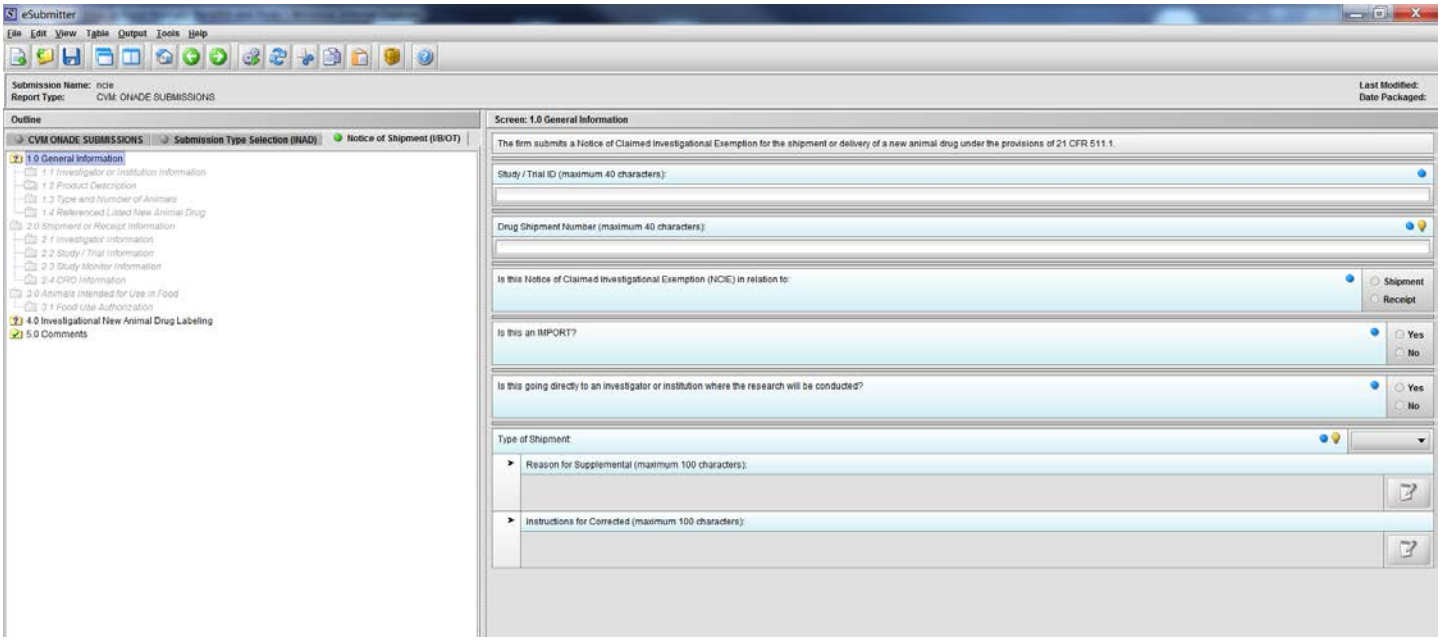
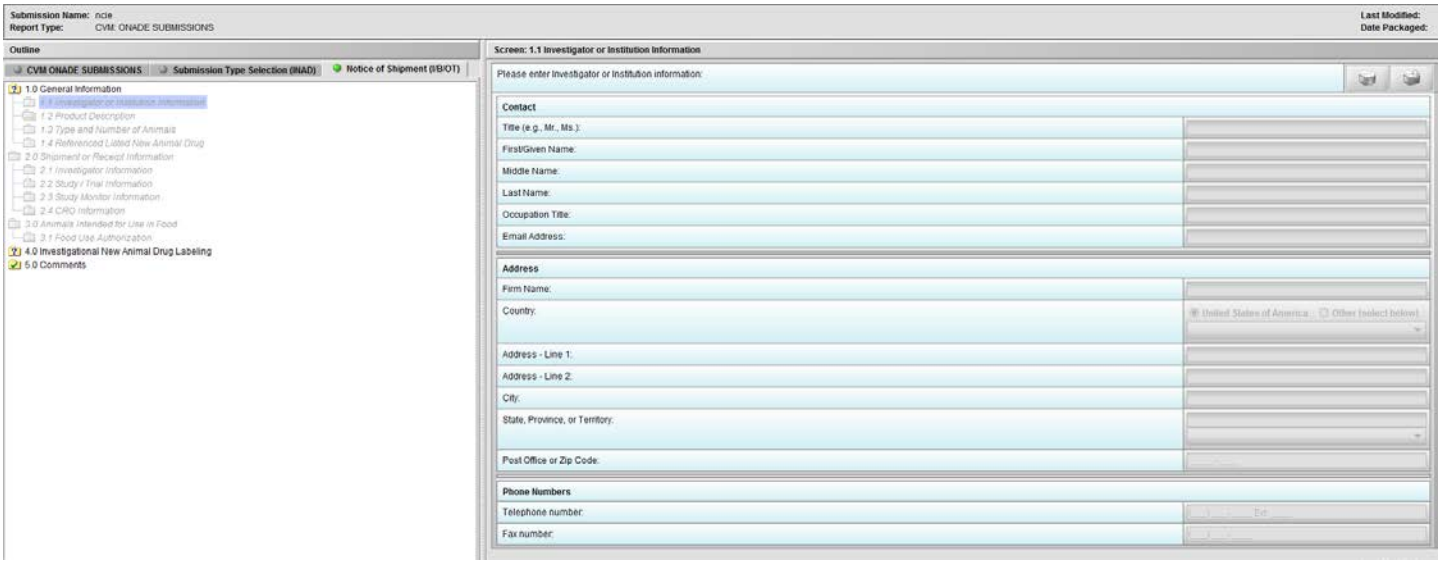
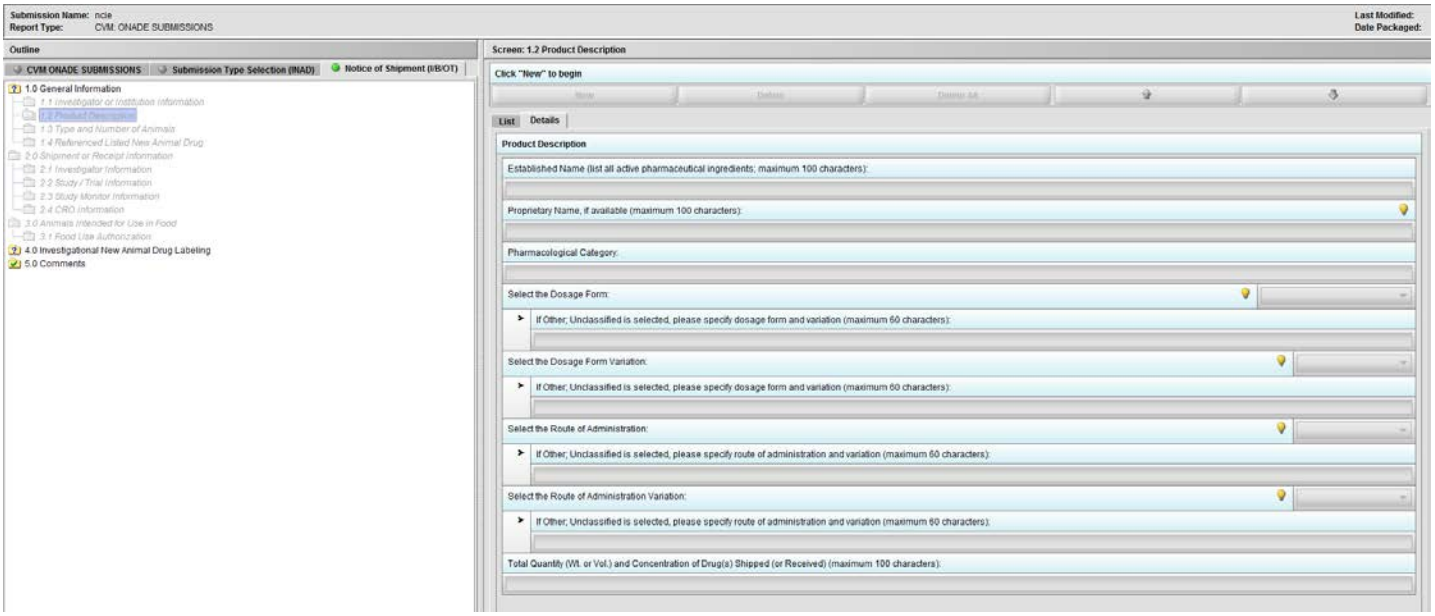
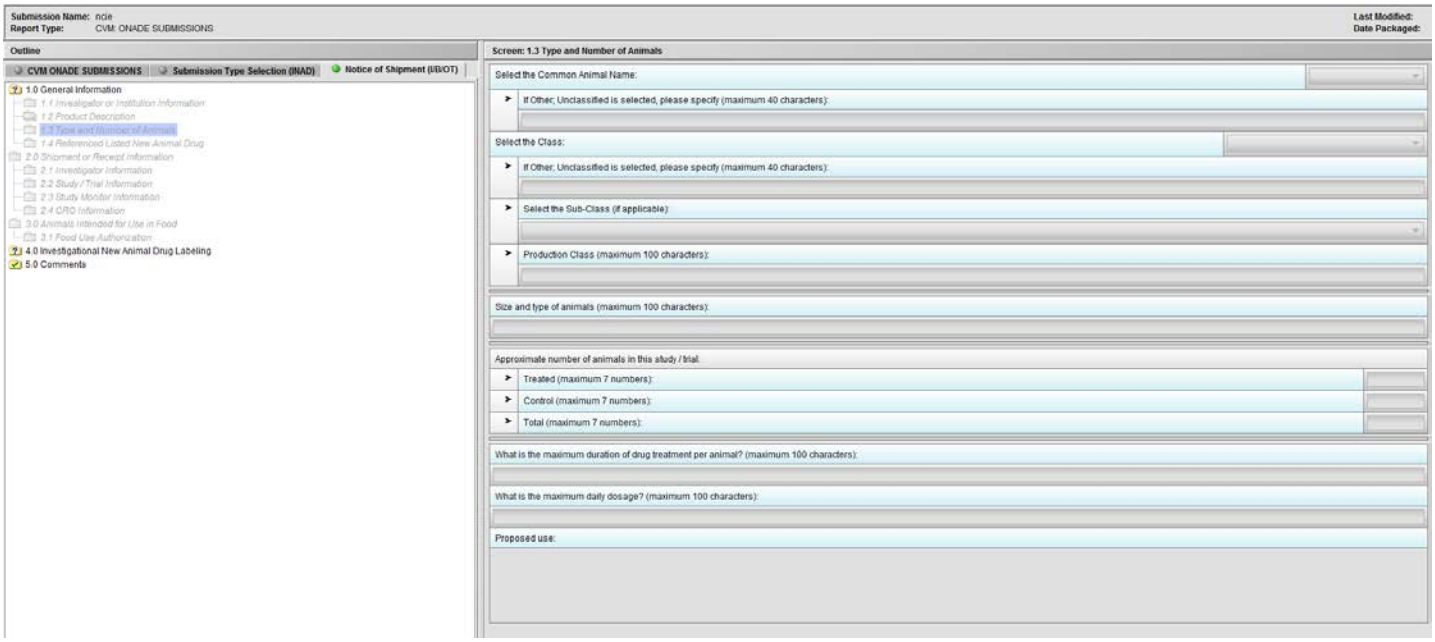
Notice of Claimed Investigational Exemption (I-B-OT) Template From eSubmitter






Submission Name: ncie
Report Type: CVM: ONADE SUBMISSIONS
Last Modified:
Date Packaged:
Outline
CVM ONADE SUBMISSIONS
Submission Type Selection (INAD)
Notice of Shipment (I/B/OT)
1.0 General Information
1.1 Investigator or Institution Information
1.2 Product Description
1.3 Type and Number of Animals
1.4 Referenced Listed New Animal Drug
