DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

Form Approved: OMB No. 0910-0645
Expiration Date: 5/31/2019
(See mailer page for Burden Statement)

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

(For VOLUNTARY Reporting)

NOTE: This report is authorized by 21 U.S.C 352 (a) and (f). While you are not required to report, your cooperation is needed to assure comprehensive and timely assessment of product labeling.

Individual Case Safety Report Number *(FDA Assigned Number)*	Submission Type ☐ Initial ☐ Follow-up

Report Type ☐ Adverse Event ☐ Product Problem ☐ Both Adverse Event and Product Problem

Date of this Report *(mm/dd/yyyy)*	Date of Initial Report *(If this report is a follow-up) (mm/dd/yyyy)*
Month ☐ Day ☐ Year ☐	Month ☐ Day ☐ Year ☐

Sender Information

First Name	Last Name

Street Address

City	State or Province	Postal/ZIP Code
Country	Telephone Number	Telephone Number (Other)
Fax Number	Email Address	

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

Sender Previously Reported to the Manufacturer? ☐ Yes ☐ No

If Yes, provide the Manufacturer's Case Number: _____

No Identity Disclosure ☐ If you do NOT want your identity disclosed to the manufacturer, mark this box.

Preferred Method of Contact ☐ Telephone ☐ Email

Health Care Professional Information *(If different from Sender Information)*

First Name	Last Name

Street Address

City	State or Province	Postal/ZIP Code
Country	Telephone Number	Telephone Number (Other)
Fax Number	Email Address	

Owner Information *(If different from Sender Information)*

First Name	Last Name

Street Address

City	State or Province	Postal/ZIP Code

Country	Telephone Number	Telephone Number (Other)

Fax Number	Email Address

Suspected Product Informatiom

Name of Suspected Product

Diagnosis and/or Reason for Use of the Product

Dosage Form (Chewable, liquid, tablet, topical, injection, etc.)

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

Duration of Product Use

Product Use Information for Suspected Product

Dose Administered

Interval of Administration (Frequency)

Route of Administration

Product Administered By

☐ Veterinarian/Veterinary Staff ☐ Owner ☐ Other

Lot Number	Expiration Date *(mm/dd/yyyy)*
	Month ☐ Day ☐ Year ☐

Name of Manufacturer of Suspected Product

Adverse Event Information

Veterinarian's Level of Suspicion that Product Caused the Adverse Event

☐ High ☐ Medium ☐ Low ☐ Unknown

Treatment of Adverse Event *(Describe briefly)*

Did Adverse Event Abate After Stopping the Product?

☐ Yes ☐ No ☐ Not Applicable

Did Adverse Event Reappear After Reintroduction of the Product?

☐ Yes ☐ No ☐ Not Applicable

Outcome

☐ Recovered ☐ Died ☐ Other

Species and Related Information

☐ Budgerigar ☐ Cat ☐ Cattle ☐ Cockatiel ☐ Cockatoo

☐ Dog ☐ Ferret ☐ Fish ☐ Goat ☐ Guinea Pig

☐ Horse ☐ Human ☐ Parrot ☐ Pig ☐ Rabbit

☐ Sheep ☐ Other *(Specify)*: _____

Breed

Gender ☐ Male ☐ Female ☐ Male Neutered ☐ Female Neutered

Age:

Weight:

Overall Health Status When Suspected Product Given

☐ Excellent ☐ Good ☐ Fair ☐ Poor ☐ Critical

Number of Animals Treated:

Number of Animals Affected:

Adverse Event Occurrence

Date of Onset of Adverse Event *(mm/dd/yyyy)*

Month ☐ Day ☐ Year ☐

Length of Time Between First Exposure to Suspected Product(s) and Onset of Adverse Event

Length of Time Between Last Administration of Suspected Product(s) and Onset of Adverse Event

When the Adverse Event Occurred, Treatment with Suspected Product

☐ Had already been completed ☐ Was discontinued ☐ Was discontinued and replaced with another product

☐ Was discontinued and reintroduced later ☐ Was continued at an altered dose

☐ Other *(Specify)*: _____

Document Information

Attached Document Name *(Filename if Electronic)*

Attached Document Description

Attached Document Name *(Filename if Electronic)*

Attached Document Description

Attached Document Name *(Filename if Electronic)*

Attached Document Description

Concurrent Clinical Problem(s)

Were There Concurrent Clinical Problems?

