NCIE (I-B) Template

Notice of Shipment (B)

1.0 General Information

Information:	The firm submits a Notice of Claimed Investigational Exemption for the shipment or delivery of a new animal drug under the provisions of 21 CFR 511.1.

Is this submission a quarterly report for minor species partners (e.g., aquaculture) who has/have a formal agreement with ONADE for submitting batched shipment notices?	
( ) Yes ( ) No	
Warning:	A sponsor may only use this option if it has a formal agreement with ONADE for batching and quarterly reporting.

Study / Trial ID (maximum 40 characters):

Treatment year and quarter number:

Drug Shipment Number (maximum 40 characters):

Is this Notice of Claimed Investigational Exemption (NCIE) in relation to:
( ) Shipment ( ) Receipt

Is this an IMPORT?
( ) Yes ( ) No

Is this going directly to an investigator or institution where the research will be conducted?
( ) Yes ( ) No

Type of Shipment:	
[L]	
>	Reason for Supplemental (maximum 100 characters):
>	Instructions for Corrected (maximum 100 characters):

1.1 Investigator or Institution Information

Contact	
Title (e.g., Mr. Ms., Dr.):	[L]
First/Given Name:	
Middle Name:	
Last Name:	
Occupation Title:	
Email Address:	

Address	
Firm Name:	
Address - Line 1:	
Address - Line 2:	
City:	
Postal Code:	

Phone Numbers	
Telephone Number:	
Fax Number:	

1.2 Type and Number of Animals

Select the Target Animal:
[L]

Size and type of animals (maximum 100 characters):

Approximate number of animals in this study / trial:	
Investigational (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:
[HTML Text]

2.0 Shipment or Receipt Information

Date of Drug Shipment (or Receipt):	[Date]

Total Quantity (Wt. or Vol.) and Concentration of Drug(s) Shipped (or Received) (maximum 100 characters):

Type of Study / Trial (maximum 100 characters):

Is this Study or Trial intended to support a technical section or (A)NADA submission?
( ) Yes ( ) No

2.1 Investigator Information

Contact	
Title (e.g., Mr. Ms., Dr.):	[L]
First/Given Name:	
Middle Name:	
Last Name:	
Occupation Title:	
Email Address:	

Address	
Address - Line 1:	
Address - Line 2:	
City:	
Postal Code:	

Phone Numbers	
Telephone Number:	

2.2 Study / Trial Information

Approximate date(s) of study / trial:

Start:	[Date]
Finish:	[Date]

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?
	( ) Yes ( ) No

Study Site Name:	
Address	
Address - Line 1:	
Address - Line 2:	
City:	
Postal Code:	

Phone Numbers	
Telephone Number:	
Fax Number:	

2.3 Study Monitor Information

Contact	
Title (e.g., Mr. Ms., Dr.):	[L]
First/Given Name:	
Middle Name:	
Last Name:	
Occupation Title:	
Email Address:	

Address	
Firm Name:	
Address - Line 1:	
Address - Line 2:	

City:	
Postal Code:	

Phone Numbers	
Telephone Number:	

2.4 CRO Information

Was a Contract Research Organization (CRO) used?
( ) Yes ( ) No

CRO Name:	
Address	
Address - Line 1:	
Address - Line 2:	
City:	
Postal Code:	

Phone Numbers	
Telephone Number:	
Fax Number:	

Reference Number	
D&B D-U-N-S Number:	

Description of obligations transferred to CRO (maximum 500 characters):
[Multi-Line Plain Text]

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?	
( ) Yes ( ) No	
>	CVM Submission Number (maximum 4 numbers):

>	Describe the withdrawal period(s) that was approved in the food use authorization?
	[HTML Text]

Has an investigational food-use authorization request been submitted to CVM?		
( ) Yes ( ) No		
>	Correspondence Date:	[Date]
Stop:	You MUST have a food-use authorization in order for entry of edible products from investigational animals into the human food supply (21 CFR 511.(b)(5)). DO NOT CONTINUE with this submission, please contact CVM.	

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?	
( ) Yes ( ) No	
>	CVM Submission Number (maximum 4 numbers):

Check the box to acknowledge for investigational animals subject to USDA inspection that you will report the date and slaughter to the FDA and to the Residue Staff, USDA/FSIS, 1616 Capitol Avenue, Suite 260, Omaha, NE 68102, at least 10 days prior to shipment for slaughter and will identify investigational animals to the inspector in charge of the slaughtering establishment when presented for antemortem inspection. [21 CFR 511.1(b)(5)(iii)]	[ ]

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.

5.0 Comments

Please review the specifications for file attachments in the CVM eSubmitter File Specification Quick Guide.
If you have additional comments that you would like to include in this submission, add below or press the ADD (+) button to attach a single PDF file that contains the information.
[HTML Text]

File Attachment	[Single File Attachment (pdf)]