

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10061

Product Code: 13D1.22 1905.24

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard Plus 5	189	A830088	<input checked="" type="checkbox"/> Viral
2 Defensor 3	189	S835925B	<input checked="" type="checkbox"/> Viral
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Intrascapular	22	06/17/2009
2 1 ml	SQ	RR leg	22	06/17/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/17/2009
Concurrent Drugs or Procedures:	None

Event Information

* Event description:	<input checked="" type="checkbox"/> Autoimmune
Explain the event and any treatment in a concise paragraph: Severe, life threatening autoimmune thrombocytopenia, anemia and spontaneous hemorrhage. Multiple fresh whole blood transfusions, immunosuppressive Prednisone dosage orally and single Vincristine injection.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	less than 65 days
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Layla	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Golden Doodle	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos):	6 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Acquired from breeder 4/13/09. Housed indoors. Had spirochete diarrhea on 4/20/09 and was treated with sulfasalazine 125mg twice daily for 5 days. Had DHPP vaccines on 4/15/09 by the breeder and by All West Vet on 5/6/09 and 5/27/09 and the vaccines listed above.			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	All West Veterinary Hospital 105 All West Trail	Address:	
City:	Bozeman	City:	
State:	MT	State:	
Zip:	59718	Zip:	
*Phone:	406-586-4919(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	406-587-8420		
E-mail:	allwestvet@gmail.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	406-586-4919(XXX-XXX-XXXX)

*Today's Date:	08/28/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/28/2009

Verified:yes

Reviewed:yes

Date Entered: 12/22/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

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 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10060

Product Code: 1905.23 13D1.22 14P5.20

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18095B	<input checked="" type="checkbox"/> Viral
2 Vanguard Plus 5	189	A837247C	<input checked="" type="checkbox"/> Viral
3 Vanguard CV	189	A834689A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Dorsal cervical	22	08/19/2009
2 1 ml	SQ	Dorsal cervical	22	08/19/2009
3 1 ml	SQ	Dorsal cervical	22	08/19/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/19/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Some other event - Describe Below
Explain the event and any treatment in a concise paragraph: Dog was examined for breathing difficulties. Vaccinated that day. Was stressed and was 100 degrees that day. Went home, dyspneic 3-4 hours. died en route to emergency clinic	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1-4 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Low
*Outcome (select one):	<input checked="" type="checkbox"/> Died
Other:	

Animal Information

Case Identification:	Meesha Kalkhoven	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Blue Healer	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Female	Number dead: 1
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	8 yrs	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Walnut Street Veterinary Clinic 1011 SE Walnut Street	Address:	(b)(6)
City:	Hillsboro	City:	(b)(6)
State:	OR	State:	OR
Zip:	97123	Zip:	(b)(6)
*Phone:	503-640-0472(XXX-XXX-XXXX)	Phone:	(b)(6) (XXX-XXX-XXXX)
FAX:	503-648-0714		
E-mail:	(b)(6)@comcast.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	503-640-0472(XXX-XXX-XXXX)
*Today's Date:	08/28/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/28/2009

Verified:yes

Reviewed:yes

Date Entered: 12/14/2009

CVB Reporter:

Acknowledgement:

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 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10058

Product Code: 1331.20 1905.23

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867113A	<input checked="" type="checkbox"/> Viral
2 Rabvac 3 TF	112	873183A	<input checked="" type="checkbox"/> Viral
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L flank	22	08/26/2009
2 1 ml	SQ	R flank	22	08/26/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/26/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description: Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
 vaccination of a dog occurred at 1:30pm with Durammune Adult 3 and Rabvac 3TF. Within 1.5 hrs after dosing, the dog vomited twice, developed erythema of pinnae, abdomen, mucous membranes, prepuce and swelling of the muzzle. 10 mg diphenhydramine was given IM followed by 70 mg SoluDelta Cortef IV. Reaction did not progress

further and dog recovered.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1.5 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Canine 5896592	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:60	
(Other Species):		Number affected:1	
Breed :	Beagle	Number vaccinated:10	
Sex:	<input checked="" type="checkbox"/> Male	Number dead:0	
Neutered:	<input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos):	1.25 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Had prior DHLPP and Rabies 5/1/09			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Wyeth Research 500 Arcola Road	Address:	
City:	Collegeville	City:	
State:	PA	State:	
Zip:	19426	Zip:	
*Phone:	484-865-5545(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:	(b)(6)@wyeth.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
	484-865-5545(XXX-XXX-XXXX)

*Submitter's Phone Number:	
*Today's Date:	08/27/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/27/2009

Verified:yes

Reviewed:yes

Date Entered: 12/14/2009

CVB Reporter:

Acknowledgement:

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 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10056

Product Code: 2668.05

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045147A	<input checked="" type="checkbox"/> Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	25	08/18/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/18/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: vomiting, lethargic, urinary accidents day of the vaccine. Owner called 6 days later to report lump at vaccine site. No tx, recovered on own but lump still present. Rx discontinue LeptoVax or pre-med before given.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units: mins, hrs, days, wks, mos, yrs)	same day
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered without treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Westie		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Female		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 6 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): has had since puppy, had leptos in past with 1st clinic no note of reaction. Seen us in 2006 vax (lepto) administered no reaction. purina pro plan, no other pets in household. at 8/09 visit owner stated no reaction until she called on 8/19/09. she stated he also was like this in 08 visit - no phone call of owner informing us about tht visit.		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Burleigh Road Animal Hospital 13725 West Burleigh Road		Address: (b)(6)	
City: Brookfield		City: (b)(6)	
State: WI		State: WI	
Zip: 53005		Zip: (b)(6)	
*Phone: 262-781-4400(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX: 262-781-4504			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	262-781-4400(XXX-XXX-XXXX)

*Today's Date:	08/26/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	CVT

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/26/2009

Verified:yes

Reviewed:yes

Date Entered: 12/14/2009

CVB Reporter:

Acknowledgement: yes

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 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10055

Product Code: 4637.29

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5/4L	112	53442A258A	<input checked="" type="checkbox"/> Combination
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1	SQ			
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/25/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
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Explain the event and any treatment in a concise paragraph:
 within 10 mins post vax owner was at front desk check out, dog started whimpering & tucked head under owners arm. mm white salivation. resp shallow.

