><td colspan="2">Contact</td></tr><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><tr><td colspan="2">Address</td></tr><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><tr><td colspan="2">Phone Numbers</td></tr><tr><td>Telephone number:</td><td>() - - Ext: -</td></tr><tr><td>Fax number:</td><td>() - -</td></tr></table>			Contact		Title (e.g., Mr., Ms.):		First/Given Name:		Middle Name:		Last Name:		Occupation Title:		Email Address:		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:		Phone Numbers		Telephone number:	() - - Ext: -	Fax number:	() - -
Contact																																									
Title (e.g., Mr., Ms.):																																									
First/Given Name:																																									
Middle Name:																																									
Last Name:																																									
Occupation Title:																																									
Email Address:																																									
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:																																									
Phone Numbers																																									
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 for the question 'Have all 4 required Semi-Annual (6 months) DERs been submitted?'. The 'CAUTION' 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 for the question 'Have all 4 required Semi-Annual (6 months) DERs been submitted?'. The 'CAUTION' 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

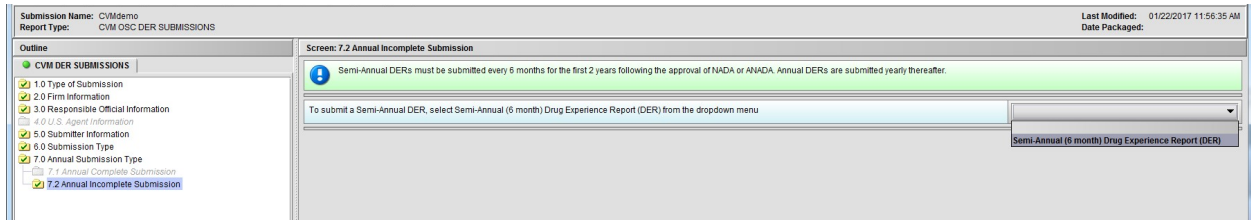


Figure 1.7.2(a): Drop Down navigates to Semi-Annual Template

2.0 DER Submission – Semi-Annual Template

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

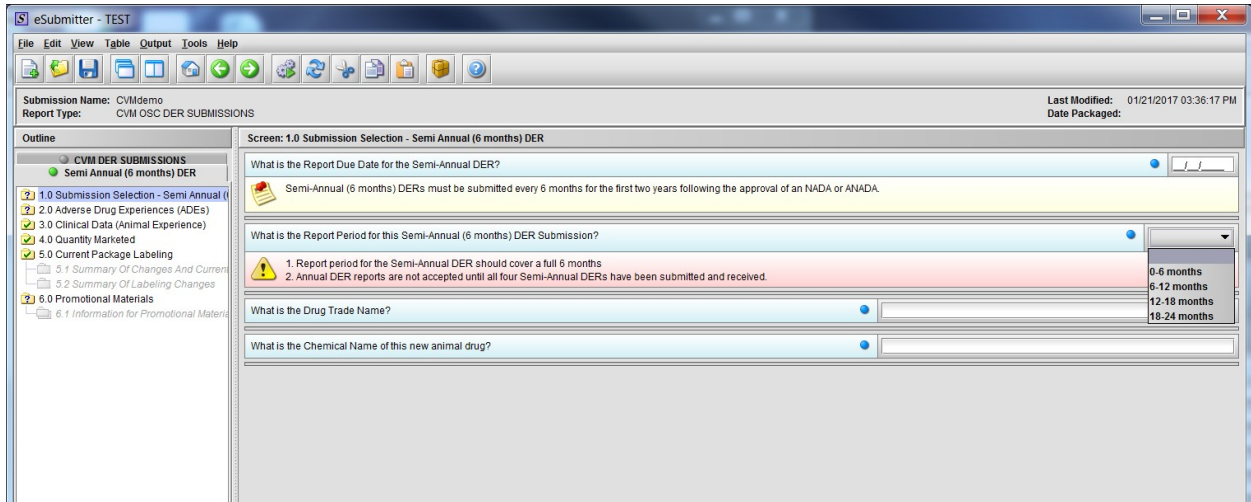



Figure 2.1(a): Submission Selection – Semi-Annual (6 months) DER. Drop Down selection for question ‘What is the Report Period for this Semi-Annual (6 months) DER Submission?’

