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: 4/30/2016
(See PRA Statement on page 9.)

Food and Drug Administration
7500 Standish Place (HFV-240)
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 (A.1.1)*	Street Address (A.1.2)*		
City (A.1.3)*	State/County or Province (A.1.4)	Mail/Zip Code (A.1.5)*	3-Character Country Code (A.1.6)*

Marketing Authorization Holder - MAH (A.2)

MAH Information (A.2.1)

Business Name (A.2.1.1)*	Street Address (A.2.1.2)*		
City (A.2.1.3)*	State/County or Province (A.2.1.4)	Mail/Zip Code (A.2.1.5)*	3-Character Country Code (A.2.1.6)*

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

Title *(e.g., Mr., Ms., Dr.)* (A.2.2.1)	First Name (A.2.2.2)	Last Name (A.2.2.3)

Telephone Number (A.2.2.4)	Fax Number (A.2.2.5)	Email Address (A.2.2.6)

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

Primary Reporter (A.3.1)

Primary Reporter Category (A.3.1.1)* *(Select One)*

☐ Veterinarian ☐ Animal Owner ☐ Physician ☐ Patient ☐ Other Health Care Professional ☐ Other ☐ Unknown

Last Name (A.3.1.2)*	First Name (A.3.1.3)

Telephone Number (A.3.1.4)	Fax Number (A.3.1.5)	Email Address (A.3.1.6)

Business Name (A.3.1.7)	Street Address (A.3.1.8)

City (A.3.1.9)	State/County or Province (A.3.1.10)	Mail/Zip Code (A.3.1.11)	3-Character Country Code (A.3.1.12)*

PSC Publishing Services (301) 443-6740 EF

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

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

Other Reporter (A.3.2)

Other Reporter Category (A.3.2.1)* (required if any of the A.3.2 information is provided) *(Select One)*

☐ Veterinarian ☐ Animal Owner ☐ Physician ☐ Patient ☐ Other Health Care Professional ☐ Other ☐ Unknown

Last Name (A.3.2.2)		First Name (A.3.2.3)
Telephone Number (A.3.2.4)	Fax Number (A.3.2.5)	Email Address (A.3.2.6)
Business Name (A.3.2.7)		Street Address (A.3.2.8)

City (A.3.2.9)	State/County or Province (A.3.2.10)	Mail/Zip Code (A.3.2.11)	3-Character Country Code (A.3.2.12)

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)* *(Select One)*

☐ Expedited ☐ Periodic ☐ Follow-up ☐ Nullification ☐ 3-Day Field Alert ☐ Other

Reason for Nullification Report (A.4.4.2) (provide if nullification is selected from A.4.4.1)

Type of Information in Report (A.4.4.3)

Part B
Description of the AE

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)		
Breed (B.1.4.1.1) of Animal 1	Breed (B.1.4.1.1) of Animal 2	Breed (B.1.4.1.1) of Animal 3

Part B - Description of the AE *(Continued)*

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

Crossbred Information (B.1.4.2)

Breed (B.1.4.2.1)	Breed (B.1.4.2.1)	Breed (B.1.4.2.1)

Gender (B.1.5) *(Select One)*

☐ Female ☐ Male ☐ Mixed ☐ Unknown

Reproductive Status (B.1.6) *(Select One)*

☐ Intact ☐ Neutered ☐ Mixed ☐ Unknown

Female Physiological Status (B.1.7) *(Select One)*

☐ Nonpregnant Lactating ☐ Nonpregnant Nonlactating ☐ Pregnant Lactating ☐ Pregnant Nonlactating

☐ Mixed ☐ Not Applicable ☐ Unknown

Weight (B.1.8)

Measured, Estimated, Unknown Weights (B.1.8.1)*	Minimum Weight in Kilograms (B.1.8.2) (provide if Measured or Estimated selected from B.1.8.1)	Maximum Weight in Kilograms (B.1.8.3)
☐ Measured ☐ Estimated ☐ Unknown		