☐ Yes ☐ No ☐ Do not know ☐ None

List Concurrent Clinical Problem(s).

Concurrent Product Information *(Excluding Treatment of Current Event)*

Please provide name(s), dose(s), interval(s), date(s) of treatment(s), and other relevant information to describe other products that the patient was taking at the time of the event. Either copy this section as needed (you may fill out this section in other copies of this form) or provide comments in the long narrative section that follows this one.

Were Concurrent Products Given?

☐ Yes ☐ No ☐ Do not know ☐ None

List Names of Concurrent Products Administered.

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

Duration of Product Use

Adverse Event/Product Problem *(Long Narrative)*

Describe the Adverse Event/Product Problem.

Adverse Event/Product Problem *(Long Narrative, Continued)*

If more space is needed, continue description below of the Adverse Event/Product Problem.

INSTRUCTIONS

GENERAL INSTRUCTIONS

- Please either type or print all entries in a font no smaller than 8 point. If filling in the form by hand, please use black ink.
- Please complete all sections that apply.
- For narrative entries, attach additional pages as needed.
- If attaching additional pages, please do the following:
  - Identify all attached pages as Page # of # (e.g., Page 1 of 4);
  - Indicate the appropriate section and block number next to the narrative continuation; and
  - Include the phrase continued at the end of each field that has additional information continued onto another page.

Individual Case Safety Report Number: This number will be assigned by the Food and Drug Administration (FDA).

Submission Type: Choose a Submission Type. If this is the first time you have sent FDA information about this, choose “Initial” report. If this is additional information for a previously submitted report, choose “Follow-up” report.

Report Type: Choose a Report Type. If you are reporting something that has affected an animal or a human, including lack of effectiveness, choose “Adverse Event.” If you are reporting something associated with a product (such as crumbled tablets or peculiar appearance), choose “Product Problem.” If both situations apply, choose “Both.”

Date of this Report and Date of Initial Report: Enter dates as mm/dd/yyyy. If exact dates are unknown, provide the best estimate.

Sender Information: Provide the contact information for the person who is filling out this form.

Sender Category: Choose the appropriate Sender Category.

Manufacturer’s Case Number: Fill in the case number, if applicable or known. If you previously reported to the manufacturer, you can contact the manufacturer for the Manufacturer’s Case Number.

Health Care Professional Information: Please provide the name, mailing address, phone number, and e-mail address of the veterinarian or other health care professional who can be contacted to provide information, if such follow-up is necessary.

If the health care professional is also the sender, there is no need to repeat the information.

Owner’s Name: Please provide the owner’s name, mailing address, and phone number. If the owner is also the sender, there is no need to repeat the information.

The owner’s information is held in strict confidence by FDA and protected to the fullest extent of the law. **The FDA will not disclose the reporter’s identity in response to a request from the public, pursuant to the Freedom of Information Act.**

Name of Suspected Product: Provide the brand name of the product.

Diagnosis and/or Reason for Use: Provide the reason or indication for which the product was prescribed or used in the animal.

Dosage Form: Provide the dosage form (e.g., chewable tablet, liquid, tablet, topical, injection, etc.).

Date(s) of First and Last Exposure: Enter the date(s) the product was started and stopped. If actual dates are unknown, enter the approximate time period the product was used in the Duration of Product Use box (e.g., 2 weeks during the summer of 2006). If the product was used less than 1 day, enter the same date in the Date of First Exposure and Date of Last Exposure boxes.

Dose Administered, Interval of Administration (Frequency), and Route of Administration: Describe how the product was administered (e.g., 250 mg), frequency of administration (e.g., every 12 hours for 5 days), and how it was administered (e.g., orally, injection, etc.). Describe how the product was administered, even if it differs from what was prescribed.