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

 0 items in the list

Title	Name	Date	Size	Path

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

 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>

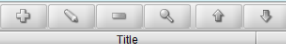
Type of Information to Report Adverse Drug Experience Reports associated with this periodic DER were submitted electronically
 Summary of Increased Frequency of Adverse Drug Experiences

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>

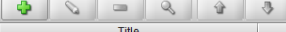
Type of Information to Report Adverse Drug Experience Reports associated with this periodic DER were submitted electronically
 Summary of Increased Frequency of Adverse Drug Experiences

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)

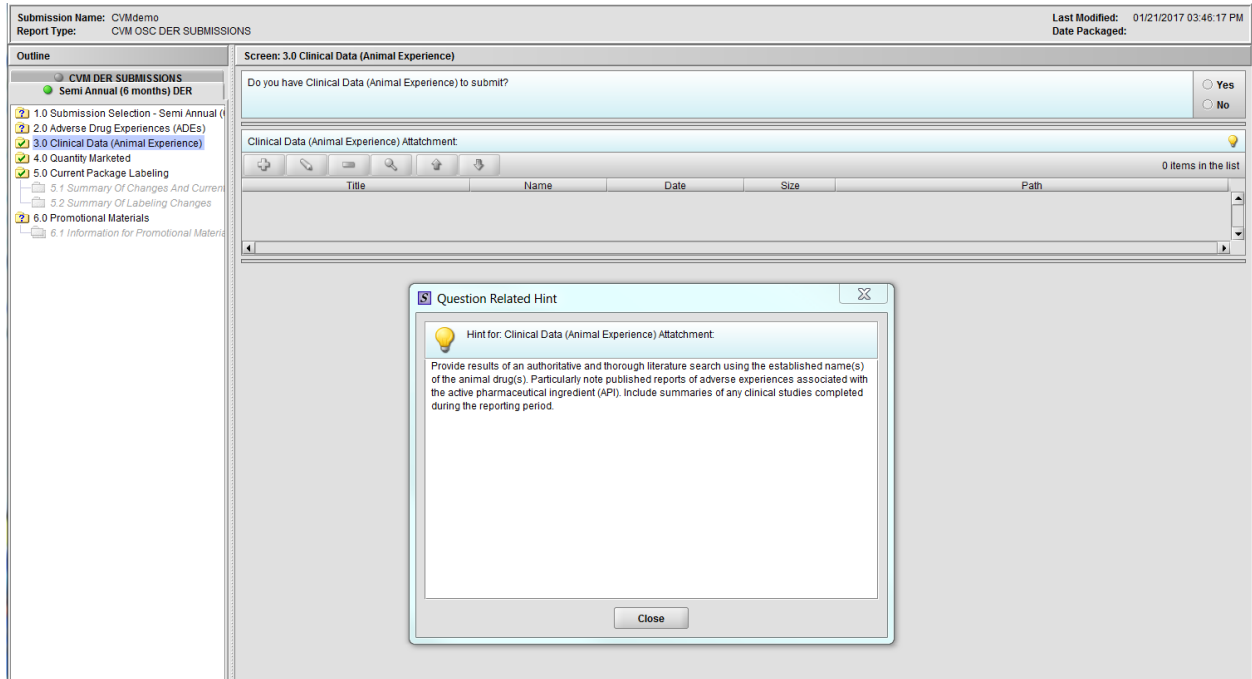


Figure 2.3(a): Clinical Data (Animal Experience). Hint for question 'Clinical Data (Animal Experience) Attachment'.

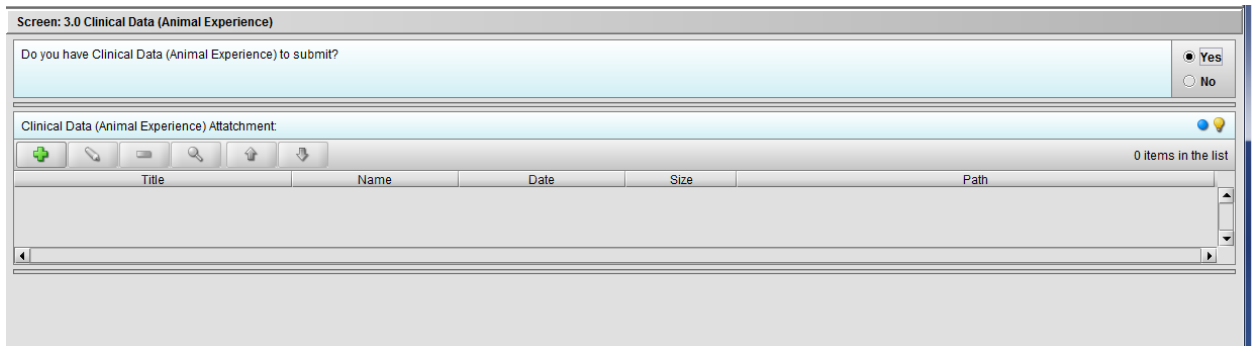


Figure 2.3(b): Selection of 'Yes' to question 'Do you have Clinical Data (Animal Experience) to submit?' enables question 'Clinical Data (Animal Experience) Attachment'.

