

FOLD, SEAL, AND RETURN

<b>VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS OR PRODUCT DEFECT REPORT</b>		DATE REPORTED	Form Approved: OMB No. 0910-0284 Expiration Date: January 31, 2010	
<i>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.</i>				
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    TELEPHONE (Include Area Code) _____		2. OWNER'S NAME OR CASE ID <i>(In Confidence)</i>	
			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 <i>(Ex. 250 mg. q 12h, 5 days, orally)</i>			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		
<b>17. REACTION INFORMATION</b>				
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: <input type="checkbox"/> RECOVERED FROM REACTION <input type="checkbox"/> DIED FROM REACTION <input type="checkbox"/> OTHER <i>(Comment Below)</i>				
d. WAS THE REACTION TREATED? <input type="checkbox"/> NO <input type="checkbox"/> YES <i>(Comment Below)</i>				
e. WHEN THE REACTION APPEARED, TREATMENT WITH SUSPECTED DRUG:				
<input type="checkbox"/> HAD ALREADY BEEN COMPLETED				
<input type="checkbox"/> WAS DISCONTINUED DUE TO REACTION				
<input type="checkbox"/> WAS DISCONTINUED AND REPLACED WITH ANOTHER DRUG				
<input type="checkbox"/> WAS DISCONTINUED AND REINTRODUCED LATER				
<input type="checkbox"/> WAS CONTINUED AT ALTERED DOSE				
<input type="checkbox"/> OTHER <i>(Comment Below)</i>				
<b>AND THE REACTION</b>				
<input type="checkbox"/> CONTINUED				
<input type="checkbox"/> STOPPED				
<input type="checkbox"/> RECURRED				
<input type="checkbox"/> OTHER <i>(Comment Below)</i>				
f. LEVEL OF SUSPICION THAT DRUG CAUSED THE REACTION: <input type="checkbox"/> HIGH <input type="checkbox"/> MEDIUM <input type="checkbox"/> LOW				
18. DESCRIBE THE REACTION, ADD DETAILS ABOUT CASE HISTORY AND OUTCOME <i>(Include numbers if group of animals involved)</i> , GIVE COMMENT ON POSSIBLE CONTRIBUTING FACTORS. DESCRIBE LACK OF EFFECTIVENESS OR PRODUCT DEFECT <i>(Include Expiration Date and Lot No.)</i>				

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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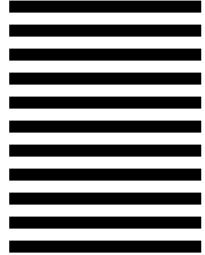
**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration  
Rockville MD 20857

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Penalty for Private use \$300



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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