

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
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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. <input type="checkbox"/>	1. VETERINARIAN'S NAME AND ADDRESS		2. OWNER'S NAME OR CASE ID <i>(In Confidence)</i>	
	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 <input type="checkbox"/> VETERINARIAN <input type="checkbox"/> 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 <input type="checkbox"/> NONE OVERALL STATE OF HEALTH WHEN SUSPECTED DRUG GIVEN: <input type="checkbox"/> GOOD <input type="checkbox"/> FAIR <input type="checkbox"/> POOR <input type="checkbox"/> CRITICAL		16. CONCURRENT DRUGS ADMINISTERED <input type="checkbox"/> 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)

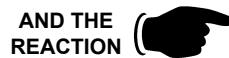
CONTINUED

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
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

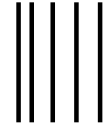
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments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

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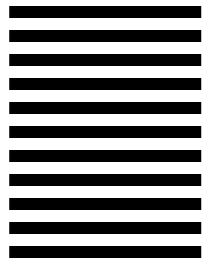
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

Official Business
Penalty for Private use \$300



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