2.0 Shipment or Receipt Information
2.1 Investigator Information
2.2 Study / Trial Information
2.3 Study Monitor Information
2.4 CRO Information
3.0 Animals Intended for Use in Food
3.1 Food Use Authorization
4.0 Investigational New Animal Drug Labeling
5.0 Comments
Screen: 1.2 Product Description
Click "New" to begin
New
Delete
Delete All
List
Details
Product Description
Established Name (list all active pharmaceutical ingredients; maximum 100 characters):
Proprietary Name, if available (maximum 100 characters):
Pharmacological Category:
Select the Dosage Form:
If Other; Unclassified is selected, please specify dosage form and variation (maximum 60 characters):
Select the Dosage Form Variation:
If Other; Unclassified is selected, please specify dosage form and variation (maximum 60 characters):
Select the Route of Administration:
If Other; Unclassified is selected, please specify route of administration and variation (maximum 60 characters):
Select the Route of Administration Variation:
If Other; Unclassified is selected, please specify route of administration and variation (maximum 60 characters):
Total Quantity (Wt. or Vol.) and Concentration of Drug(s) Shipped (or Received) (maximum 100 characters):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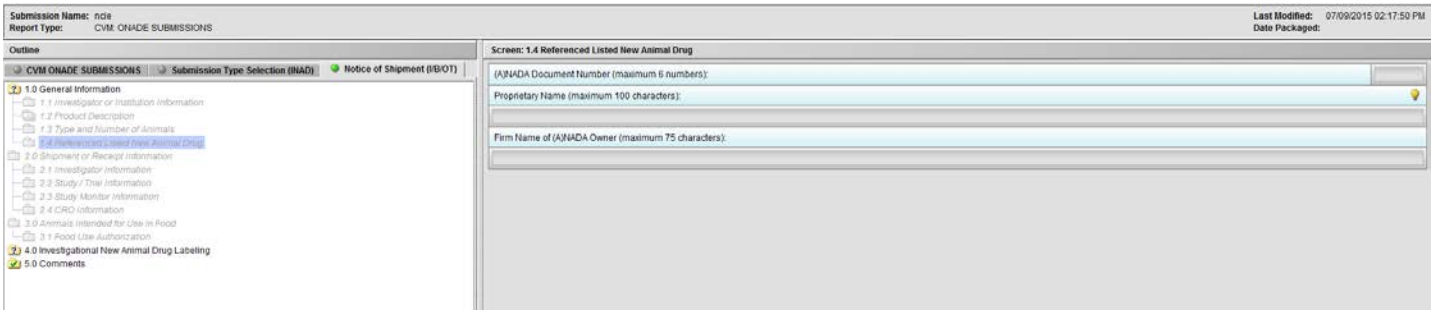
Screen: 1.3 Type and Number of Animals
Select the Common Animal Name:
If Other; Unclassified is selected, please specify (maximum 40 characters):
Select the Class:
If Other; Unclassified is selected, please specify (maximum 40 characters):
Select the Sub-Class (if applicable):
Production Class (maximum 100 characters):
Size and type of animals (maximum 100 characters):
Approximate number of animals in this study / trial.
