

**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)

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)\*

Measured  Estimated  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)

**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) <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



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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 60 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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