Template Form: Notice of Shipment (B)(SHIPMENT_TEMPLATE_107.xml)

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 report for minor species partners (e.g., aquaculture) or for sponsors submitting to the Division of Animal Bioengineering and Cellular Therapies (DABCT) who have a formal agreement with ONADE for submitting batched notices?

( ) Yes
( ) No

Warning:	A sponsor may only use this option if it has a formal agreement with ONADE for periodic batch reporting.

Which type of report is this?

( ) Minor species partner reporting
( ) For the Division of Animal Biotechnology and Cellular Therapies (DABCT)

> Treatment year and quarter number:

> Is this submission an initial estimated report or a follow-up report with actuals?

( ) Initial estimated report
( ) Follow-up report

State the time period for this estimated report

– Beginning

– Ending

– State the submission number of the initial estimated report:

Study / Trial ID (maximum 40 characters):

Drug Shipment Number (maximum 40 characters):

Is the drug being imported into the United States?

( ) Yes
( ) No

Are you shipping the drug directly to the site where the clinical study will be conducted?

( ) Yes ( ) No

Information:	While not required, if you want to provide intermediate shipping steps of your finished drug product, please provide the details in Section 5.0 "Comments" of this template.
Note:	Based on your selections, you do not need to submit an NCIE. Instead, please submit your notification of import of a finished product as a separate submission (J)INAD general correspondence (J/I-G-OT, Notification of Import). See 21 CFR 511.1(b)(9) and ONADE P&P 1243.4065. You may provide intermediate shipping details if you so choose.
Stop:	Based on your selections, you do not need to submit an NCIE.

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

1.1 Type and Number of Animals

Select the Target Animal(s):	
Item 1	
Item 2	
Item 3	

Size and type of animals (maximum 100 characters):

Approximate number of animals in this study site:	
Investigational:	
Control:	
Total:	

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 Information

Date of Drug Shipment:	[Date]

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

2.1 Investigator Information

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

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

Phone Numbers	
Telephone Number:	
Fax Number:	

2.2 Study / Trial Information

Type of Study / Trial (maximum 100 characters):

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:	

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

Phone Numbers	
Telephone Number:	
Fax Number:	

2.4 CRO Information

Will a Contract Research Organization (CRO) be 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:	

Identify sponsor obligations transferred to a CRO (select all that apply):	
[ ] All sponsor obligations [ ] Design of a protocol [ ] Selection of investigations [ ] Monitoring of investigations [ ] Evaluation of reports [ ] Preparation of materials to be submitted to FDA [ ] Other [ ] None	
Stop:	Validation Error: "None" can only be selected above when no other options are selected. Either deselect all other options but "None" or deselect "None".
>	Please describe other sponsor obligations transferred to the CRO.
	[Multi-Line Plain Text]

3.0 Animals Intended for Use in Food

Are investigational study 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: Has 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

Which investigational labeling statement under 21 CFR 511.1 will be affixed to the 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.

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If you have additional comments that you would like to include in this submission, provide below or attach a single PDF file that contains the information.	
[HTML Text]	
File Attachment	[Single File Attachment (pdf)]