Treated (maximum 7 numbers):
Control (maximum 7 numbers):
Total (maximum 7 numbers):
What is the maximum duration of drug treatment per animal? (maximum 100 characters):
What is the maximum daily dosage? (maximum 100 characters):
Proposed use: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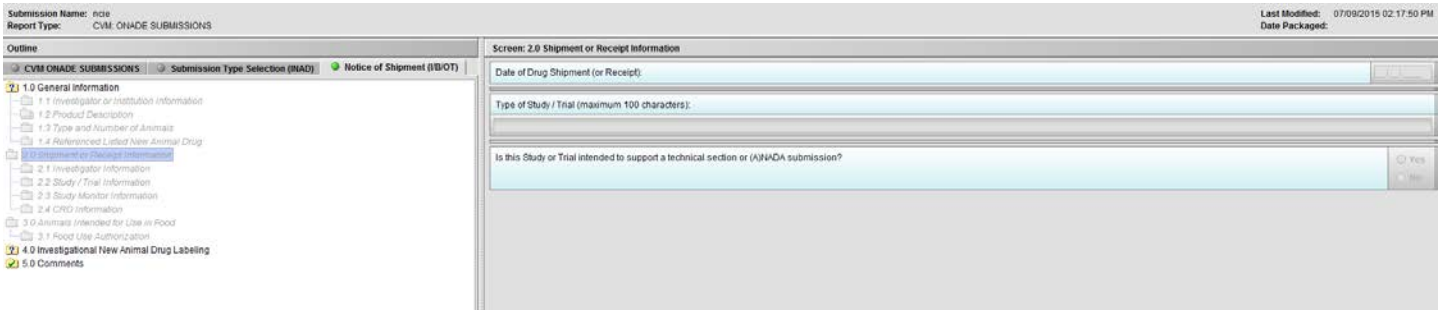
Screen: 1.4 Referenced Listed New Animal Drug
(A)NADA Document Number (maximum 6 numbers):
Proprietary Name (maximum 100 characters):
Firm Name of (A)NADA Owner (maximum 75 characters):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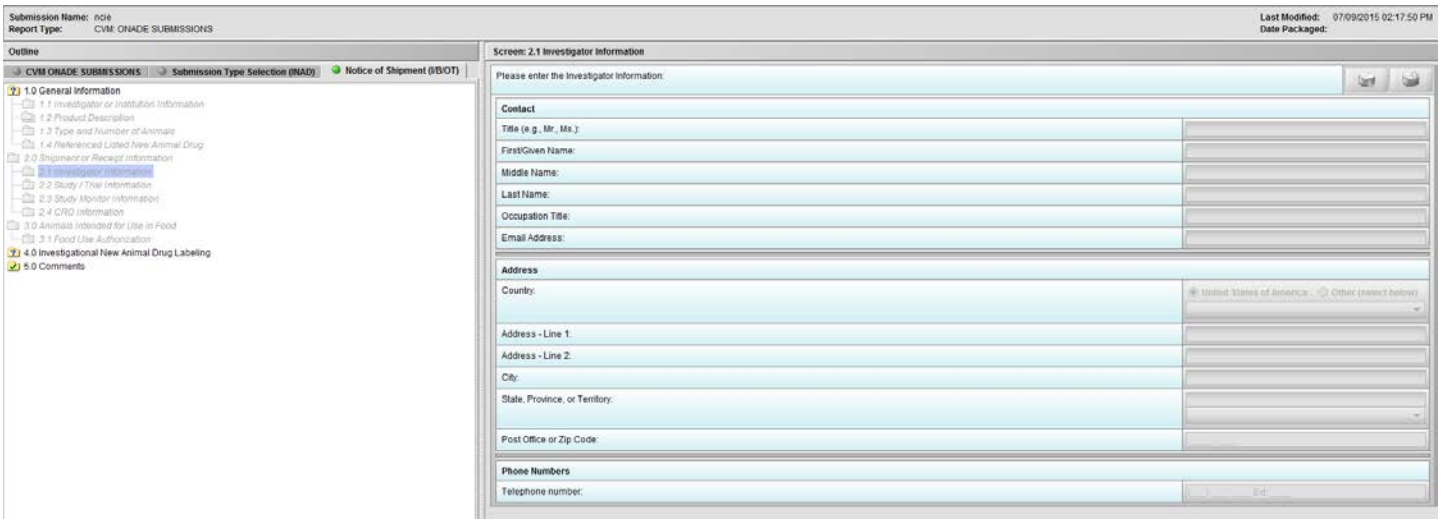
4.0 Investigational New Animal Drug Labeling
5.0 Comments
Screen: 2.0 Shipment or Receipt Information
Date of Drug Shipment (or Receipt):
Type of Study / Trial (maximum 100 characters):
Is this Study or Trial intended to support a technical section or (A)NADA submission?