10 min post vaccination, patient began to whimper and tucked his head into the arm of the owner. Dr. found this strange that the dog whined 10 min. post vaccine. Dr checked mm which were white. Patient was transferred to triage and placed on oxygen. Was given the following treatments: 0.5 ml Dex. Pet was Bradycardiac and IV was then started with Normal Saline Solution IV Wide open with mini drip. Hot water bottles applied to patient. Solu-Delta Cortef 1 ml given IV push. Open Mouth respirations T=100.5. Benadryl 0.05 ml and Atropine 0.05 ml given. T100.2. No longer open mouth breathing. HR increased, mm pale pink, More alert, lung sounds crackly, Resp slightly labored, but even. MM pale pink, Oxygen set to 2 liter/min. Lung sounds more clear, T=100.6. Pulse Ox 89% on 1 liter/min. Lungs are clearer, much more alert, Resp are relaxed and even, IV capped, flushed. IV discontinued and discharged to home.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	10 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Patches	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Shih Tzu	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Male	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> Not Listed	
Age (i.e., 2 yrs or 2 mos):	11 wks 5 days	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Was vaccinated on 7/16/09 Ft. Dodge Da2PPV - no complications		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	New Stanton Veterinary Service 119 Stan Avenue	Address:	(b)(6)
City:	New Stanton	City:	(b)(6)
State:	PA	State:	PA
Zip:	15672	Zip:	(b)(6)
*Phone:	724-925-8244 (XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:			

E-mail:		E-mail:	
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This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	724-925-8244(XXX-XXX-XXXX)
*Today's Date:	08/26/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Not Listed
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 09/29/2009

Verified:yes

Reviewed:yes

Date Entered: 12/14/2009

CVB Reporter:

Acknowledgement:

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 510 South 17th Street, Suite 104
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 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10054

Product Code: 47K1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard Plus	189	A722612	<input checked="" type="checkbox"/> Viral
2			<input checked="" type="checkbox"/> [Click arrow for selections]
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 Single	SQ	LHip	22	08/14/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/14/2009
Concurrent Drugs or Procedures:	None

Event Information

* Event description:	<input checked="" type="checkbox"/> Local
Explain the event and any treatment in a concise paragraph: An abscess formed at the injection site and needed to be surgically removed	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	3 days	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Shih Tzu		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 4 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Starch Pet Hospital 2222 University Avenue		Address:	
City: Des Moines		City:	
State: IA		State:	
Zip: 50311		Zip:	
*Phone: 515-283-1576(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	515-283-1576(XXX-XXX-XXXX)
*Today's Date:	08/20/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/20/2009

Verified:yes

Reviewed:yes

Date Entered: 12/14/2009

CVB Reporter:

Acknowledgement:

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 Phone: (515) 232-5785
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Record Number: AIV10047

Product Code: 1331.R1 2126.R0 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Recombitek C 3	298	47012-10694	<input checked="" type="checkbox"/> Recombinant
2 Recombitek Lyme	298	42147	<input checked="" type="checkbox"/> Recombinant
3 Duramune LCI/GP	112	045153A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	23	08/13/2009
2 1 ml	SQ	Interscap region	23	08/13/2009
3 1 ml	SQ	R shoulder	23	08/13/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/13/2009
Concurrent Drugs or Procedures:	No

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
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Explain the event and any treatment in a concise paragraph:
 Patient presented for routine vaccinations (part of puppy series). Previously had been given the DAP and Lyme vaccine without event. Received the DAP, Lyme and Leptospirosis vaccine. Presented 1 hour after appointment was finished. Presented with with facial swelling. Dexamethasone and Diphenhydramine was administered IM. Facial

swelling resolved by evening.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):	Number affected: 1
Breed:	Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Not Listed	Number dead: 0
Neutered: <input checked="" type="checkbox"/> Not Listed	
Age (i.e., 2 yrs or 2 mos): 17 wks	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):	

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Token Creek Veterinary Clinic 3790 State Road	Address:	
City:	Sun Prairie	City:	
State:	WI	State:	
Zip:	53590	Zip:	
*Phone:	608-834-9700(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	608-834-0700		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
	608-834-9700(XXX-XXX-XXXX)

*Submitter's Phone Number:	
*Today's Date:	08/14/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/14/2009

Verified:yes

Reviewed:yes

Date Entered: 12/14/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10043

Product Code: 13D1.22

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard Plus 5	189	A830088	<input checked="" type="checkbox"/> Viral
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Between shoulders	24	
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/30/2009
Concurrent Drugs or Procedures:	exam, oticalm was used to clean ear, animax was given to treat yeast in ears.

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Gave puppy DHPP vaccine 2 of 3. Owner brought to emergency clinic because we were closed. Puppy had swollen eyes and lips, no breathing problems or vomiting. Treatment was Dexamethasone and Diphenhydramine.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	20 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):	Number affected:	1
Breed: Dachshund	Number vaccinated:	1
Sex: <input checked="" type="checkbox"/> Female	Number dead:	0
Neutered: <input checked="" type="checkbox"/> Not Listed		
Age (i.e., 2 yrs or 2 mos):	3 mos	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): pet		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Southfork Animal Hospital 17445 Kenrick Avenue	Address:	(b)(6)
City:	Lakeville	City:	(b)(6)
State:	MN	State:	MN
Zip:	55044	Zip:	(b)(6)
*Phone:	952-892-7970(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	952-892-7781		
E-mail:	sfah@frontiernet.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	952-892-7970(XXX-XXX-XXXX)

*Today's Date: 08/13/2009(MM/DD/YYYY)	
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	vet assistant

