

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine	<b>Protocol for  Non-Clinical Laboratory and  Effectiveness Studies</b>	Form Approved: OMB No. 0910-0524 Expiration Date: 2/28/07
<b>PAPERWORK REDUCTION ACT STATEMENT:</b> 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 5 to 20 minutes, with an average of 12 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.		
<b>Submit this notice electronically to:</b> <b>Food and Drug Administration</b> <b>Center for Veterinary Medicine, HFV-</b> <b>7500 Standish Place</b> <b>Rockville, Maryland 20855</b> <b>(E-mail: cvmdcu@fda.gov)</b>	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.

**III. Protocol:**

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

#### **IV. Sponsor Information:**

- |     |                         |                  |
|-----|-------------------------|------------------|
| 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: |                  |