Screen: 3.0 Clinical Data (Animal Experience)

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

Clinical Data (Animal Experience) Attachment

0 items in the list

Title	Name	Date	Size	Path

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

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/23/2017 12:23:27 PM
Date Packaged:

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: 4.0 Quantity Marketed

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

QUANTITY MARKETED

Quantity Marketed (Distribution) Data Attachment:

0 items in the list

Title	Name	Date	Size	Path

NO QUANTITY MARKETED

Please select one of the options:

This product has not been marketed or manufactured
 This is a combination product

Figure 2.4(a): Quantity Marketed

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/22/2017 11:22:36 AM
Date Packaged:

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: 4.0 Quantity Marketed

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

QUANTITY MARKETED

Quantity Marketed (Distribution) Data Attachment:

0 items in the list

Title	Name	Date	Size	Path

NO QUANTITY MARKETED

Please select one of the options:

This product has not been marketed or manufactured
 This is a combination product

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:'.

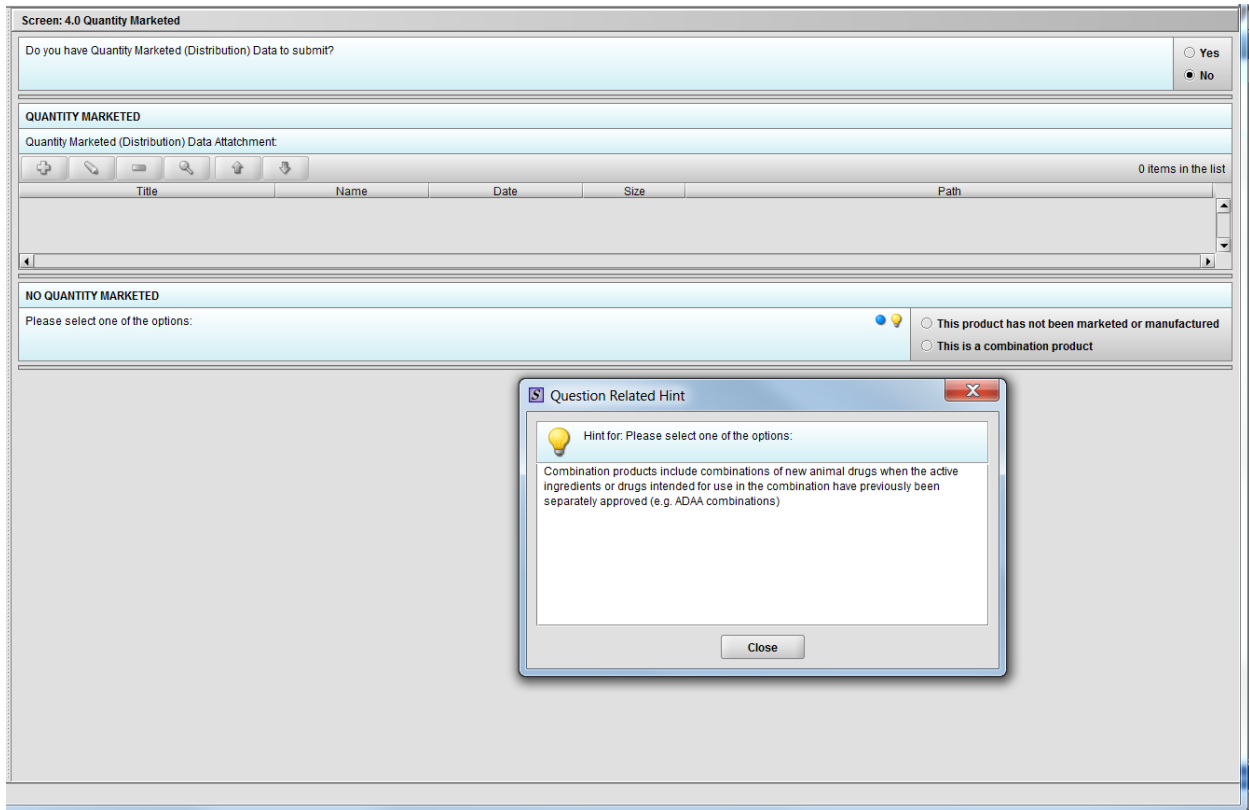


Figure 2.4(c): Selection of 'No' to question 'Do you have Quantity Marketed (Distribution) Data to submit?' navigates to next Node. Hint to question 'Quantity Marketed (Distribution) Data Attachment:'