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/21/2009

Verified: yes

Reviewed: yes

Date Entered: 12/11/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10042

Product Code: 47K1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard Plus	189		<input checked="" type="checkbox"/> Combination
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/30/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Puppy was given distemper vaccination 2 of 3. Owner had to bring her to the emergency clinic because we were closed. Puppy had swollen eyes and lips. Treated with Dexamethasone and Diphenhydramine swelling went down.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	20 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Dachshund	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Female	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> Not Listed	
Age (i.e., 2 yrs or 2 mos):	12 wks	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Southfork Animal Hospital 17445 Kenrick Avenue	Address:	
City:	Lakeville	City:	
State:	MN	State:	
Zip:	55044	Zip:	
*Phone:	952-892-7870(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	952-892-7970(XXX-XXX-XXXX)
*Today's Date:	08/13/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 09/15/2009

Verified:yes

Reviewed:yes

Date Entered: 12/11/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10040

Product Code: 2668.05

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045151A	<input checked="" type="checkbox"/> Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	25	
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/12/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Client says pt was listless and lethargic approx 2-3 hours after vaccine given. Pt. also had a limp by the afternoon, so client returned for physical exam with vet and received pain meds.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	2-3 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):	Number affected:	1
Breed: Pitbull	Number vaccinated:	1
Sex: <input checked="" type="checkbox"/> Male	Number dead:	0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 8 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Doc Side Vet Medical Center of Fell's Point 1705 Bank Street		Address: (b)(6)	
City: Baltimore		City: (b)(6)	
State: MD		State: MD	
Zip: 21231		Zip: (b)(6)	
*Phone: 410-522-0055(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 410-327-8254			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	410-522-0055(XXX-XXX-XXXX)
*Today's Date:	08/12/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/12/2009

Verified:yes

Reviewed:yes

Date Entered: 12/11/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10036

Product Code: 1905.23 13D1.29 14P5.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18096C	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916403A	<input checked="" type="checkbox"/> Viral
3 Duramune Cv-K	112	145265A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R hip	23	08/03/2009
2 1 ml	SQ	R shoulder	23	08/03/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/03/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: vomiting, facial swelling
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	5 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	9690	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):		Number affected: 1	
Breed:	Pug	Number vaccinated: 1	
Sex:	<input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	16 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Animal Medical Clinic 234 Snelling Avenue South	Address:	
City:	St. Paul	City:	
State:	MN	State:	
Zip:	55105	Zip:	
*Phone:	651-690-1564(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	651-698-9595		
E-mail:	amc234@goldengate.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	651-690-1564(XXX-XXX-XXXX)
*Today's Date:	08/06/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other: CVT

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/06/2009

Verified: yes

Reviewed: yes

Date Entered: 12/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10035

Product Code: 1905.24 13D1.29 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Defensor 3	189	5830707	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916409A	<input checked="" type="checkbox"/> Viral
3 Intra-Trac III	165A	54196A	<input checked="" type="checkbox"/> Combination
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RR leg	22	07/24/2009
2 1 ml	SQ	RF shoulder	22	07/24/2009
3 1 ml	IN	Nostrils	n/a	07/24/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/24/2009
Concurrent Drugs or Procedures:	n/a

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
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Explain the event and any treatment in a concise paragraph:
 After arriving home from doctor appointment, began vomiting, having diarrhea, and acting lethargic. Upon arrival at the clinic temp was 102.0, normal heart and respiratory rhythms. Evidence of diarrhea, no facial swelling or presence of hives. Administered 0.17mls diphenhydramine 50mg/ml IM in left caudal femoral region. Took home to monitor as

per owner.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 hour
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	12228	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Dachshund	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	1 yrs 10 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Valley Veterinary Hospital 3210 Main Avenue North	Address:	
City:	Fargo	City:	
State:	ND	State:	
Zip:	58103	Zip:	
*Phone:	701-232-3391(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
	701-232-3391(XXX-XXX-XXXX)

*Submitter's Phone Number:	
*Today's Date:	08/06/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Not Listed
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/06/2009

Verified:yes

Reviewed:yes

Date Entered: 12/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10031

Product Code: 13D1.22 1905.24 2100.02

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard 5 Plus	189	A839305B	<input checked="" type="checkbox"/> Viral
2 Defensor 1	189	S834806C	<input checked="" type="checkbox"/> Viral
3 Bronchicine	189	A939630A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	25	08/04/2009
2 1 ml	SQ	R hip	25	08/04/2009
3 1 ml	SQ	L shoulder	25	08/04/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/04/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description: Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
 Within 5 minutes of vaccination, dog began vomiting, initially white foam followed by bile and dry heaving. Mucous membranes became pale. Dexamethasone sp 4mg was given intravenously, 5mg Diphenhydramine given IM, a 24 g IV Catheter was placed in the left cephalic and fluids administered at 50ml/hr. Mucous membrane color and capillary

refill time returned to normal within 10 minutes.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	5 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	0443-2 Shadow	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Yorkshire Terrier	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Male	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	1 yrs 3 mos	

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
 Owner obtained as puppy. He first presented to our clinic 7/11/08 at 10 weeks of age for routine health care. He was vaccinated for DHPPC and an intranasal Bordetella. On 8/4/08 he received a DHPPC and Bronchicine. On 8/21/08, he received a DHPPC and Defensor Rabies vaccination. He was neutered uneventfully and had normal pre-anesthetic bloodwork on 9/16/08. He received the Dental Vaccine manufactured by Pfizer on 8/21/08 and 9/16/08. He presented 8/4/09 for routine health care and booster vaccines. He had bloodwork drawn that day as part of a routine wellness panel performed by Antech Lab and all results were normal. He currently eats lams food and housed inside only.