Age (B.1.9)

Measured, Estimated, Unknown Age (B.1.9.1)*

☐ Measured ☐ Estimated ☐ Unknown

Minimum Age (B.1.9.2) (provide if Measured or Estimated selected from B.1.9.1)	Minimum Age Units (B.1.9.2.1) (provide if B.1.9.2 is given) *(Select One)* ☐ Second ☐ Minute ☐ Hour ☐ Day ☐ Month ☐ Year
Maximum Age (B.1.9.3)	Maximum Age Units (B.1.9.3.1) (provide if B.1.9.3 is given) *(Select One)* ☐ Second ☐ Minute ☐ Hour ☐ Day ☐ Month ☐ Year

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-B.2.1.7.1.3.3) are applicable only if an animal is associated with the report.

MAH Assessment (B.2.1.5)

RA Assessment (B.2.1.6)

RA Assessment Term (B.2.1.6.1)

Explanation Relating to Assessment (B.2.1.6.1.1)

Route of Exposure (B.2.1.7)

Dose Per Administration (B.2.1.7.1)

Numeric Value for Dose (Numerator) (B.2.1.7.1.1)	Units of Value for Dose (Numerator) (B.2.1.7.1.1.1) (provide if B.2.1.7.1.1 is given)
Numeric Value for Dose (Denominator) (B.2.1.7.1.2)	Units of Value for Dose (Denominator) (B.2.1.7.1.2.1) (provide if B.2.1.7.1.2 is given)

Part B - Description of the AE *(Continued)*

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

Interval of Administration (B.2.1.7.1.3)

Numeric Value for Interval of Administration (B.2.1.7.1.3.1)	Units of Value for Interval of Administration (B.2.1.7.1.3.1.1) (provide if B.2.1.7.1.3.1 is given) *(Select One)*
	☐ Second ☐ Minute ☐ Hour ☐ Day ☐ Month ☐ Year

Date of First Exposure (B.2.1.7.1.3.2) *(dd/mm/yyyy)*	Date of Last Exposure (B.2.1.7.1.3.3) *(dd/mm/yyyy)*
Day ☐ Month ☐ Year ☐	Day ☐ Month ☐ Year ☐

Active Ingredient(s) (B.2.2)

1st Entry

Active Ingredient(s) (B.2.2.1)*

Numeric Value for Strength (Numerator) (B.2.2.1.1)*	Units for Numeric Value for Strength (Numerator) (B.2.2.1.1.1)*
Numeric Value for Strength (Denominator) (B.2.2.1.2)*	Units for Numeric Value for Strength (Denominator) (B.2.2.1.2.1)*

Active Ingredient Code (B.2.2.1.3):

2nd Entry

Active Ingredient(s) (B.2.2.1)*

Numeric Value for Strength (Numerator) (B.2.2.1.1)*	Units for Numeric Value for Strength (Numerator) (B.2.2.1.1.1)*
Numeric Value for Strength (Denominator) (B.2.2.1.2)*	Units for Numeric Value for Strength (Denominator) (B.2.2.1.2.1)*

Active Ingredient Code (B.2.2.1.3):

3rd Entry

Active Ingredient(s) (B.2.2.1)*

Numeric Value for Strength (Numerator) (B.2.2.1.1)*	Units for Numeric Value for Strength (Numerator) (B.2.2.1.1.1)*
Numeric Value for Strength (Denominator) (B.2.2.1.2)*	Units for Numeric Value for Strength (Denominator) (B.2.2.1.2.1)*

Active Ingredient Code (B.2.2.1.3):

Dosage Form (B.2.2.2)