2.4 Node 5.0 Current Package Labeling

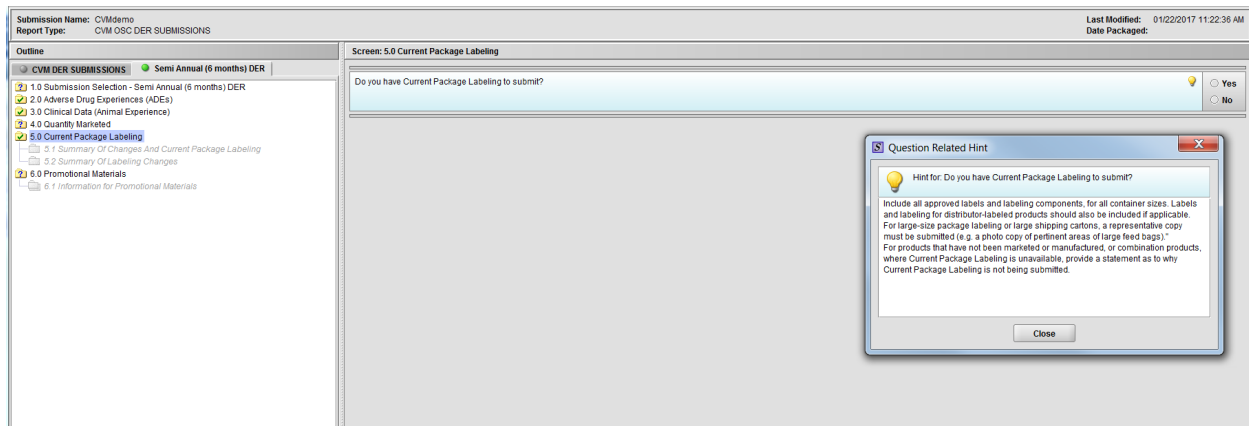


Figure 2.5(a): Current Package Labeling. Hint for question 'Do you have Current Package Labeling to submit?'

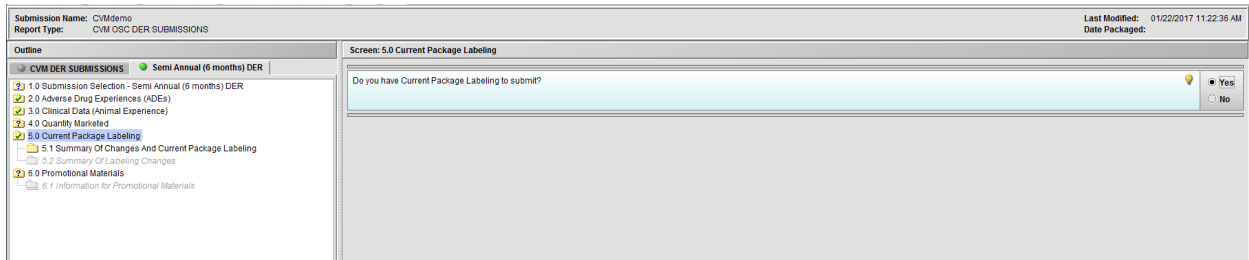


Figure 2.5(b): Selection of 'Yes' to question 'Do you have Current Package Labeling to submit?' enables Node 5.1

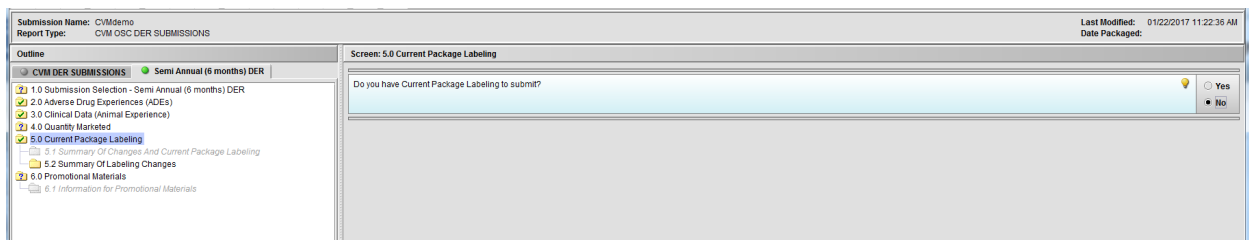


Figure 2.5(c): Selection of 'No' to question 'Do you have Current Package Labeling to submit?' enables Node 5.2