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Chicago Drive Veterinary Clinic 6418 Center Industrial Drive	Address:	(b)(6)
City:	Jenison	City:	(b)(6)
State:	MI	State:	MI
Zip:	49428	Zip:	(b)(6)
*Phone:	616-669-0501(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	616-669-2850		
E-mail:	chicagodrivevet@comcast.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	616-669-0501 (XXX-XXX-XXXX)
*Today's Date:	08/05/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 08/05/2009

Verified:yes

Reviewed:yes

Date Entered: 12/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10014

Product Code: 13D1.29 2668.05 14M1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916411A	<input checked="" type="checkbox"/> Viral
2 LCI-GP	112	045151A	<input checked="" type="checkbox"/> Bacterial
3 Intra-Trac II	165A	53662A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	25	07/16/2009
2 1 ml	SQ	L shoulder	25	07/16/2009
3 1 ml	IN	Nose	NA	07/16/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/16/2009
Concurrent Drugs or Procedures:	On Metronidazole for diarrhea previous to this. Frontline, Interceptor and Strongid were dispensed but I don't know when she received these.

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph:	

Several hours after receiving these vaccines she presented to the local emergency clinic with angioneurotic edema in the face, moderate pruritis in the face, excessive panting. The EC gave her Dexamethasone 1.6mg IV and Diphenhydramine 7mg IM. Discharged her with instructions to continue diphenhydramine at 7mg TID. The following day she was lethargic and developed diarrhea. This was treated with a bland diet and continuation of the diphenhydramine.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	3 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):	Number affected:	1
Breed: Maltese Cross	Number vaccinated:	1
Sex: <input checked="" type="checkbox"/> Female	Number dead:	0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 1 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Acquired from a rescue group two weeks prior to this exam. History unknown. PE was unremarkable.		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: All Paws Animal Hospital 5225 Excelsior Blvd		Address: (b)(6)	
City: St. Louis Park		City: (b)(6)	
State: MN		State: MN	
Zip: 55416		Zip: (b)(6)	
*Phone: 952-848-0913(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 952-848-0896			
E-mail: (b)(6)@allpawsvets.com		E-mail:	

This event has been reported to	<input checked="" type="checkbox"/> Yes
---------------------------------	---

the manufacturer(s):	
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	952-848-0913(XXX-XXX-XXXX)
*Today's Date:	07/22/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 07/22/2009

Verified:yes

Reviewed:yes

Date Entered: 11/09/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10006

Product Code: 1331.20 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867113A	<input checked="" type="checkbox"/> Viral
2 LeptoVax 4	112	045152A	<input checked="" type="checkbox"/> Bacterial
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Over shoulder	22	06/18/2009
2 1 ml	SQ	L shoulder	22	06/18/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/18/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description: <input checked="" type="checkbox"/> Some other event - Describe Below
Explain the event and any treatment in a concise paragraph: Owner phones 6/19/08 to report that diarrhea developed the day after vaccination.
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	12-24 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Medium
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered without treatment
Other:	

Animal Information

Case Identification:	Dakota Seven	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:1
(Other Species):		Number affected:1
Breed:	Pug	Number vaccinated:1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:0
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	10 yrs 2 mos	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): House dog. 1 other dog in household. Generally healthy		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Truesdell Animal Care Hospital 4214 Milwaukee Street	Address:	(b)(6)
City:	Madison	City:	(b)(6)
State:	WI	State:	WI
Zip:	53714	Zip:	(b)(6)
*Phone:	608-244-2555(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	608-244-2555(XXX-XXX-XXXX)
*Today's Date:	07/17/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 07/17/2009

Verified:yes

Reviewed:yes

Date Entered: 11/09/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV10005

Product Code: 2126.R0 2668.00

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Recombitek Lyme	298	42146	<input checked="" type="checkbox"/> Recombinant
2 Vanguard L4	189	A838205C	<input checked="" type="checkbox"/> Bacterial
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	22	07/14/2009
2 1 ml	SQ	R shoulder	22	07/14/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/14/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: facial swelling. patient was given 11 mg/Benadryl IM and 5 mg prednisone IM
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	45 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Toy Poodle	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Female	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 9 yrs 9 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: West Frederick Veterinary Hospital, PC 6902 Bowers Road		Address: (b)(6)	
City: Frederick		City: (b)(6)	
State: MD		State: MD	
Zip: 21702		Zip: (b)(6)	
*Phone: 301-473-4478(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	301-473-4478(XXX-XXX-XXXX)
*Today's Date:	07/17/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other: Technician

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 07/17/2009

Verified: yes

Reviewed: yes

Date Entered: 11/09/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09352

Product Code: 2668.00

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard L4	189	A832033C	<input checked="" type="checkbox"/> Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	02/14/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Patient presented for 3rd set of puppy vaccines. Lepto was introduced for first time; within 10 mins patient had facial swelling and vomiting, hives. Gave diphenhydramine and dex sp as Tx.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	10 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Sandefur/52955	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Pug	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Not Listed		
Age (i.e., 2 yrs or 2 mos):	3 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	VCA Woodlands Animal Hospital 428 Rayford Road	Address:	
City:	Spring	City:	
State:	TX	State:	
Zip:	77386	Zip:	
*Phone:	281-367-7553(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	281-367-7553(XXX-XXX-XXXX)
*Today's Date:	02/14/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Not Listed
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 09/15/2009

Verified:yes

Reviewed:yes

Date Entered: 09/30/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09344

Product Code: 13D1.29 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916425A	<input checked="" type="checkbox"/> Viral
2 Lepto Vax 4	112	350257A	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Unknown	Unknown	06/04/2009
2 1 ml	SQ	Unknown	Unknown	06/04/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/04/2009
Concurrent Drugs or Procedures:	heart worm test blood and fecal sample

