Section 9a

FOOD AND DRUG ADMINISTRATION 7500 Standish Place (HFV-210), Room N403 Rockville, MD 20855	**VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT** *(Forward to address at left. Attach all correspondence that pertains to this reaction)*	**Form Approved: OMB No. 0910-0284** **Expiration Date: January 31, 2010**

Public reporting burden for this collection of information is estimated to average 2 hours 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

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.

NOTE: This report is required by law. Failure to report can result in withdrawal of approval of the application (see 21 CFR 514.80).

1. REPORT SOURCE AND ADDRESS *(Mfr., Distr.)*

2a. DATE REPORT RECEIVED

b. DATE SENT TO FDA

c. NUMBER OF DAYS BETWEEN 2a AND b:

3a. TYPE OF REPORT
☐ 3-day Alert ☐ 15-day Alert
☐ Periodic Report

3b. ☐ Initial Report
☐ Follow Up Report
Of *(Give Date)* _____

4. NAME, ADDRESS AND PHONE NO. OF ATTENDING VETERINARIAN *(In confidence)*
Name:
Street Address:
City: State: ZIP:
Phone No. (__ __ __) __ __ __ - __ __ __ __

5. NAME OR CASE IDENTIFICATION OF OWNER *(In confidence)*

6. TRADE NAME AND GENERIC NAME(S) OF ACTIVE INGREDIENT(S) *(Include dosage form and strength - Ex., tab, 500 mg.)*

7a. NAME OF MANUFACTURER

b. NADA NO.

8. LOT NUMBER(S)

9. DOSAGE ADMINISTERED AND ROUTE *(Ex. 250 mg., q 12 h, p.o.)*

10. DATE(S) OF ADMINISTRATION

11. ILLNESS/REASON FOR USE OF THIS DRUG

12. DRUG WAS ADMINISTERED BY
☐ VETERINARIAN, STAFF ☐ OWNER, OTHER

13. NUMBER OF ANIMALS IN THIS INCIDENT

a. TREATED WITH DRUG	b. REACTED	c. DIED

14. REACTING ANIMALS

a. SPECIES	b. BREED

15. CONCOMITANT MEDICAL PROBLEMS

c. AGE	d. WEIGHT

e. SEX
☐ FEMALE ☐ MALE ☐ PREGNANT ☐ NEUTERED

16. OVERALL STATE OF HEALTH AT TIME OF REACTION
☐ GOOD ☐ FAIR ☐ POOR ☐ CRITICAL

17. DID ANY NEW ILLNESS DEVELOP OR DID INITIAL DIAGNOSIS CHANGE AFTER SUSPECT DRUG STARTED?
☐ NO ☐ YES *(Explain)*

18. **CONCOMITANT DRUGS ADMINISTERED**

NAME OF DRUG	ROUTE	DOSAGE REGIMEN	DATE(S) OF ADMINISTRATION

FOR FDA USE ONLY

1. _____ ☐ D ☐ NAI
2. _____ ☐ PR ☐ AI
3. _____ ☐ PO ☐ AP
4. _____ ☐ R ☐ AL
5. _____ ☐ NC
6. _____
T. _____

☐ I.L. ☐ CR ☐ CONT

COMMENT

PSC Graphics: (301) 443-1090 EF

REACTION DATA

19. DESCRIBE SUSPECTED ADVERSE REACTION: INCLUDE ALL SIGNS, RESULTS OF PERTINENT LAB TESTS, NECROPSY RESULTS, POSSIBLE CONTRIBUTING FACTORS, ETC. ALSO, INCLUDE IN THIS SECTION PRODUCT INEFFECTIVENESS AND PRODUCT DEFECTS SUCH AS CRACKED TABLETS, CLOUDY SOLUTION, ETC.

20a. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED REACTION

☐ HIGH ☐ MEDIUM ☐ LOW ☐ NO ATTENDING VET.

20b. WAS THERE EXTRA LABEL USE (ELU) INVOLVED?

☐ NO ☐ YES *(Explain)* _____

21. LENGTH OF TIME BETWEEN LAST ADMINISTRATION OF SUSPECT DRUG AND ONSET OF REACTION

22. DATE OF ONSET *(Mo., day, yr.)*

23. DURATION OF REACTION *(Hrs., days, etc.)*

24. WAS THE ADVERSE REACTION TREATED?

☐ NO ☐ YES *(Describe treatment)*

25. OUTCOME OF REACTION TO DATE

☐ DIED *(Give date)* _____
☐ REMAINS UNDER TREATMENT
☐ ALIVE WITH SEQUELAE
☐ RECOVERED
☐ UNKNOWN

26. WHEN REACTION APPEARED, SUSPECT DRUG:

☐ HAD ALREADY BEEN COMPLETED
☐ WAS DISCONTINUED DUE TO THE REACTION
☐ WAS REPLACED WITH ANOTHER DRUG
☐ WAS REINTRODUCED LATER
☐ WAS CONTINUED AT ALTERED DOSE
☐ OTHER *(Explain)*_____

AND THE REACTION

☐ CONTINUED
☐ STOPPED
☐ RECURRED
☐ OTHER *(Explain)* _____

27. HAD ANIMAL(S) BEEN PREVIOUSLY EXPOSED TO THIS DRUG?

☐ NO ☐ YES ☐ UNKNOWN

28. DID ANIMAL(S) PREVIOUSLY REACT TO THIS DRUG?

☐ NO ☐ YES ☐ UNKNOWN

29. HAD ANIMAL(S) PREVIOUSLY REACTED TO OTHER DRUGS?

☐ NO ☐ YES ☐ UNKNOWN

(If yes, give drug(s) and reaction if known)

30. HAS THE ATTENDING VETERINARIAN SEEN SIMILAR REACTIONS TO THIS DRUG IN ANY OTHER ANIMALS?

☐ NO ☐ YES *(Describe treatment)*

31. NAME AND TITLE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED INFORMATION *(Type or print)*

32. SIGNATURE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED INFORMATION