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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

Notice of Claimed Investigational Exemption

Form Approved: OMB No. 0910-0117
Expiration Date: 08/31/2011

Food and Drug Administration
Center for Veterinary Medicine, HFV-
7500 Standish Place
Rockville, Maryland 20855

A1. DATE:
A2. DOCUMENT ID:
A3. STUDY / TRIAL ID:
A4. DRUG SHIPMENT NO:
A5. TYPE OF SHIPMENT:

The applicant, , 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. This information is submitted in electronic form.

I. ☐ Shipment or ☐ Receipt Information:

1. NAME(S) OF THE DRUG(S)
   1a. Established Name(s):
   1b. Trade Name(s):
2. PROPOSED USE OF THE DRUG(S):
3. DATE OF DRUG SHIPMENT (OR RECEIPT):
4. TOTAL QUANTITY (WT. OR VOL.) AND CONCENTRATION OF DRUG(S) SHIPPED (OR RECEIVED):
5. TYPE OF STUDY / TRIAL:
6. INTENDED USE OF STUDY OR TRIAL:
   ☐ PIVOTAL (INTENDED FOR SUPPORT OF NADA or ANADA) ☐ NON-PIVOTAL
7. INVESTIGATOR INFORMATION:
   7a. Name:
   7b: Address:
   7c: Address 2:
   7d: City:
   7e. State/Prov:
   7f. Country: **USA**
   7g. Postal Code:
   7h. Phone Number:
8. LOCATION OF STUDY / TRIAL INFORMATION:
   8a. Name:
   8b. Address:
   8c. Address 2:
   8d. City:
   8e. State/Prov:
   8f. Country: **USA**
   8g. Postal Code:
   8h. Phone Number:

9. STUDY MONITOR INFORMATION

9a. Name:

9b. Address:

9c. Address 2:

9d. City: 9e. State/Prov:

9f. Country: **USA** 9g. Postal Code:

9h. Phone Number:

10. APPROXIMATE DATE OF STUDY/TRIAL 10a. START: 10b. FINISH:

11. PROTOCOL PREVIOUSLY SUBMITTED TO CVM: ☐ YES ☐ NO

IF Yes, 11a. Date Submitted to CVM: 11b. CVM Submission Identifier:

12. SPECIES OF ANIMALS: PRODUCTION CLASS:

13. SIZE AND TYPE OF ANIMALS:

14. APPROXIMATE NUMBER OF ANIMALS IN THIS STUDY/TRIAL:

Total: **0** Treated: **0** Control: **0**

15. NUMBER OF ANIMALS PREVIOUSLY USED:

Total: **0** Treated: **0** Control: **0**

16. MAXIMUM DAILY DOSE:

Duration:

17. METHOD OF ADMINISTRATION :

18. CONTRACT RESEARCH ORGANIZATION (CRO) USED: ☐ YES ☐ NO

18a. Name:

18b. Address:

18c. Address 2:

18d. City: 18e. State/Prov:

18f. Country: 18g. Postal Code:

18h. Phone Number:

18i. Descripton of Obligations Transferred to CRO:

19. IS THIS ADDITIONAL INFORMATION FOR A NOTICE PREVIOUSLY SUBMITTED TO CVM:

☐ YES ☐ NO

If Yes, 19a. Date Submitted to CVM: 19b. CVM Submission Identifier:

II. Animals Intended For Human Food Purposes:

1. DATE OF CVM AUTHORIZATION LETTER:
2. WITHDRAWAL PERIOD:
3. ACKNOWLEDGMENT: Acknowledgment that the date and place of slaughter will be reported 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. Experimentally treated animals will be identified to the inspector in charge of the slaughtering establishment when presented for antemortem inspection.

   ☐ YES ☐ NO

4. NOTIFICATION WAIVER: A waiver of requirements for notification of the date and place of slaughter after a 30-day holding and observation period following the required withdrawal period has been granted by FDA.

   ☐ YES ☐ NO

III. Investigational New Animal Drug Labeling:

1. SELECT ONE LABEL

   a. 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.

   b. 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.

   c. 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.

2. IF THE DRUG IS INTENDED FOR FOOD-PRODUCING ANIMALS, THE LABEL MUST ALSO BEAR:

   No official withdrawal time has been established for this product under the proposed investigational use.

IV. Comments:

If you have additional comments that you would like to include in this submission please press the Insert Comments button below. All comments must be included within a PDF document.

Insert Comments

V. Applicant Information:

1. Name:
2a. Address:
2b. Address 2:
2c. City:
2d. State/Prov:
2e. Country: USA
2f. Postal Code:

3. Contact Name:
4. Contact Phone Number:
5. Contact Fax Number:
6. Contact E-Mail Address:

1 - Validate | 2 - Save | 3 - Signature