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Trouble breathing and facial swelling after vaccine administration.	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	10 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):	Number affected:	1
Breed: Dachshund	Number vaccinated:	1
Sex: <input checked="" type="checkbox"/> Male	Number dead:	0
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 3.5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): None available		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Triangle Veterinary Hospital Inc. 3301 Old Chappel Hill Road		Address: (b)(6)	
City: Durham		City: (b)(6)	
State: NC		State: NC	
Zip: 27707		Zip: (b)(6)	
*Phone: 919-489-2391 (XXX-XXX-XXXX)		Phone: (b)(6) (XXX-XXX-XXXX)	
FAX: 919-489-0853			
E-mail: (b)(6)@trianglevet.com		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	919-489-2391 (XXX-XXX-XXXX)
*Today's Date:	07/09/2009 (MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other: Administrative assistant

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 07/09/2009

Verified: yes

Reviewed: yes

Date Entered: 09/30/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09336

Product Code: 47K1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard Plus 5 L4	189	A836001	<input checked="" type="checkbox"/> Combination
2			<input checked="" type="checkbox"/> [Click arrow for selections]
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	06/22/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/22/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Deceased
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	approximately 45 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Medium
*Outcome (select one):	<input checked="" type="checkbox"/> Died
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Labrador Retriever	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Male	Number dead: 1
Neutered:	<input checked="" type="checkbox"/> No	
Age (i.e., 2 yrs or 2 mos):	12 yrs	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): vaccinated annually		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name	(b)(6)
Address:	Kaukauna Veterinary Clinic 625 Hyland Avenue	Address	(b)(6)
City:	Kaukauna	City	(b)(6)
State:	WI	State:	WI
Zip:	54130	Zip	(b)(6)
*Phone:	920-766-3380(XXX-XXX-XXXX)	Phone	(b)(6) XXX-XXX-XXXX
FAX:	920-766-0730		
E-mail:	eklowe@newbc.rr.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	920-766-3380(XXX-XXX-XXXX)
*Today's Date:	06/25/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/25/2009

Verified:yes

Reviewed:yes

Date Entered: 09/17/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09335

Product Code: 46E8.21 13D1.29

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 CvK/LCI-GP	112	094234A	<input checked="" type="checkbox"/> Combination
2 Duramune Max 5	112	9166420A	<input checked="" type="checkbox"/> Viral
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Interscapular	22	06/22/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/22/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: markedly swollen face, lethargy, pruritis	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	15-20 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Bernese Mountain Dog		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Not Listed		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Not Listed		
Age (i.e., 2 yrs or 2 mos): 4 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Nelson Road Veterinary Clinic 8875 Nelson Road		Address: (b)(6)	
City: Longmont		City: (b)(6)	
State: CO		State: CO	
Zip: 80503		Zip: (b)(6)	
*Phone: 303-678-8387(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX)	
FAX: 303-678-7221			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	303-678-8387(XXX-XXX-XXXX)
*Today's Date:	06/23/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Veterinarian
Other:

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/22/2009

Verified:yes

Reviewed:yes

Date Entered: 09/17/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09333

Product Code: 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045142A	<input checked="" type="checkbox"/> Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Left	22	
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/03/2009
Concurrent Drugs or Procedures:	Bordetella IN

Event Information

* Event description: <input checked="" type="checkbox"/> Some other event - Describe Below
Explain the event and any treatment in a concise paragraph: 24 hrs 30 sec seizure episodes
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	24 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Medium
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered without treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Lab	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 2 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Heartland Animal Hospital 1051 West Stearns Road		Address:	
City: Barlett		City: (b)(6)	
State: IL		State: IL	
Zip: 60103		Zip: (b)(6)	
*Phone: 630-372-2000(XXX-XXX-XXXX)		Phone: (b)(6) (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	630-372-2000(XXX-XXX-XXXX)
*Today's Date:	06/22/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/22/2009

Verified:yes

Reviewed:yes

Date Entered: 09/17/2009

CVB Reporter: Murtle

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09325

Product Code: 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045147A	<input checked="" type="checkbox"/> Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	22	04/23/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/23/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Systemic
Explain the event and any treatment in a concise paragraph: the patient was extremely lethargic and inappetant for 3 days after vaccination.	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): hrs (Include Units:mins, hrs, days, wks, mos, yrs)	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered without treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Boston Terrier		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 3 yrs 1 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): previously healthy		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Truesdell Animal Care Hospital 4214 Milwaukee Street		Address: (b)(6)	
City: Madison		City: (b)(6)	
State: WI		State: WI	
Zip: 53714		Zip: (b)(6)	
*Phone: 608-244-2555(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 608-310-8127			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	608-244-2555(XXX-XXX-XXXX)
*Today's Date:	06/18/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/19/2009

Verified: yes

Reviewed: yes

Date Entered: 09/17/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09324

Product Code: 1905.20 13D1.29 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Rabvac I	112	1213175A	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916358A	<input checked="" type="checkbox"/> Viral
3 LCI-GP	112	350249A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	
2 1 ml	SQ	L shoulder	22	01/09/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	01/09/2009
Concurrent Drugs or Procedures:	N/A

Event Information

* Event description:	<input checked="" type="checkbox"/> Local
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Explain the event and any treatment in a concise paragraph:
 Owner noted the area was tender and sore in January. The owner noted two spots of alopecia on left side of neck at the end of January/early February 2009. Presented to Purdue University Veterinary Teaching Hospital with 4 in by 1.5 in area of alopecia, hyperpigmentation, and lichenification. Biopsies were taken. Histopathologic diagnosis:

lymphoplasmacytic panniculitis and alopecia consistent with vaccination panniculitis.

<p>If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.</p>	
Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	About 1 month
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Other
Other:	Currently being treated. Outcome to be determined.

