DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT

(Forward to address at right. Attach all correspondence that pertains to this reaction.)

Form Approved: OMB No. 0910-0645
Expiration Date: 9/30/2012
(See Burden Statement on page 8.)

Food and Drug Administration
7500 Standish Place (HFV-210), Rm N403
Rockville, MD 20855-9921

NOTE: This report is required by law (21 CFR 514.80 and 512 (l) of the Federal Food, Drug, and Cosmetic Act (FDCA)). Failure to report can result in withdrawal of approval of the application (21 CFR 514.80 (h) and 512 (e) of the FDCA).

The data elements marked with an asterisk [*] require a value or text to be entered. An asterisk at the section level applies to all fields within that section. An asterisk at the subsection level applies to all fields within that subsection. Otherwise, asterisks apply to individual fields.

Part A
Administrative and Identification Information

Regulatory Authority - RA (A.1)*

RA Name	Street Address		
City	State/County or Province	Mail/Zip Code	3-character country code

Marketing Authorization Holder - MAH (A.2)

*MAH Information (A.2.1)**

Business Name	Street Address		
City	State/County or Province	Mail/Zip Code	3-character country code

Person Acting on Behalf of the MAH (A.2.2)

Title *(e.g., Mr., Ms., Dr.)*	First Name	Last Name
Telephone Number	Fax Number	Email Address

Person(s) Involved in the AER (A.3)

Primary Reporter (A.3.1)

Title *(e.g., Mr., Ms., Dr.)*	First Name	Last Name*
Telephone Number	Fax Number	Email Address
Business Name		Street Address

City	State/County or Province	Mail/Zip Code	3-character country code*

Primary Reporter Category (A.3.1.1)*:

Part A - Administrative and Identification Information *(Continued)*

Person(s) Involved in the AER (A.3) *(Continued)*

Other Reporter (A.3.2)

Title *(e.g., Mr., Ms., Dr.)*	First Name	Last Name

Telephone Number	Fax Number	Email Address

Business Name	Street Address

City	State/County or Province	Mail/Zip Code	3-character country code

Other Reporter Category (A.3.2.1):

AER Information (A.4)

Unique AER Identification Number (A.4.1)*:

Original Receive Date (A.4.2)* *(dd/mm/yyyy)*	Date of Current Submission (A.4.3)* *(dd/mm/yyyy)*
Day ☐ Month ☐ Year ☐	Day ☐ Month ☐ Year ☐

Type of Report (A.4.4)

Type of Submission (A.4.4.1)*

Reason for Nullification Report (A.4.4.2)

Type of Information in Report (A.4.4.3)

Part B
Description of the Adverse Event

Animal Data (B.1) *(The fields within this section (B.1) are applicable only if an animal is associated with the report.)*

Number of Animals Treated (B.1.1)	Number of Animals Affected (B.1.2)*

Attending Veterinarian's Assessment of Animal Health Status Prior to VMP Use (B.1.2.1)

Species (B.1.3)*:

Breed (B.1.4)

Purebred Information (B.1.4.1)		
Animal 1 [Breed (B.1.4.1.1)]	Animal 2 [Breed (B.1.4.1.1)]	Animal 3 [Breed (B.1.4.1.1)]
Crossbreed Information (B.1.4.2)		
Animal 1 [Breed (B.1.4.2.1)]	Animal 2 [Breed (B.1.4.2.1)]	Animal 3 [Breed (B.1.4.2.1)]

Part B - Description of the Adverse Event *(Continued)*

Animal Data (B.1) *(Continued)*

Gender (B.1.5)	Reproductive Status (B.1.6)

Female Physiological Status (B.1.7)

Weight (B.1.8)

Measured, Estimated,Unknown Weights (B.1.8.1)*	Minimum Weight in Kilograms (B.1.8.2)	Maximum Weight in Kilograms (B.1.8.3)

Age (B.1.9)

Measured, Estimated, Unknown Age (B.1.9.1)*		Minimum Age (B.1.9.2)
Minimum Age Units (B.1.9.2.1)	Maximum Age (B.1.9.3)	Maximum Age Units (B.1.9.3.1)

VMP(s) Data and Usage (B.2)

(For additional VMP(s), fill out appropriate B.2.1-B.2.6.5 entries on corresponding pages of additional forms.)

Registered or Brand Name (B.2.1)*	Product Code (B.2.1.1)
Registration Identifier (B.2.1.2)*	ATCvet Code (B.2.1.3)*

Company or MAH (B.2.1.4)

The following fields (B.2.1.5 through B.2.1.7.1.2.3) are applicable only if an animal is associated with the report.