Yes
No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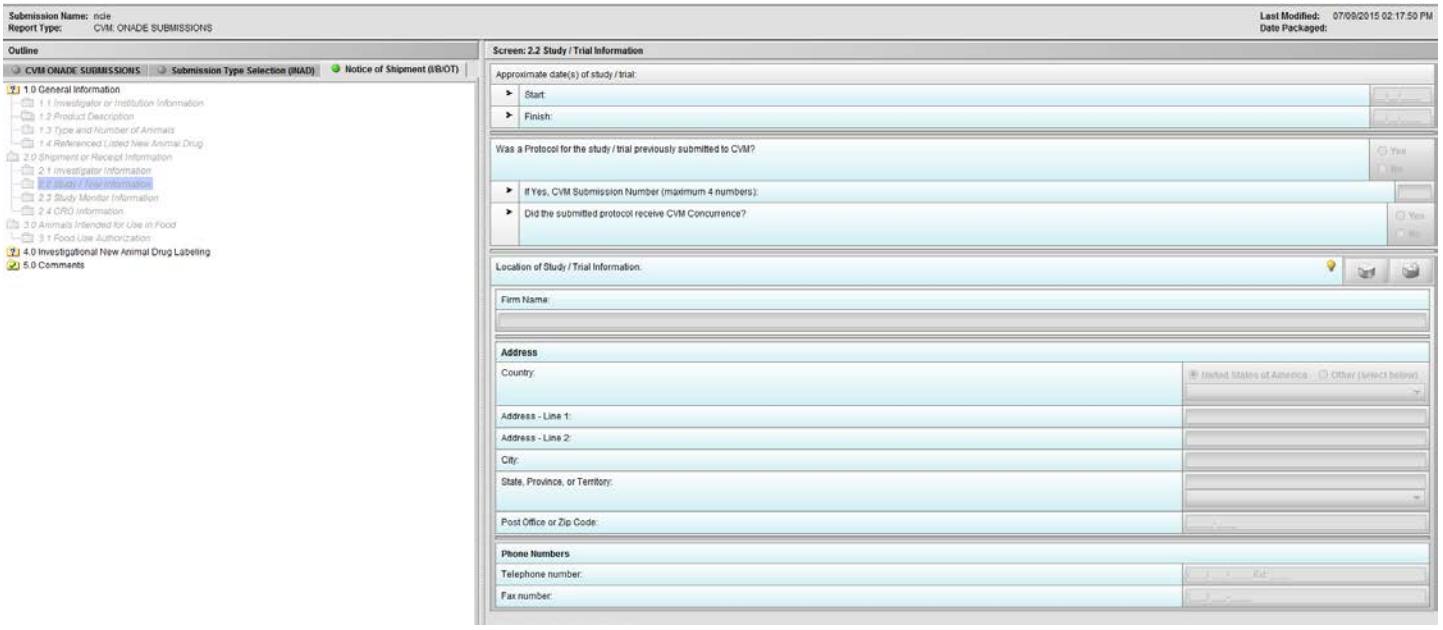
Screen: 2.1 Investigator Information
Please enter the Investigator Information:
Contact
Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Occupation Title:
Email Address:
Address
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Phone Numbers
Telephone number:
Ext.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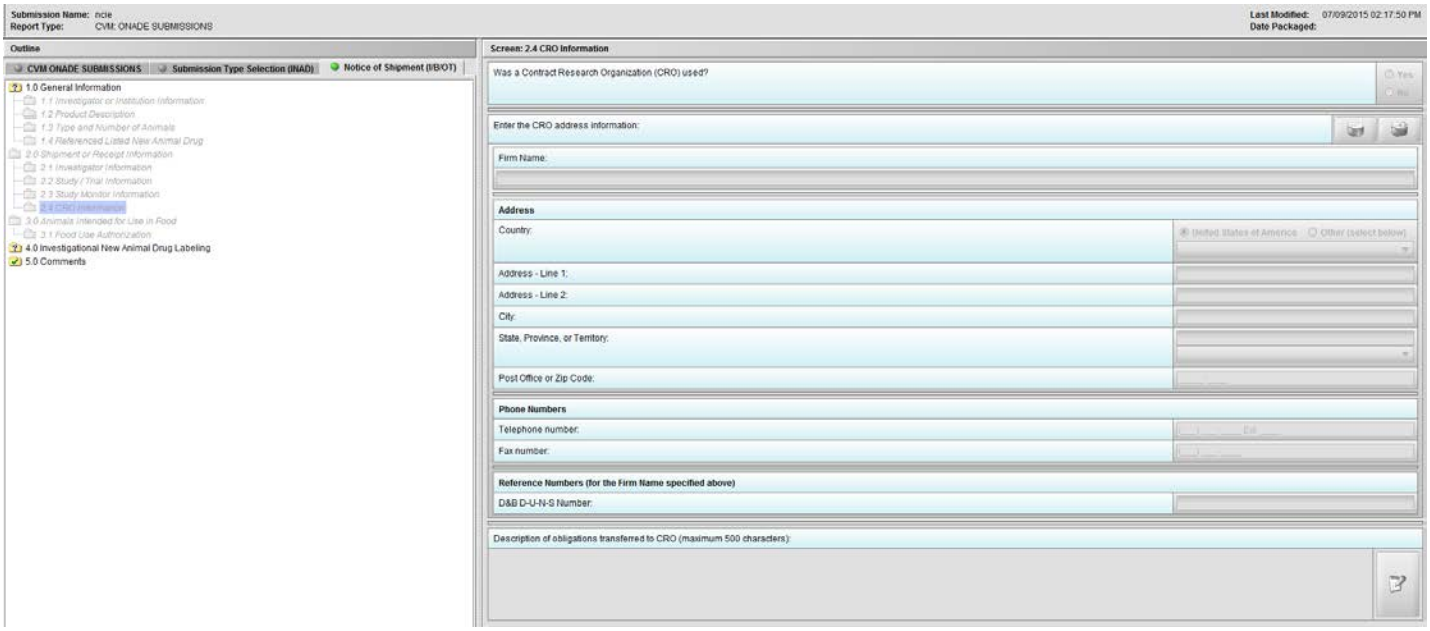
Screen: 2.2 Study / Trial Information