Product Administered By: Please check the appropriate box. If given by a member of the veterinarian's staff, please identify (e.g., technician, assistant) in the narrative section at the end of the form. If given by someone other than the owner (e.g., pet sitter, trainer), choose "Owner" but identify in the narrative section.

Lot Number and Expiration Date: Please provide the lot number and expiration date from the product, if available.

Name of Manufacturer of Suspected Product: Provide the name of the manufacturer.

Treatment of Adverse Event: If the adverse event was treated, describe the treatment given.

Did Adverse Event Abate after Stopping the Product? Choose "Yes" if the adverse event lessened or went away when the product was stopped or the dose was decreased. Choose "Not Applicable" if the product was not stopped or decreased.

Outcome: Choose an outcome for the adverse event. If "Other" is chosen, describe this outcome in the narrative section at the end of the form (e.g., the dog lived but never recovered fully, since it was left with a permanent elevation of liver enzymes).

Species: Choose a box for species (e.g., cat, dog, ferret, horse, human, other, etc.). If "Other" is chosen, identify the species in the space provided; if more space is needed, use the narrative section at the end of the form.

Breed: Enter the breed (e.g., Yorkie, Mixed Breed, Lab mix, Siamese/Persian mix). Note: This category is not applicable if the patient is human.

Age: Provide the patient's age at the time of the adverse event, including a time descriptor (e.g., 8 years). Provide the best estimate if exact age is unknown.

Weight: Provide the patient's weight in pounds (lb). Make a best estimate if exact weight is unknown.

Overall Health Status: Check the box that best describes the patient's overall state of health when drug/product was first given.

Number of Animals Treated: If more than one animal was treated with the same drug/product at the same time, please tell us how many were treated (e.g., two kittens received Drug X).

Number of Animals Affected: If more than one animal had an adverse event after the treatment, please tell us how many. If more than one animal had an adverse event, and the reaction was not the same, please submit a separate report for each animal (e.g., two kittens received Drug X, a de-worming medication. One vomited and wouldn't eat for several days, whereas the other had a seizure).

Date of Onset: Provide the date when the adverse event first started.

Length of Time Between Exposure to Suspected Product and Onset of Adverse Event: Enter the length of time from the first day the product was given to the onset of the adverse event (e.g., 3 days).

Length of Time Between Last Administration of Suspected Product(s) and Onset of Adverse Event: Enter the length of time from the last dose of the product to the onset of the adverse event (e.g., 3 hours).

When the Reaction Occurred, Treatment with Suspected Product: Check the appropriate box that applies to the reported adverse event. If "Other" is chosen, identify in the space provided; if more space is needed, use the narrative section at the end of the form.

Attached Document Name: If attaching any supporting documents, such as letters, medical records, or photos, provide the name of the file here.

Examples:

- Documents for Princess.doc.
- Spreadsheet of Princess's laboratory results.xls
- Photographs of Princess before and after treatment.jpg
- Newspaper article about the product.pdf

If you mail your report, these attachments should accompany the paper Form FDA 1932a.

Attached Document Description: If attaching any supporting documents, provide the description of the contents (e.g., medical records, lab tests, photograph, newspaper article, etc.).

Concurrent Clinical Problem(s): Provide information on other known health problems of the patient at the time of exposure to the product (e.g., chronic allergic dermatitis, intermittent vomiting, allergic reaction following vaccination). Check "None" if there are no known concurrent problems.

Concurrent Product Information: Please provide names, doses, and dates of treatments for products that the patient was taking at the time of the event. Do include over-the-counter products, such as supplements, vitamins, and homeopathic preparations. Do not include products used to treat the event. Check "None" if nothing else was being given at the time of the adverse event.

Adverse Event/Product Defect (Long Narrative): Use this space to describe the event, possible contributing factors, and outcome. Include a description of what happened and a summary of all available clinical information.

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 1 hour 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

"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 number."

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DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

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Rockville, MD 20855-9921

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THANK YOU FOR SHARING YOUR CONCERN ABOUT ANIMAL DRUG EFFECTS.

Confidentiality: The owner's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of self-reporter, may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

WHEN MAILING, FOLD THIS SECTION INSIDE.