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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

NOTE: This report is required by law (21 CFR 510.300). Failure to report can result in withdrawal of approval of the application.

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

c. AGE	d. WEIGHT

e. SEX
☐ FEMALE ☐ MALE ☐ PREGNANT ☐ NEUTERED

15. CONCOMITANT MEDICAL PROBLEMS

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

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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 REACT

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, TREATMENT WITH SUSPECT DRUG:

☐ HAD ALREADY BEEN COMPLETED DISCONTINUED
☐ DUE TO THE REACTION DISCONTINUED,
☐ REPLACE WITH ANOTHER DRUG DISCONTINUED,
☐ REINTRODUCED LATER 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