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

Part B - Description of the AE *(Continued)*

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

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

Who Administered the VMP? (B.2.4) *(Select One)*

☐ Veterinarian ☐ Animal Owner ☐ Physician ☐ Patient ☐ Multiple Administrators

☐ Other Health Care Professional ☐ Other ☐ Unknown

Use According to Label (B.2.5) *(Select One)*

☐ Yes ☐ No ☐ No Information

Explanation for the Off-Label Use Code (B.2.5.1) *(Select All That Apply)*

Was the target species Off-Label (B.2.5.1.1)

☐ Yes ☐ No ☐ No Information

Was the route of administration Off-Label (B.2.5.1.2)

☐ Yes ☐ No ☐ No Information

Was the animal overdosed (B.2.5.1.3)

☐ Yes ☐ No ☐ No Information

Was the animal underdosed (B.2.5.1.4)

☐ Yes ☐ No ☐ No Information

Was the treatment regime Off-Label (B.2.5.1.5)

☐ Yes ☐ No ☐ No Information

Was the indication Off-Label (B.2.5.1.6)

☐ Yes ☐ No ☐ No Information

Was the storage condition Off-Label (B.2.5.1.7)

☐ Yes ☐ No ☐ No Information

Was the product expired (B.2.5.1.8)

☐ Yes ☐ No ☐ No Information

Was there any other Off-Label issue (B.2.5.1.9)

☐ Yes ☐ No ☐ No Information

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) (*select one* if B.2.6.1 is given)

☐ FEI Number ☐ DUNS Number

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)

AE Data (B.3)

Narrative of AE (B.3.1)*

Part B - Description of the AE *(Continued)*

AE Data (B.3) *(Continued)*

Narrative of AE (B.3.1)* (Continue, if needed)

Adverse Clinical Manifestations (B.3.2)*	Number of Animals (B.3.2.1)	Accuracy of the Number of Animals (B.3.2.1.1)
		☐ Actual ☐ Estimated
		☐ Actual ☐ Estimated
		☐ Actual ☐ Estimated
		☐ Actual ☐ Estimated
		☐ Actual ☐ Estimated
		☐ Actual ☐ Estimated

Part B - Description of the AE *(Continued)*

AE Data (B.3) *(Continued)*

Date of Onset of AE/PP Found Date (B.3.3)* *(dd/mm/yyyy)*

Day ☐ Month ☐ Year ☐

The following fields (B.3.4-B.5.1) are applicable only if an animal is associated with the report.

Length of Time Between Exposure to VMP(s) and Onset of AE (B.3.4) *(Select One)*

☐ <2 Minutes ☐ <24 Hours ☐ <7 Days ☐ >30 Days and <6 Months ☐ Unknown
☐ <1 Hour ☐ <48 Hours ☐ <14 Days ☐ >6 Months and <12 Months
☐ <12 Hours ☐ <3 Days ☐ <30 Days ☐ >12 Months

Duration of AE (B.3.5)

Duration (B.3.5.1)	Duration Time Units (B.3.5.1.1) (provide if B.3.5.1 is given) *(Select One)*
	☐ Second ☐ Minute ☐ Hour ☐ Day ☐ Month ☐ Year

Serious AE (B.3.6)* *(Select One)*	Treatment of AE (B.3.7) *(Select One)*
☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown ☐ No Information

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) *(Select One)*	Previous AE to the VMP? (B.3.10) *(Select One)*
☐ Yes ☐ No ☐ Unknown ☐ No Information	☐ Yes ☐ No ☐ Unknown ☐ No Information

Dechallenge - Rechallenge Information (B.4)

Did AE Abate After Stopping the VMP? (B.4.1) *(Select One)*

☐ Yes ☐ No ☐ Unknown ☐ No Information ☐ Not Applicable

Did AE Reappear After Re-introduction of the VMP? (B.4.2) *(Select One)*

☐ Yes ☐ No ☐ Unknown ☐ No Information ☐ Not Applicable

Assessment of AE (B.5)

