Section 9a

	VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT FORM FDA 1932 (Forward to address at left. Attach all correspondence that pertains to this reaction.)	Form Approved: OMB No. 0910-0645 Expiration Date:

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.

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).

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**	
Mail/Zip Code		**Country (3 Character Code)**	

Marketing Authorization Holder - MAH (A.2)

MAH Information (A.2.1)*

Business Name		**Street Address**	
City		**State/County**	
Mail/Zip Code		**Country (3 Character Code)**	

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

Title		**First Name**		**Last Name**	
Telephone Number		**Fax Number**		**e-Mail Address**	

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

Primary Reporter (A.3.1)

Last Name*		**First Name**	
Telephone Number		**Fax Number**	
e-Mail Address			
Business Name		**Street Address**	
City		**State/County**	
Mail/Zip Code		**Country (3 Character Code)***	
Primary Reporter Category (A.3.1.1)*			

Other Reporter (A.3.2)

Last Name		**First Name**	
Telephone Number		**Fax Number**	**e-Mail Address**
Business Name		**Street Address**	
City		**State/County**	
Mail/Zip Code		**Country (3 Character 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)*

Day		**Month**		**Year**	

Date of Current Submission (A.4.3)*

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 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 (B.1.2.1)			
Species (B.1.3)*			

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)**
Animal 1	**Animal 2**	**Animal 3**

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)		**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)

(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)	**Date of Last Exposure (B.2.1.7.1.2.3)**
Day **Month** **Year**	**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**