

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: 3/31/05
PAPERWORK REDUCTION ACT STATEMENT: A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a current valid OMB control number. The public reporting burden for the collection of information is estimated to vary from 15 minutes to 2 hours, with an average of 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.		
Submit this notice electronically to: Food and Drug Administration Center for Veterinary Medicine, HFV- 7500 Standish Place Rockville, Maryland 20855 (E-mail: cvmdcu@fda.gov)	A1. DATE: A2. DOCUMENT ID: A3. STUDY / TRIAL ID: A4. DRUG SHIPMENT NO: A5. TYPE OF SHIPMENT:	

The sponsor, _____, 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. Proprietary 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:
7c. Address:
7d. Address 2:
7e. City:
7g. Country:
7i. Phone Number:

7f. State/Prov:
7h. Postal Code:

7b. FEI #:
8. LOCATION OF STUDY / TRIAL INFORMATION:

8a. Name:
8c. Address:
8d. Address 2:
8e. City:
8g. Country:
8i. Phone Number:

8f. State/Prov:
8h. Postal Code:

8b. FEI #:

9. STUDY MONITOR INFORMATION:
- 9a. Name: 9b. FEI #:
- 9c. Address:
- 9d. Address 2:
- 9e. City: 9f. State/Prov:
- 9g. Country: 9h. Postal Code:
- 9i. 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: Treated: Control:
15. NUMBER OF ANIMALS PREVIOUSLY USED:
- Total: Treated: Control:
16. MAXIMUM DAILY DOSE:
- Duration:
17. METHOD OF ADMINISTRATION:
18. CONTRACT RESEARCH ORGANIZATION (CRO) USED: YES NO
- 18a. Name: 18b. FEI #:
- 18c. Address:
- 18d. Address 2:
- 18e. City: 18f. State/Prov:
- 18g. Country: 18h. Postal Code:
- 18i. Phone Number:
- 18j. Description 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 USDA/FSIS Technical Service Center, ATTN: INAD/Residue, Division of Technical Assistance and Correlation, 1299 Farnam Street, Suite 300, 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.

V. Sponsor Information:

- | | | |
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| 1. | Name: | 1a. FEI #: |
| 2a. | Address: | |
| 2b. | Address 2: | |
| 2c. | City: | 2d. State/Prov: |
| 2e. | Country: | 2f. Postal Code: |
| 3. | Contact Name: | |
| 4. | Contact Phone Number: | |
| 5. | Contact Fax Number: | |
| 6. | Contact E-Mail Address: | |