Animal Information

Case Identification:	Fezz	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Poodle mix	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	2 yrs 9 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Acquired from Trisha's No-Kill Shelter. Indoor pet only. Only dog in household.			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Purdue University, VTH 625 Harrison Street	Address:	(b)(6)
City:	West Lafayette	City:	(b)(6)
State:	IN	State:	IN
Zip:	47907	Zip:	(b)(6)
*Phone:	765-494-1107(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	765-496-1000		
E-mail:	(b)(6)@purdue.edu	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)

*Submitter's Phone Number:	765-494-1107(XXX-XXX-XXXX)
*Today's Date:	06/17/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Not Listed
Other:	Veterinary Student

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/17/2009

Verified:yes

Reviewed:yes

Date Entered: 09/17/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09323

Product Code: 1331.20 2100.02

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867112A	<input checked="" type="checkbox"/> Viral
2 Bronchicine CAe	189	A836743C	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L hip	22	06/16/2009
2 1 ml	SQ	R hip	22	06/16/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/16/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Owner called approx. 20 mins after vaccines and stated face swelling and vomiting (once). Returned to clinic with hives over whole body and head. Gave Dexamethasone 0.2mL/Diphenhydramine 0.2mL IM. No fever.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	20 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Nathan	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Mini Dachshund	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	2 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Suburban Animal Clinic 640 North Wilson Road	Address:	(b)(6)
City:	Columbus	City:	(b)(6)
State:	OH	State:	OH
Zip:	43204	Zip:	(b)(6)
*Phone:	614-276-5479(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	614-276-9989		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	614-276-5479(XXX-XXX-XXXX)
*Today's Date:	06/17/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	RVT

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/17/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09320

Product Code: 1905.23 13D1.29 46E5.21 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Rabvac 3 TF	112	873179A	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916420A	<input checked="" type="checkbox"/> Viral
3 CvK/LCI-GP	112	094234A	<input checked="" type="checkbox"/> Combination
4 Bronchi-Shield III	112	112445A	<input checked="" type="checkbox"/> Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	06/02/2009
2 1 ml	SQ	L shoulder	22	06/02/2009
3 1 ml	SQ	L shoulder	22	06/02/2009
4 1 ml	INTRANASAL	INTRANASAL	N/A	06/02/2009

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/02/2009
Concurrent Drugs or Procedures:	NA

Event Information

* Event description: <input checked="" type="checkbox"/> Local
Explain the event and any treatment in a concise paragraph: Large mass at injection site on right shoulder 1 week post vaccination.
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 wks
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Other
Other:	Monitoring for regression

Animal Information

Case Identification:	Max Nerbonne	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Golden Retriever	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	10 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Skin allergies			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Fox Hollow Animal Hospital 2950 South Bear Creek Blvd.	Address:	
City:	Lakewood	City:	
State:	CO	State:	
Zip:	80228	Zip:	
*Phone:	303-980-4444(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	303-980-1054		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	303-980-4444(XXX-XXX-XXXX)
*Today's Date:	06/16/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

[Submit](#)

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/16/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09319

Product Code: 1905.23 13D1.29 46E5.21 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Rabvac 3 TF	112	873179A	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916420A	<input checked="" type="checkbox"/> Viral
3 CvK/LCI-GP	112	094234A	<input checked="" type="checkbox"/> Combination
4 Bronchi-Shield III	112	112445A	<input checked="" type="checkbox"/> Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	06/02/2009
2 1 ml	SQ	L shoulder	22	06/02/2009
3 1 ml	SQ	L shoulder	22	06/02/2009
4 1 ml	INTRANASAL	INTRANASAL	N/A	06/02/2009

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/02/2009
Concurrent Drugs or Procedures:	NA

Event Information

* Event description: <input checked="" type="checkbox"/> Local
Explain the event and any treatment in a concise paragraph: Large mass at injection site on right shoulder 1 week post vaccination.
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 wks
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Other
Other:	Monitoring for regression

Animal Information

Case Identification:	Abby Nerbonne	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Golden Retriever	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	10 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Skin allergies			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Fox Hollow Animal Hospital 2950 South Bear Creek Blvd.	Address:	
City:	Lakewood	City:	
State:	CO	State:	
Zip:	80228	Zip:	
*Phone:	303-980-4444(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	303-980-1054		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	303-980-4444(XXX-XXX-XXXX)
*Today's Date:	06/16/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/16/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09318

Product Code: 12X1.20 1905.23 13D1.29

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Bronchi-Shield III	112	112431A	<input checked="" type="checkbox"/> Combination
2 Rabvac 3 TF	112	873178A	<input checked="" type="checkbox"/> Viral
3 Duramune Max 5	112	916402A	<input checked="" type="checkbox"/> Viral
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	IN	nostrils		06/10/2009
2 1 ml	SQ	RR leg	25	06/10/2009
3 1 ml	SQ	L shoulder	25	06/10/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/10/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description: <input checked="" type="checkbox"/> Systemic
Explain the event and any treatment in a concise paragraph: onset of lethargy, 24 hrs post vaccinate dog brought in for vaccines 6/10/09. lethargic & decreased appetite by 6/11/09 swollen R popliteal lymph node RR leg.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	24 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Medium
*Outcome (select one):	<input checked="" type="checkbox"/> Other
Other:	undetermined

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Chihuahua	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 1yrs 4 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Newport Harbor Animal Hospital 125 Mesa Drive		Address: (b)(6)	
City: Costa Mesa		City: (b)(6)	
State: CA		State: CA	
Zip: 92627		Zip: (b)(6)	
*Phone: 949-631-1030(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX: 949-631-3354			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	949-631-1030(XXX-XXX-XXXX)
*Today's Date:	06/12/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/12/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09317

Product Code: 12X1.20 13D1.29 1905.24

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Bronchi-Shield III	112	112439A	<input checked="" type="checkbox"/> Combination
2 Duramune Max 5	112	916402A	<input checked="" type="checkbox"/> Viral
3 Defensor 1	189	S834803A	<input checked="" type="checkbox"/> Viral
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	Intranasal	nose		06/12/2009
2 1 ml	SQ	L shoulder	25	06/12/2009
3 1 ml	SQ	RR leg	25	06/12/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/12/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: facial swelling. owner returned with patient within 30 mins of vacc administered
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	30 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:1
(Other Species):		Number affected:1
Breed:	Pug	Number vaccinated:1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:0
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	1 yrs 4 mos	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): pet woned, no travel history		

