

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

Food and Drug Administration
7500 Standish Place (HFV-240)
Rockville, MD 20855-9921

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

*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)*

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 <input type="text"/> Month <input type="text"/> Year <input type="text"/>	Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>

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)*
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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)
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Gender (B.1.5) (Select One) <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Mixed <input type="checkbox"/> Unknown	Reproductive Status (B.1.6) (Select One) <input type="checkbox"/> Intact <input type="checkbox"/> Neutered <input type="checkbox"/> Mixed <input type="checkbox"/> Unknown
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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)* <input type="checkbox"/> Measured <input type="checkbox"/> Estimated <input type="checkbox"/> Unknown	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)
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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) <input type="checkbox"/> Second <input type="checkbox"/> Minute <input type="checkbox"/> Hour <input type="checkbox"/> Day <input type="checkbox"/> Month <input type="checkbox"/> Year
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Maximum Age (B.1.9.3)	Maximum Age Units (B.1.9.3.1) (provide if B.1.9.3 is given) (Select One) <input type="checkbox"/> Second <input type="checkbox"/> Minute <input type="checkbox"/> Hour <input type="checkbox"/> Day <input type="checkbox"/> Month <input type="checkbox"/> Year
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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)
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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)
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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) <input type="checkbox"/> Second <input type="checkbox"/> Minute <input type="checkbox"/> Hour <input type="checkbox"/> Day <input type="checkbox"/> Month <input type="checkbox"/> Year
Date of First Exposure (B.2.1.7.1.3.2) (dd/mm/yyyy) Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>	Date of Last Exposure (B.2.1.7.1.3.3) (dd/mm/yyyy) Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>

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 <input type="text"/> Month <input type="text"/> Year <input type="text"/>
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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 indication Off-Label (B.2.5.1.6)

- Yes No No Information

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

- Yes No No Information

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

- Yes No No Information

Was the animal overdosed (B.2.5.1.3)

- Yes No No Information

Was the product expired (B.2.5.1.8)

- Yes No No Information

Was the animal underdosed (B.2.5.1.4)

- Yes No No Information

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

- Yes No No Information

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

- 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)
		<input type="checkbox"/> Actual <input type="checkbox"/> Estimated
		<input type="checkbox"/> Actual <input type="checkbox"/> Estimated
		<input type="checkbox"/> Actual <input type="checkbox"/> Estimated
		<input type="checkbox"/> Actual <input type="checkbox"/> Estimated
		<input type="checkbox"/> Actual <input type="checkbox"/> Estimated
		<input type="checkbox"/> Actual <input type="checkbox"/> 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)

- Yes No

Treatment of AE (B.3.7) (Select One)

- 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)

- Yes No Unknown No Information

Previous AE to the VMP? (B.3.10) (Select One)

- 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.

The burden time for this collection of information is estimated to average 90 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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