

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION

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 currently 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 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, 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 to:

Food and Drug Administration
Center for Veterinary Medicine (HFV-____)
Document Control Unit, HFV-199, Rm. N-403
(Attention: Review Division HFV-____)
7500 Standish Place
Rockville, MD 20855

DATE:

INAD / IFA NO.:

STUDY / TRIAL ID:

DRUG SHIPMENT NO.:

TYPE OF SHIPMENT:

Initial

Supplement

Discontinued

Other

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 paper (triplicate).

I. SHIPMENT OR RECEIPT INFORMATION

1. NAME(S) OF THE DRUG(S)

Established Name(s):

Trade Name(s):

2. PROPOSED USE OF 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. NAME AND ADDRESS OF INVESTIGATOR:

Phone Number:

8. LOCATION OF STUDY / TRIAL:

9. NAME AND ADDRESS OF STUDY MONITOR:

Phone Number:

10. APPROXIMATE DATE OF STUDY / TRIAL

Start:

Finish:

11. PROTOCOL SUBMITTED TO CVM:

Yes

No

If Yes, date submitted to CVM and / or CVM submission number:

12. SPECIES OF ANIMALS:

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:

and DURATION:

17. METHOD OF ADMINISTRATION:

18. CONTRACT RESEARCH ORGANIZATION (CRO) USED: Yes

No

Name and address of CRO:

Phone Number:

Description of obligations transferred to CRO:

INAD / IFA NO.:

DATE:

II. ANIMALS INTENDED FOR HUMAN FOOD PURPOSES

1. DATE OF CVM AUTHORIZATION LETTER:

2. WITHDRAWAL PERIOD:

3. ACKNOWLEDGEMENT: Acknowledgement that the date and place of slaughter will be reported to FDA and to Dr. Julie Cornett, USDA/FSIS, Technical Service Center, 1299 Farnam Street, Suite 300, Landmark Center, 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 (*Please select one label*)

1. NEW ANIMAL DRUGS FOR TESTS *IN VITRO* AND IN LABORATORY RESEARCH ANIMALS:

Caution. *Contains a new animal drug for investigational use only in laboratory research animals or for tests **in vitro**. Not for use in humans.*

2. NEW ANIMAL DRUGS FOR CLINICAL INVESTIGATION IN ANIMALS:

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.*

3. NEW ANIMAL DRUGS FOR EXPORT IN ANIMALS:

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.*

If the drug is intended for food-producing animals, the label must also bear (*check if applicable*):

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

IV. SPONSOR INFORMATION

1. SPONSOR'S NAME:

2. SPONSOR'S ADDRESS:

3. SPONSOR CONTACT'S SIGNATURE:

4. SPONSOR CONTACT'S NAME:

5. SPONSOR CONTACT'S PHONE NUMBER:

6. SPONSOR CONTACT'S FAX NUMBER:

7. SPONSOR CONTACT'S E-MAIL ADDRESS:

V. COMMENTS:

Are there additional comments? Yes No

NOTE: IF THE INVESTIGATION IS DISCONTINUED, THE CENTER FOR VETERINARY MEDICINE SHOULD BE NOTIFIED, GIVING THE REASON AND DISPOSITION OF THE DRUG.