Approximate date(s) of study / trial:
Start:
Finish:
Was a Protocol for the study / trial previously submitted to CVM?
Yes
No
If Yes, CVM Submission Number (maximum 4 numbers):
Did the submitted protocol receive CVM Concurrence?
Location of Study / Trial Information:
Firm Name:
Address
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: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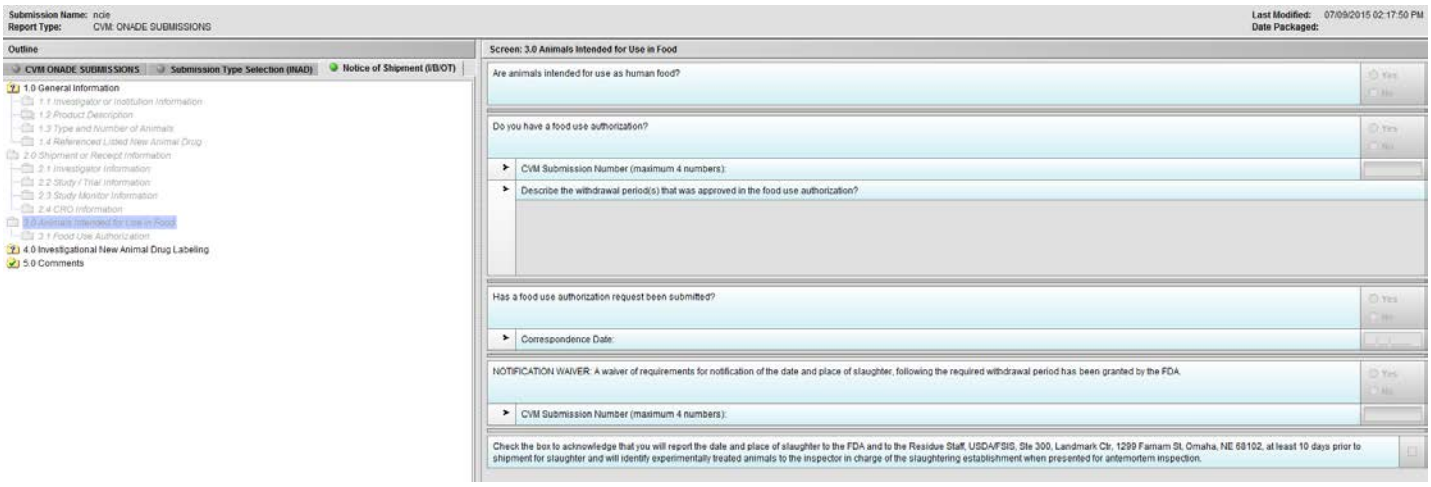
Screen: 2.4 CRO Information
Was a Contract Research Organization (CRO) used?
