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: June 30, 2006

Public reporting burden for this collection of information is estimated to average 2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Food and Drug Administration 7500 Standish Place (HFV-210), Room N403 Rockville, MD 20855

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 b   | y law (21 CFR 510.: | 300). Failure te | o report can result in withdrawa                   |   |  |
|---|---------------------|------------------|--|---|--|
| 1. REPORT SOURCE AND ADDRESS (Mfr., Distr.)   |                     |                  | 2a. DATE REPORT RECEIVED                           | 3a. TYPE OF REPORT                        |  |
|   |                     |                  |  | 3-day Alert                               |  |
|   |                     |                  | b. DATE SENT TO FDA                                | Periodic Report                           |  |
|   |                     |                  | - NUMBER OF RAVO RETWEEN                           | 3b. Initial Report                        |  |
|   |                     |                  | c. NUMBER OF DAYS BETWEEN 2                        | 2a AND b: Follow Up Report Of (Give Date) |  |
| 4. NAME, ADDRESS AND PHONE NO. OF ATTENDING VETERINARIAN  |                     |                  | 5. NAME OR CASE IDENTIFICAT                        | ION OF OWNER                              |  |
| (In confidence)   |                     |                  | (In confidence)                                    |   |  |
| Name:   |                     |                  |  |   |  |
| Street Address:   |                     |                  |  |   |  |
| City: State:  | ZIP:                |                  |  |   |  |
| Phone No. ()  |                     |                  |  |   |  |
| <ol> <li>TRADE NAME AND GENERIC NAME(S) OF ACTIVE INGREDIENT(S)<br/>(Include dosage form and strength - Ex., tab, 500 mg.)</li> </ol> |                     |                  | 7a. NAME OF MANUFACTURER                           |   |  |
|   |                     |                  | b. NADA NO.  |   |  |
| 8. LOT NUMBER(S) 9. DOSAGE ADMINISTERED AND ROUTE   |                     |                  | 10. DATE(S) OF ADMINISTRATION                      |   |  |
| (Ex. 250 mg., q 12 h, p.o.)   |                     |                  |  |   |  |
|   |                     |                  |  |   |  |
| 11. ILLNESS/REASON FOR USE OF THIS DRUG   |                     |                  | 12. DRUG WAS ADMINISTERED                          | BY  |  |
|   |                     |                  | UETERINARIAN, STAFF                                | OWNER, OTHER                              |  |
| 13. NUMBER OF ANIMALS IN THIS INCIDENT  |                     |                  | 14. REA  | CTING ANIMALS                             |  |
| a. TREATED WITH DRUG b. REACT   | ED                  | c. DIED          | a. SPECIES   | b. BREED                                  |  |
|   |                     |                  |  |   |  |
| 15. CONCOMITANT MEDICAL PROBLEMS  |                     | c. AGE           | d. WEIGHT  |   |  |
|   |                     |                  |  |   |  |
|   |                     |                  | e. SEX   |   |  |
|   |                     |                  | FEMALE MALE  | PREGNANT NEUTERED                         |  |
|   |                     |                  | NY NEW ILLNESS DEVELOP OR DID<br>ECT DRUG STARTED? | ) INITIAL DIAGNOSIS CHANGE AFTER          |  |
| ☐ GOOD ☐ FAIR ☐ POOR ☐ CRITICAL ☐ N   |                     |                  | O YES (Explain)                                    |   |  |
| 18. CONCOMITANT DRUGS ADMINISTERED  |                     |                  |  |   |  |
| NAME OF DRUG ROUTE  |                     |                  | DOSAGE REGIMEN                                     | DATE(S) OF ADMINISTRATION                 |  |
|   |                     |                  |  |   |  |
|   |                     |                  |  |   |  |
|   |                     |                  |  |   |  |
|   |                     |                  |  |   |  |
|   |                     |                  |  |   |  |
|   |                     |                  |  |   |  |
|   |                     | FOR FDA          | LISE ONLY  |   |  |
| FOR FDA USE ONLY COMMENT  |                     |                  |  |   |  |
| 1 D   | NAI                 |                  |  |   |  |
| 2 PR  |                     |                  |  |   |  |
| 3 PO [  | AP                  |                  |  |   |  |
| 4 R [   | AL                  |                  |  |   |  |
| 5 NC  |                     |                  |  |   |  |
| 6   |                     |                  |  |   |  |
| T   |                     |                  |  |   |  |
| I.L. CR CC  | DNT                 |                  |  |   |  |

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| 19. DESCRIBE SUSPECTED ADVERSE REACTION: INCLUDE ALL SIGNS, RESULTS OF CONTRIBUTING FACTORS, ETC. ALSO, INCLUDE IN THIS SECTION PRODUCT IN TABLETS, CLOUDY SOLUTION, ETC.   | EFFECTIVENESS AND PRODUCT DEFECTS SUCH AS CRACKED   |  |
|---|---|--|
| 20a. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED REACTION  | 20b. WAS THERE EXTRA LABEL USE (ELU) INVOLVED?  |  |
| ☐ HIGH ☐ MEDIUM ☐ LOW ☐ NO ATTENDING VET.   | 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) | : —   |  |
| 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  |  |
|   | NO YES UNKNOWN (If yes, give drug(s) and reaction if known)   |  |
| 30. HAS THE ATTENDING VETERINARIAN SEEN SIMILAR REACTIONS TO THIS DRUG  | G IN ANY OTHER ANIMALS?   |  |
| NO YES (Describe treatment)   |   |  |
| 31. NAME AND TITLE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED INFORMATION (Type or print)  SIGNAT INFORM  FORM FDA 1932 (9/03)  | URE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED MATION   |  |
| FURIVI FDA 1932 (9/03)  |   |  |

**REACTION DATA**