I028710

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date 6/1/2018

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier: 20684-1 (In Confidence)
2. Age: ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) — or Date of Birth (e.g., 08 Feb 1925): 23-12-2010
3. Sex: ☐ Female ☒ Male Altered
4. Weight: 113.6 ☒ lb ☐ kg

5.a. Ethnicity (Check single best answer): ☐ Hispanic/Latino ☐ Not Hispanic/Latino

5.b. Race (Check all that apply): ☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply: ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply): ☐ Death Include date (dd-mmm-yyyy): ☐ Life-threatening ☐ Disability or Permanent Damage ☒ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects ☐ Other Serious (Important Medical Events) ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy): 11-02-2016
4. Date of this Report (dd-mmm-yyyy): 17-02-2016

5. Describe Event, Problem or Product Use Error
Seresto collar for large dogs applied to pet, developed depression and mild muscle tremors in pelvic limbs overnight.

6. Relevant Tests/Laboratory Data, Including Dates
CBC – leukocytosis (18.67 K/ul), neutrophilia 15 K/ul, monocytosis 1.96 K/ul, PCV/TS: 50%/8.1g/dl
Serum chemistry normal values

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
Collar was part of a treatment for flea allergic dermatitis. pet also started on prednisone + cephalexin P.O.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA): ☐ Yes ☒ No ☐ Returned to Manufacturer on (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)

#1 – Name and Strength: Seresto flea collar for large dogs	#1 – NDC # or Unique ID: AHNL063T
#1 – Manufacturer/Compounder: Bayer	#1 – Lot #: AHNL098T
#2 – Name and Strength:	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

3. Dose or Amount / Frequency / Route
#1: 45g / Continuous / Topical
#2:

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1: 11/02/2016
#2:

5. Diagnosis or Reason for Use (indication)
#1: Flea allergy
#2: House flea infestation

6. Is the Product Compounded? #1 ☐ Yes ☒ No #2 ☐ Yes ☐ No

7. Is the Product Over-the-Counter? #1 ☐ Yes ☒ No #2 ☐ Yes ☐ No

8. Expiration Date (dd-mmm-yyyy) #1 #2

9. Event Abated After Use Stopped or Dose Reduced? #1 ☒ Yes ☐ No ☐ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction? #1 ☐ Yes ☐ No ☒ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name: CTU
2b. Procode
3. Manufacturer Name, City and State
MAR – 3 2016
4. Model #
Lot #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other
Catalog #
Expiration Date (dd-mmm-yyyy)
Serial #
Unique Identifier (UDI) #
6. If Implanted, Give Date (dd-mmm-yyyy)
7. If Explanted, Give Date (dd-mmm-yyyy)
8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☒ No
9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)
prednisone 20mg BID
cephalexin 500mg 2 caps BID

G. REPORTER (See confidentiality section on back)

1. Name and Address
Last Name: HARRISON First Name: ELLEN
Address: CALVERT ANIMAL HOSPITAL
City: OWINGS State/Province/Region: MD
Country: ZIP/Postal Code:
Phone #: Email:

2. Health Professional? ☒ Yes ☐ No
3. Occupation: Veterinarian
4. Also Reported to: ☒ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.