

<b>VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT FORM FDA 1932</b>		Form Approved: OMB No. 0910-0645 Expiration Date:
(Forward to address at left. Attach all correspondence that pertains to this reaction.)		
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 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-199), 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.		
<b>NOTE: This report is required by law (21 CFR 514.80 and section 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 section 512 (e) of the FDCA).</b>		
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)\***

<b>RA Name</b>	<input type="text"/>	<b>Street Address</b>	<input type="text"/>
<b>City</b>	<input type="text"/>	<b>State/County</b>	<input type="text"/>
<b>Mail/Zip Code</b>	<input type="text"/>	<b>Country (3 Character Code)</b>	<input type="text"/>

**Marketing Authorization Holder - MAH (A.2)**

**MAH Information (A.2.1)\***

<b>Business Name</b>	<input type="text"/>	<b>Street Address</b>	<input type="text"/>
<b>City</b>	<input type="text"/>	<b>State/County</b>	<input type="text"/>
<b>Mail/Zip Code</b>	<input type="text"/>	<b>Country (3 Character Code)</b>	<input type="text"/>

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

<b>Title</b>	<input type="text"/>	<b>First Name</b>	<input type="text"/>	<b>Last Name</b>	<input type="text"/>
<b>Telephone Number</b>	<input type="text"/>	<b>Fax Number</b>	<input type="text"/>	<b>e-Mail Address</b>	<input type="text"/>

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

**Primary Reporter (A.3.1)**

<b>Last Name*</b>	<input type="text"/>	<b>First Name</b>	<input type="text"/>
<b>Telephone Number</b>	<input type="text"/>	<b>Fax Number</b>	<input type="text"/>
<b>e-Mail Address</b>	<input type="text"/>		
<b>Business Name</b>	<input type="text"/>	<b>Street Address</b>	<input type="text"/>
<b>City</b>	<input type="text"/>	<b>State/County</b>	<input type="text"/>
<b>Mail/Zip Code</b>	<input type="text"/>	<b>Country (3 Character Code)*</b>	<input type="text"/>
<b>Primary Reporter Category (A.3.1.1)*</b>	<input type="text"/>		

**Other Reporter (A.3.2)**

Last Name	<input type="text"/>	First Name	<input type="text"/>		
Telephone Number	<input type="text"/>	Fax Number	<input type="text"/>	e-Mail Address	<input type="text"/>
Business Name	<input type="text"/>	Street Address	<input type="text"/>		
City	<input type="text"/>	State/County	<input type="text"/>		
Mail/Zip Code	<input type="text"/>	Country (3 Character Code)	<input type="text"/>		
Other Reporter Category (A.3.2.1)	<input type="text"/>				

**AER Information (A.4)**

Unique AER Identification Number (A.4.1)*	<input type="text"/>										
Original Receive Date (A.4.2)*			Date of Current Submission (A.4.3)*								
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)*	<input type="text"/>										
Reason for Nullification Report (A.4.4.2)	<input type="text"/>										
Type of Information in Report (A.4.4.3)	<input type="text"/>										

**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)	<input type="text"/>	Number of Animals Affected (B.1.2)*	<input type="text"/>		
Attending Veterinarian's Assessment of Animal Health Status Prior to VMP (B.1.2.1)	<input type="text"/>				
Species (B.1.3)*	<input type="text"/>				
Breed (B.1.4)					
Purebred Information (B.1.4.1)					
Breed (B.1.4.1.1)	Breed (B.1.4.1.1)	Breed (B.1.4.1.1)	Breed (B.1.4.1.1)		
Animal 1	<input type="text"/>	Animal 2	<input type="text"/>	Animal 3	<input type="text"/>
Crossbred Information (B.1.4.2)					
Breed (B.1.4.2.1)	Breed (B.1.4.2.1)	Breed (B.1.4.2.1)	Breed (B.1.4.2.1)		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Gender (B.1.5)	<input type="text"/>	Reproductive Status (B.1.6)	<input type="text"/>		
Female Physiological Status (B.1.7)	<input type="text"/>				

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)**  
(Repeat Fields B.2.1-B.2.6.5 for Additional VMP(s))

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.2.1.7.1.2.3) 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)**

Day  Month  Year

**Date of Last Exposure (B.2.1.7.1.2.3)**

Day  Month  Year

**Active Ingredient(s) (B.2.2)**

Dosage Form (B.2.2.2)

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)

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)

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) Day  Month  Year

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)  Use According to Label (B.2.5)

Explanation for Off-Label Use Code (B.2.5.1)

**Product/Manufacturing Defect Information (B.2.6)**

The following fields (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) 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)**

**Narrative of AE (B.3.1)\***



**Adverse Clinical Manifestations (B.3.2)\***


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

**Date of Onset of AE (B.3.3)\***

Day

Month

Year

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

**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)**

**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)**

**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)**

**Assessment of AE (B.5)**

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

**Supplemental Documents (B.6)**

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

**Attached Document Type (B.6.2)**

**US Only Specific Information (B.7)**

**Report Identifier (B.7.1)\***

**Domestic vs Foreign Category (B.7.2)\***

**US-Based Pharmacovigilance Contact Person for the MAH (B.7.3)**

**Title**

**First Name**

**Last Name**

**Telephone Number**

**Fax Number**

**e-Mail Address**