Personal Information

Veterinarian		Owner	
*Name:	[Redacted]	Name:	[Redacted]
Address:	Newport Harbor Animal Hospital 125 Mesa Drive	Address:	(b)(6)
City:	Costa Mesa	City:	[Redacted]
State:	CA	State:	Ca
Zip:	92627	Zip:	(b)(6)
*Phone:	949-631-2211(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	949-631-3354		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	949-631-2211(XXX-XXX-XXXX)
*Today's Date:	06/12/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/12/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09314

Product Code: 1331.20 2668.00

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867112A	
2 Vanguard L4	189	A833410B	<input checked="" type="checkbox"/> Bacterial
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L neck	25	06/01/2009
2 1 ml	SQ	L neck	25	06/01/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/01/2009
Concurrent Drugs or Procedures:	heartworm test

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Patient presented with pruritic facial swelling. The owner gave 25 mg benadryl PO. The veterinarian administered 0.5 ml diphenhydramine IM and 0.6 ml dexamethasone SP IV.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	4 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Cockapoo		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 3 yrs 4 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Okemos Animal Hospital 1716 Hamilton	Address:	
City:	Okemos	City:	
State:	MI	State:	
Zip:	48864	Zip:	
*Phone:	517-349-0110(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	517-349-0110(XXX-XXX-XXXX)
*Today's Date:	06/10/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/10/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09311

Product Code: 14M1.20 1905.23 2126.R0 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Intra-Trac II	165A	53657B	<input checked="" type="checkbox"/> Combination
2 Imrab 3 TF	298	18093C	<input checked="" type="checkbox"/> Viral
3 Recombitek Lyme	298	42145	<input checked="" type="checkbox"/> Recombinant
4 LeptoVax 4	112	045147A	<input checked="" type="checkbox"/> Bacterial

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	Intranasal	Both nostrils		05/26/2009
2 1 ml	SQ	RR leg	22	05/26/2009
3 1 ml	SQ	LR leg	22	05/26/2009
4 1 ml	SQ	LF leg	22	05/26/2009

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/26/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Autoimmune
----------------------	--

Explain the event and any treatment in a concise paragraph:
 Presented 8 days after annual exam, where vaccinations were given with lethargy, icterus, and a fever of 104.7. Abdominal rads showed an enlarged spleen. Bloodwork showed a decreased RBC and increased total bilirubin. Patient was transferred to a 24 hour clinic for treatment. After 6 days of treatment at the 24 hour clinic with multiple

transfusions and immunosuppressive drugs, Toby died on 6/9/09 at 3 pm.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	8 days
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Died
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Dachshund		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 1
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 5 yrs		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
 Toby has been vaccinated yearly with multiple vaccines at each appointment. April 16, 2005: fort dodge leptovax 4/c, fort dodge duramune adult, merial recombitek lyme, merial imrab 3. 5/13/2005: merial recombitek lyme. 9/23/2005: Intervet progard-kc. 5/9/2006: fort dodge leptovax 4, intervet prolyme. 10/6/2006: Intervet Progard kc. 4/26/2007: Merial imrab 3tf, fort dodge leptovax 4, intervet prolyme. 4/25/2008: Intervet prolyme, schering-Plough Intra-trac II, Fort Dodge leptovax 4, Schering Plough Galaxy. Negative 4dx 5/26/09, 4/25/08, 4/26/2007. Negative 3dx 5/9/2006

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name	(b)(6)
Address:	Northern Rhode Island Animal Hospital 152 School Street, P.O. 129	Address	(b)(6)
City:	Forestdale	City	(b)(6)
State:	RI	State:	RI
Zip:	02824	Zip	(b)(6)
*Phone:	401-762-2400(XXX-XXX-XXXX)	Phone	(b)(6) XXX-XXX-XXXX
FAX:	401-765-7679		
E-mail:		E-mail:	

This event has been reported to Yes

the manufacturer(s):	
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	401-762-2400(XXX-XXX-XXXX)
*Today's Date:	06/09/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/09/2009

Verified:yes

Reviewed:yes

Date Entered: 09/11/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09307

Product Code: 1331.20 2668.00 14M1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867112A	<input checked="" type="checkbox"/> Viral
2 Vanguard L4	189	A833410B	<input checked="" type="checkbox"/> Bacterial
3 Recombitek KC2	124	104589	<input checked="" type="checkbox"/> Combination
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L neck	25	06/08/2009
2 1 ml	SQ	L neck	25	06/08/2009
3 1 ml	Intranasal	Nose		06/08/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/08/2009
Concurrent Drugs or Procedures:	heartworm test

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: The patient presented with pruritic angioedema. The owner reports the patient also vomited at home. She was treated with 1.0 ml dexamethasone SP IV and diphenhydramine 1.0 ml IM. 4 mg chlorpheniamune was prescribed.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	10 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Beagle Mix	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Female	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	2 yrs 2 mos	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Okemos Animal Hospital 1716 Hamilton	Address:	
City:	Okemos	City:	
State:	MI	State:	
Zip:	48864	Zip:	
*Phone:	517-349-0110(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	517-349-0110(XXX-XXX-XXXX)
*Today's Date:	06/09/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/10/2009

Verified:yes

Reviewed:yes

Date Entered: 08/18/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09306

Product Code: 1331.20 2668.00 14M1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867112A	<input checked="" type="checkbox"/> Viral
2 Vanguard L4	189	A833410B	<input checked="" type="checkbox"/> Bacterial
3 Recombitek KC2	124	104589	<input checked="" type="checkbox"/> Recombinant
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L neck	25	06/06/2009
2 1 ml	SQ	L neck	25	06/06/2009
3 1 ml	Intranasal	Nose		06/06/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/06/2009
Concurrent Drugs or Procedures:	Heartworm test

