FOLD, SEAL, AND RETURN

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

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.

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FOLD

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
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