2.4.1 Node 5.1 Summary of Changes and Current Package Labeling

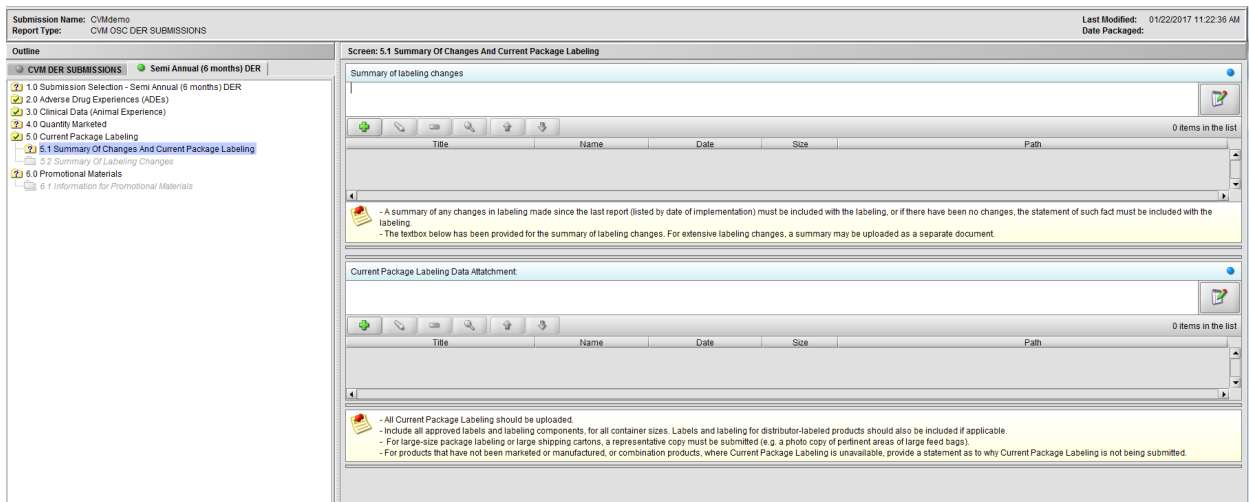


Figure 2.5.1(a): Summary Of Changes And Current Package Labeling

2.4.2 Node 5.2 Summary of Labeling Changes

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/22/2017 11:31:1 AM
Date Packaged:

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: 5.2 Summary Of Labeling Changes

I certify that there have been no changes.

Summary of labeling changes

Title	Name	Date	Size	Path
0 items in the list				

- 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.
- The textbox above has been provided for the summary of labeling changes.

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

2.5 Node 6.0 Promotional Materials

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/22/2017 11:31:1 AM
Date Packaged:

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: 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

Figure 2.6(a): Promotional Materials

Submission Name: CVMdemo
Report Type: CVM OSC DER SUBMISSIONS
Last Modified: 01/22/2017 11:31:1 AM
Date Packaged:

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: 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

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

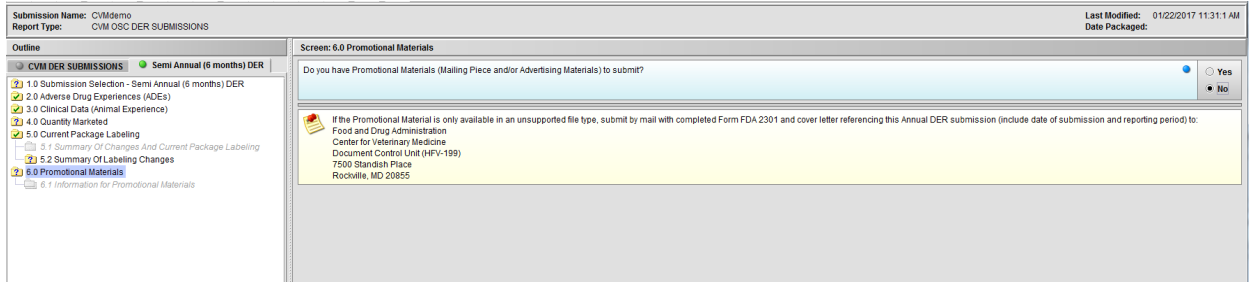


Figure 2.6(c): Selection of 'No' to question 'Do you have Promotional Materials (Mailing Piece and/or Advertising Materials) to submit?' completes the submission questions