Attending Veterinarian's Assessment (B.5.1) *(Select One)*

☐ Probable ☐ Possible ☐ Unlikely ☐ Unknown ☐ No Assessment ☐ No Attending Veterinarian

Report Number(s) of Linked Report(s) (B.6)

Unique AER Identification Number (B.6.1)

Explanation for Linkage (B.6.1.1) (provide if B.6.1 is given) *(Select One)*

☐ Parent - Offspring ☐ Same patient ☐ Duplicate report ☐ Similar reports from same reporter (cluster) ☐ Other link type

Supplemental Documents (B.7)

Attached Document Name(s) *(Filename(s) if Electronic)* (B.7.1)	Attached Document Type(s) (B.7.1.1) (provide if B.7.1 is given)

Part B - Description of the AE *(Continued)*

HL7 ICSR Wrapper Data Elements (B.8)
Only sections B.8.2.2.3-B.8.2.2.8, B.8.2.5, and B.8.2.6 are relevant for submission of the paper form.

Batch Wrapper (B.8.1)
*Batch Number/Identifier (B.8.1.1)**

Batch Number/Identifier - Root (B.8.1.1.1) Not Applicable for Paper Form	Batch Number/Identifier - Extension (B.8.1.1.2) Not Applicable for Paper Form

Batch Sender (B.8.1.2)

Batch Sender - Root (B.8.1.2.1)* Not Applicable for Paper Form	Batch Sender - Extension (B.8.1.2.2)* Not Applicable for Paper Form

Batch Sender - Title (B.8.1.2.3)
Not Applicable for Paper Form

Batch Sender - Last Name (B.8.1.2.4)* Not Applicable for Paper Form	Batch Sender - First Name (B.8.1.2.5)* Not Applicable for Paper Form
Batch Sender - Telephone (B.8.1.2.6)* Not Applicable for Paper Form	Batch Sender - Fax (B.8.1.2.7) Not Applicable for Paper Form

Batch Sender - Email (B.8.1.2.8)*
Not Applicable for Paper Form

Batch Receiver (B.8.1.3)

Batch Receiver - Root (B.8.1.3.1)* USFDA	Batch Receiver - Extension (B.8.1.3.2) US Food and Drug Administration
Date of Batch Creation (B.8.1.4)* Not Applicable for Paper Form Day ☐ Month ☐ Year ☐	VICH AER Version Number (B.8.1.5)* VICH AER 1.0.0

Transmission Wrapper (B.8.2)
*Message Number (B.8.2.1)**

Message Number - Root (B.8.2.1.1) Not Applicable for Paper Form	Message Number - Extension (B.8.2.1.2) Not Applicable for Paper Form

Pharmacovigilance Contact Person for the MAH (Message Sender) (B.8.2.2)

Message Sender - Root (B.8.2.2.1) Not Applicable for Paper Form	Message Sender - Extension (B.8.2.2.2) Not Applicable for Paper Form

Title (Message Sender - Title) (B.8.2.2.3)

Last Name (Message Sender - Last Name) (B.8.2.2.4)*	First Name (Message Sender - First Name) (B.8.2.2.5)*
Telephone (Message Sender - Telephone) (B.8.2.2.6)*	Fax (Message Sender - Fax) (B.8.2.2.7)

Email (Message Sender - Email) (B.8.2.2.8)*

Message Receiver (B.8.2.3)

Message Receiver - Root (B.8.2.3.1)* USFDACVM	Date of Message Creation (B.8.2.4)* Not Applicable for Paper Form Day ☐ Month ☐ Year ☐
Report Identifier (B.8.2.5)*	Domestic vs. Foreign Report Category (B.8.2.6)* *(Select One)* ☐ Domestic ☐ Foreign - Same ☐ Other ☐ Foreign - Similar

Profile Identifier (B.8.2.7)* Not Applicable for Paper Form *(Select One)*
☐ Adverse Event ☐ Adverse Event and Product Problem ☐ Product Problem

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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