FOLD, SEAL, AND RETURN

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

DATE REPORTED

Form Approved: OMB No. 0910-0284
Expiration Date: January 31, 2010

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

TELEPHONE (Include Area Code) __ __ __ — __ __ __ — __ __ __ __

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

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

OVERALL STATE OF HEALTH WHEN SUSPECTED DRUG GIVEN:
☐ GOOD ☐ FAIR ☐ POOR ☐ CRITICAL

16. CONCURRENT DRUGS ADMINISTERED
☐ NONE

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.

FOLD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

Official Business
Penalty for Private use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

BUSINESS REPLY MAIL

FIRST CLASS PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

Department of Health and Human Services
Food and Drug Administration
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