2.5.1 Node 6.1 Information for Promotional Material

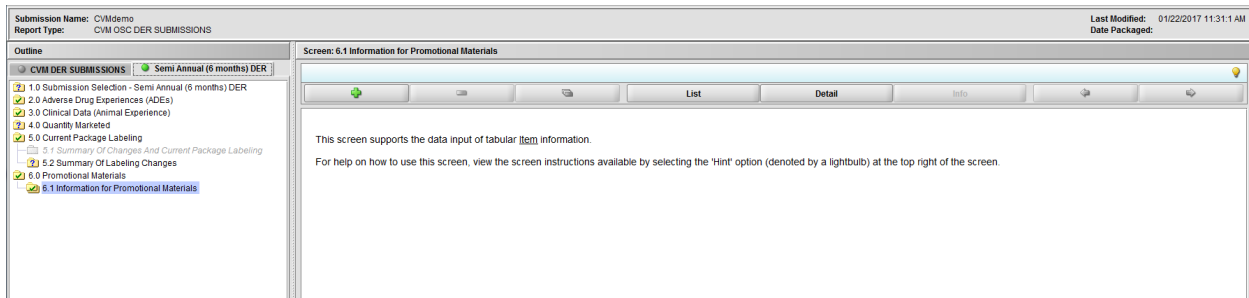


Figure 2.6.1(a): Information for Promotional Materials

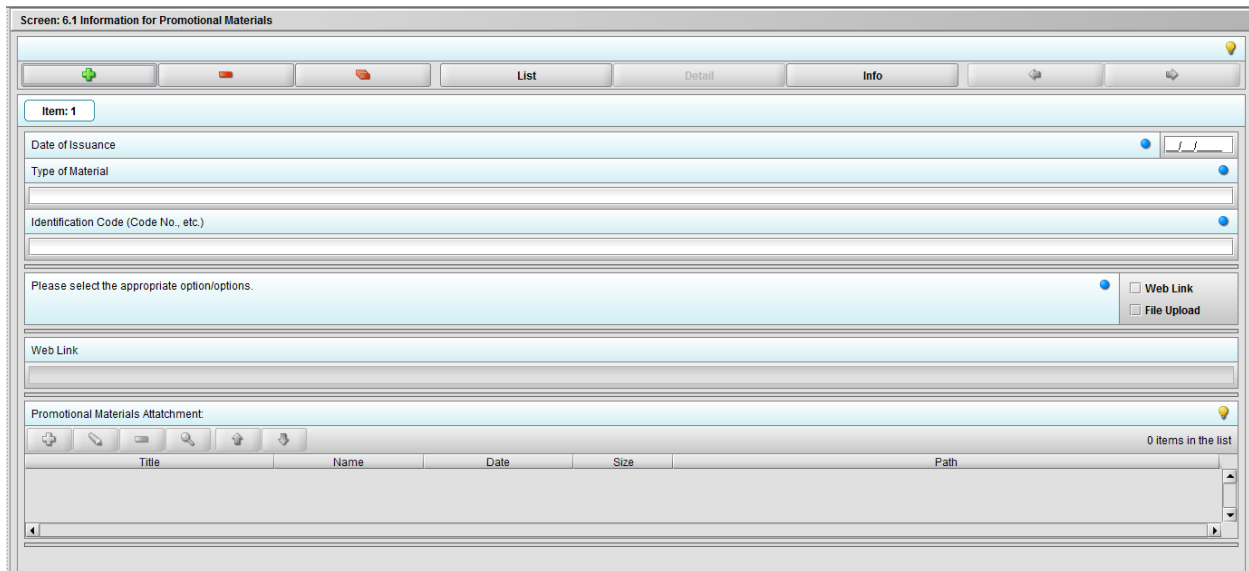


Figure 2.6.1(b): Clicking the '+' navigates to the questions associated with Promotional Materials.

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: 0 items in the list

Title	Name	Date	Size	Path
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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: 0 items in the list

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

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 0 items in the list

Title	Name	Date	Size	Path

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