Guidance | Export Data | Import Data | Reset Form

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

Protocol for Non-Clinical Laboratory and Effectiveness Studies

Form Approved: OMB No. 0910-0524
Expiration Date: 2/28/07

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. TYPE OF STUDY: ☐ Pivotal ☐ Non-pivotal

The sponsor, , submits a protocol for use of an investigational new animal drug. Protocols for non-clinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Sponsors may request that CVM review protocols for safety and effectiveness studies of new animal drugs. This information is submitted in electronic form.

I. Requesting Protocol CVM Review: ☐ Yes ☐ No

1. NAME(S) OF THE DRUG(S):
   1a. Established Name(s):
   1b. Proprietary Name(s):
2. PROTOCOL TITLE:
   2a. Short Abstract Title:
   2b. Full Title:
   2c. Version Number (If Applicable):
3. PROTOCOL PREVIOUSLY SUBMITTED TO CVM: ☐ YES ☐ NO
   If Yes, 3a. Date Submitted to CVM: 3b. CVM Submission Identifier:

II. 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

III. Protocol:

Please press the Insert Protocol button to include your Protocol. All Protocols must be included within a PDF document.

Insert Protocol

IV. Sponsor Information:

1. Name: 1a. FEI #:
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 - Add Password | 3 - Save | 4 - Signature | 5 - Send to CVM