Yes
No
Enter the CRO address information:
Firm Name:
Address
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Phone Numbers
Telephone number:
Fax number:
Reference Numbers (for the Firm Name specified above)
D&B D-U-N-S Number:
Description of obligations transferred to CRO (maximum 500 characters):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Screen: 3.0 Animals Intended for Use in Food
Are animals intended for use as human food?
Yes
No
Do you have a food use authorization?
CVM Submission Number (maximum 4 numbers):
Describe the withdrawal period(s) that was approved in the food use authorization?
Has a food use authorization request been submitted?
Correspondence Date:
NOTIFICATION WAIVER: A waiver of requirements for notification of the date and place of slaughter, following the required withdrawal period has been granted by the FDA.
CVM Submission Number (maximum 4 numbers):
Check the box to acknowledge that you will report the date and place of slaughter to the FDA and to the Residue Staff, USDA/FSIS, Ste 300, Landmark Ctr, 1299 Farnam St, Omaha, NE 68102, at least 10 days prior to shipment for slaughter and will identify experimentally treated animals to the inspector in charge of the slaughtering establishment when presented for antemortem inspection.


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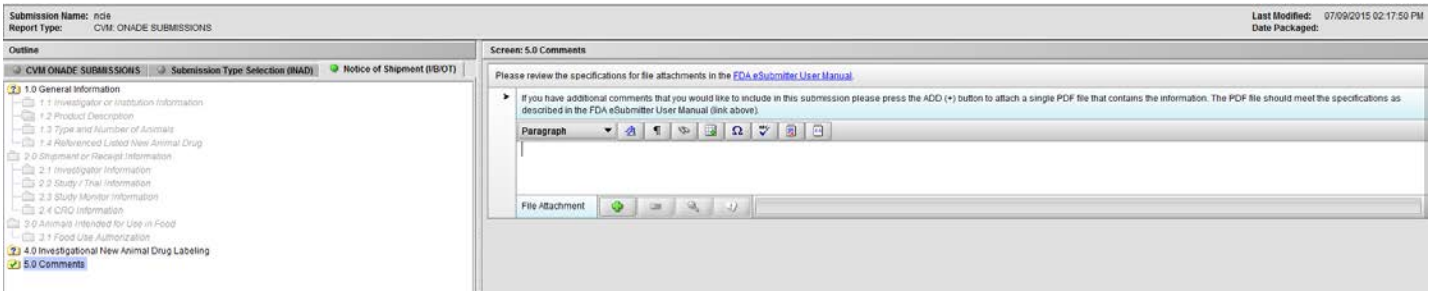
Screen: 4.0 Investigational New Animal Drug Labeling
Please select the labeling text that will be used on your investigational new animal drug:
New animal drugs for tests in vitro and in laboratory research: Caution. Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.
New animal drugs for clinical investigation: Caution. Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.
New animal drugs for EXPORT: Caution. Contains a new animal drug for use only in investigational clinical trials. Not for use in humans. Edible products from animals used for investigation are not to be used for food in any manner contrary to the requirements of the country in which the clinical trials are to be conducted.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Screen: 5.0 Comments
Please review the specifications for file attachments in the FDA eSubmitter User Manual.
If you have additional comments that you would like to include in this submission 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).
Paragraph
File Attachment