MAH Assessment (B.2.1.5)

RA Assessment (B.2.1.6)

Explanation Relating to Assessment (B.2.1.6.1)

Route of Exposure (B.2.1.7)

Dose per Administration (B.2.1.7.1)

Numeric Value for Dose (B.2.1.7.1.1)	Units of Value for Dose (B.2.1.7.1.1.1)

Interval of Administration (B.2.1.7.1.2)

Numeric Value for Interval of Administration (B.2.1.7.1.2.1)	Units of Value for Interval of Administration (B.2.1.7.1.2.1.1)
Date of First Exposure (B.2.1.7.1.2.2) *(dd/mm/yyyy)* Day ☐ Month ☐ Year ☐	Date of Last Exposure (B.2.1.7.1.2.3) *(dd/mm/yyyy)* Day ☐ Month ☐ Year ☐

Part B - Description of the Adverse Event *(Continued)*

VMP(s) Data and Usage (B.2) *(Continued)*

Active Ingredient(s) (B.2.2)

Dosage Form (B.2.2.2)

1st Entry

1st Entry - Active Ingredient(s) (B.2.2.1)*

Strength (B.2.2.1.1)	Strength (Numerator)*	Strength (Denominator)*
Strength Unit (B.2.2.1.1.1)	Strength Unit (Numerator)*	Strength Unit (Denominator)*

Active Ingredient Code (B.2.2.1.2):

2nd Entry

2nd Entry - Active Ingredient(s) (B.2.2.1)*

Strength (B.2.2.1.1)	Strength (Numerator)*	Strength (Denominator)*
Strength Unit (B.2.2.1.1.1)	Strength Unit (Numerator)*	Strength Unit (Denominator)*

Active Ingredient Code (B.2.2.1.2):

3rd Entry

3rd Entry - Active Ingredient(s) (B.2.2.1)*

Strength (B.2.2.1.1)	Strength (Numerator)*	Strength (Denominator)*
Strength Unit (B.2.2.1.1.1)	Strength Unit (Numerator)*	Strength Unit (Denominator)*

Active Ingredient Code (B.2.2.1.2):

Lot Number (B.2.3)	Expiration Date (B.2.3.1) *(dd/mm/yyyy)* Day ☐ Month ☐ Year ☐

The following fields (B.2.4 through B.2.5.1) are applicable only if an animal is associated with the report.

Who Administered the VMP? (B.2.4)

Use According to Label (B.2.5)

Part B - Description of the Adverse Event *(Continued)*

VMP(s) Data and Usage (B.2) *(Continued)*

Explain the Off-Label Use Code (B.2.5.1)

Product/Manufacturing Defect Information (B.2.6)

The fields within this subsection (B.2.6.1-B.2.6.5) are applicable only if reporting a product/manufacturing defect.

Manufacturing Site Identifier Number (B.2.6.1)	Manufacturer's Identifier Type (B.2.6.1.1)

Manufacturing Date (B.2.6.2) *(dd/mm/yyyy)*

Day ☐ Month ☐ Year ☐

Number of Defective Items (B.2.6.3)	Defective Item Units (B.2.6.3.1)
Number of Items Returned (B.2.6.4)	Returned Item Units (B.2.6.4.1)

ORA District Field Office (B.2.6.5)

Adverse Event Data (B.3)

Provide narrative of AE (B.3.1)*

Part B - Description of the Adverse Event *(Continued)*

Adverse Event Data (B.3) *(Continued)*

Continue (if needed) narrative of AE (B.3.1)*

*Adverse Clinical Manifestations (B.3.2)**

Part B - Description of the Adverse Event *(Continued)*

Adverse Event Data (B.3) *(Continued)*

The following fields (B.3.3 through B.5.1) are applicable only if an animal is associated with the report.

Date of Onset of AE (B.3.3)* *(dd/mm/yyyy)*	Length of Time Between Exposure to VMP(s) and Onset of AE (B.3.4)
Day ☐ Month ☐ Year ☐	

Duration of AE (B.3.5)

Duration (B.3.5.1)	Duration Time Units (B.3.5.1.1)

Serious AE (B.3.6)*	Treatment of AE (B.3.7)

Outcome to Date (B.3.8) (Enter appropriate numbers where applicable)

Ongoing (B.3.8.1) _____ Recovered/Normal (B.3.8.2) _____ Recovered with Sequela (B.3.8.3) _____

Died (B.3.8.4) _____ Euthanized (B.3.8.5) _____ Unknown (B.3.8.6) _____

Previous Exposure to the VMP? (B.3.9)	Previous AE to the VMP? (B.3.10)
☐ Yes ☐ No ☐ Unknown ☐ Non-Applicable	☐ Yes ☐ No ☐ Unknown ☐ Non-Applicable

Dechallenge - Rechallenge Information (B.4)

Did AE Abate After Stopping the VMP? (B.4.1)	Did AE Reappear After Re-introduction of the VMP? (B.4.2)
☐ Yes ☐ No ☐ Unknown ☐ Not Applicable	☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

Assessment of AE (B.5)

Attending Veterinarian's Assessment (B.5.1)

Part B - Description of the Adverse Event *(Continued)*

Supplemental Documents (B.6)

Attached Document Name(s) *(Filename(s) if Electronic)* (B.6.1)

Attached Document Type(s) (B.6.2)

U.S. Only Specific Information (B.7)

Report Identifier (B.7.1)*	Domestic vs Foreign Category (B.7.2)*
	☐ Domestic ☐ Foreign-Same ☐ Foreign-Similar

U.S.-Based Pharmacovigilance Contact Person for the MAH (B.7.3)

Title *(e.g., Mr., Ms., Dr.)*	First Name	Last Name

Telephone Number	Fax Number	Email Address

Public reporting burden for this collection of information is estimated to average 90 minutes 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 the Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

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.