

**VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS OR PRODUCT DEFECT REPORT**

DATE REPORTED

Form Approved: OMB No. 0910-0012  
Expiration Date: 12/31/01

*NOTE: This report is authorized by 21 U.S.C 352(a) and (f). While you are not required to report, your cooperation is needed to assure comprehensive and timely assessment of product labeling.*

**If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.**

1. VETERINARIAN'S NAME AND ADDRESS

2. OWNER'S NAME OR CASE ID  
*(In Confidence)*

TELEPHONE (Include Area Code) \_\_\_\_\_

3. NADA NUMBER (For FDA Use)

4. SUSPECTED DRUG AND DOSAGE FORM

5. MANUFACTURER'S NAME

6. DIAGNOSIS AND / OR REASON FOR USE OF DRUG

7. ADMINISTERED BY  
 VETERINARIAN  
 OWNER

8. DOSAGE ADMINISTERED AND ROUTE *(Ex. 250 mg. q 12h, 5 days, orally)*

9. DATE(S) OF ADMINISTRATION

10. SPECIES

11. BREED

12. AGE

13. SEX

14. WEIGHT

\_\_\_\_\_ LBS.

15. CONCURRENT CLINICAL PROBLEMS

NONE

16. CONCURRENT DRUGS ADMINISTERED

NONE

OVERALL STATE OF HEALTH WHEN SUSPECTED DRUG GIVEN:

GOOD  FAIR  POOR  CRITICAL

**17. REACTION INFORMATION**

a. TIME BETWEEN INITIATION OF THERAPY WITH SUSPECTED DRUG AND ONSET OF REACTION WAS \_\_\_\_\_

b. TIME BETWEEN LAST ADMINISTRATION OF SUSPECTED DRUG AND ONSET OF REACTION WAS \_\_\_\_\_

c. OUTCOME:  RECOVERED FROM REACTION  DIED FROM REACTION  OTHER *(Comment Below)*

d. WAS THE REACTION TREATED?  NO  YES *(Comment Below)*

e. WHEN THE REACTION APPEARED, TREATMENT WITH SUSPECTED DRUG:

HAD ALREADY BEEN COMPLETED

WAS DISCONTINUED DUE TO REACTION

WAS DISCONTINUED AND REPLACED WITH ANOTHER DRUG

WAS DISCONTINUED AND REINTRODUCED LATER

WAS CONTINUED AT ALTERED DOSE

OTHER *(Comment Below)*

**AND THE REACTION**

CONTINUED

STOPPED

RECURRED

OTHER *(Comment Below)*

f. LEVEL OF SUSPICION THAT DRUG CAUSED THE REACTION:  HIGH  MEDIUM  LOW



18. DESCRIBE THE REACTION, ADD DETAILS ABOUT CASE HISTORY AND OUTCOME *(Include numbers if group of animals involved)*, GIVE COMMENT ON POSSIBLE CONTRIBUTING FACTORS. DESCRIBE LACK OF EFFECTIVENESS OR PRODUCT DEFECT *(Include Expiration Date and Lot No.)*

*NOTE: Triple fold as marked, seal with tape, no postage required, additional space on back, if needed.*

An 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.

Department of Health and Human Services  
Food and Drug Administration  
CVM, HFV-210 (0910-0012)  
7500 Standish Place  
Rockville, MD 20855

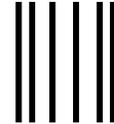
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration  
Rockville MD 20857

Official Business  
Penalty for Private use \$300



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POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

Department of Health and Human Services  
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CVM, HFV-210 (0910-0012)  
7500 Standish Place  
Rockville MD 20855



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THANK YOU FOR SHARING YOUR CONCERN ABOUT ANIMAL DRUG EFFECTS

18. (Continued)

**FOR FDA USE ONLY**

- 1. \_\_\_\_\_  D  NAI
- 2. \_\_\_\_\_  PR  AI
- 3. \_\_\_\_\_  PO  AP
- 4. \_\_\_\_\_  R  AL
- 5. \_\_\_\_\_  NC
- 6. \_\_\_\_\_
- T. \_\_\_\_\_
- I.L.  CR  CONT

**Confidentiality:** The owner's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of self-reporter, may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

COMMENT

WHEN MAILING FOLD THIS SECTION INSIDE