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: The patient presented with angioedema and was treated with 0.5 ml dexamethasone SP IV and diphenhydramine 0.6 ml IM. Chlorpheniamune 4 mg 1/2 tab PO every 4-6 hrs for 3-4 days was prescribed.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	3 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):	Number affected:	1
Breed: Jack Russell Terrier Mix	Number vaccinated:	1
Sex: <input checked="" type="checkbox"/> Female	Number dead:	0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	3 yrs 11 mos	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Okemos Animal Hospital 1716 Hamilton	Address:	
City:	Okemos	City:	
State:	MI	State:	
Zip:	48864	Zip:	
*Phone:	517-349-0110(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	517-349-0110(XXX-XXX-XXXX)
*Today's Date:	06/09/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/10/2009

Verified:yes

Reviewed:yes

Date Entered: 08/18/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09305

Product Code: 1331.20 2126.R0 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Adult 3	112	1867113A	<input checked="" type="checkbox"/> Viral
2 Recombitek Lyme	298	42144	<input checked="" type="checkbox"/> Recombinant
3 LeptoVax 4	112	045151A	<input checked="" type="checkbox"/> Bacterial
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	between shoulder	25	
2 1 ml	SQ	between shoulder	25	
3 1 ml	SQ	between shoulder	25	
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/06/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: immediately after vaccine - vomited 2X temp 102.7 HR - 200 (tachycardia) drooling. head down, depressed non responsive. start IV fluids LRS 500 bolus then decrease 125 ml/hr. IV dex naphes 6 cc (24 mg) IV. responded to treatment within 1 hr - full recovery - 6 hrs.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	immediate
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Collie		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Female		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 2 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): house pet, fine prior to vaccination.		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Nassau Veterinary Clinic 3930 US Rte 2, P.O. Box 400		Address: (b)(6)	
City: Nassau		City: (b)(6)	
State: NY		State: NY	
Zip: 12123		Zip: (b)(6)	
*Phone: 518-766-2636(XXX-XXX-XXXX)		Phone: (b)(6) (XXX-XXX-XXXX)	
FAX: 518-766-3934			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	518-766-2636(XXX-XXX-XXXX)

*Today's Date:	06/09/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/12/2009

Verified:yes

Reviewed:yes

Date Entered: 08/18/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09304
 Product Code: 13D1.29 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916406A	<input checked="" type="checkbox"/> Viral
2 LeptoVax 4	112	350256A	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	22	05/30/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/30/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description: <input checked="" type="checkbox"/> Local
Explain the event and any treatment in a concise paragraph: Patient came in for final DHLPP booster, has had lepto one other time (5/07/09). No reaction then, swelling around initial vaccination area. Patient recovered withing 48 hours. No treatment administered.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	5-6 hrs	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered without treatment	
Other:		

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Pug		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 0
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 18 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Babcock Hills 6600 West Prue Road		Address: (b)(6)	
City: San Antonio		City: (b)(6)	
State: TX		State: TX	
Zip: 78240		Zip: (b)(6)	
*Phone: 210-697-8581 (XXX-XXX-XXXX)		Phone: (b)(6) (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	210-697-8581 (XXX-XXX-XXXX)
*Today's Date:	06/08/2009 (MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Not Listed
Other:	Veterinary Technician

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/08/2009

Verified:yes

Reviewed:yes

Date Entered: 08/18/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09303

Product Code: 2668.05 2126.R0

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045151A	<input checked="" type="checkbox"/> Bacterial
2 Recombitek Lyme	298	42145	<input checked="" type="checkbox"/> Recombinant
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	dorsal scapular	25	
2 1 ml	SQ	dorsal scapular	25	
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/06/2009
Concurrent Drugs or Procedures:	no others

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: allergic reaction - 1 hour post vaccination, facial swelling. treatment = diphenhydramine 125 mg then Q12 hrs 100 mg PO x 5 doses. Some improvement with diphenhydramine within 4 hours, but ? 2nd to fully resolve.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):	Number affected: 1
Breed: Swiss Mountain Dog	Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Female	Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos): 3 yrs	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): family pet, acquired 2/09, diet = Wysong + Fromm's, indoor housing. ?? vaccine given 12/15/08. Heartworm (neg)/lyme(neg)/anaplasma(neg)/ehrlichia(neg) 12/15/08.	

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Nassau Veterinary Clinic 3930 US Rt. 20		Address: (b)(6)	
City: Nassau		City: (b)(6)	
State: NY		State: NY	
Zip: 12123		Zip: (b)(6)	
*Phone: 518-766-2636(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 518-766-3934			
E-mail: www.nassauvet.com		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	518-766-2636(XXX-XXX-XXXX)

*Today's Date: 06/08/2009(MM/DD/YYYY)	
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	practice manager

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/08/2009

Verified: yes

Reviewed: yes

Date Entered: 08/18/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09298

Product Code: 13D1.29 14P5.20 1905.24

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916403A	<input checked="" type="checkbox"/> Viral
2 Duramune Cv-K	112	145265A	<input checked="" type="checkbox"/> Viral
3 Imrab 1 TF	298	22018A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L hip	23	06/03/2009
2 1ml	SQ	R hip	23	06/03/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/03/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Facial Swelling	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	6 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	446	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Dachshund	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	3 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Animal Medical Clinic 234 Snelling Avenue South	Address:	
City:	St. Paul	City:	
State:	MN	State:	
Zip:	55105	Zip:	
*Phone:	651-690-1564(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	651-698-9595		
E-mail:	amc234@goldengate.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	651-690-1564(XXX-XXX-XXXX)
*Today's Date:	06/04/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other: CVT

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 06/04/2009

Verified: yes

Reviewed: yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09297

Product Code: 1905.23 13D1.29

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18092B	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916393A	<input checked="" type="checkbox"/> Viral
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Distal R hindleg	23	11/01/2009
2 1 ml	SQ	L shoulder	23	05/26/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/26/2009
Concurrent Drugs or Procedures:	None

Event Information

* Event description:	<input checked="" type="checkbox"/> Some other event - Describe Below
Explain the event and any treatment in a concise paragraph: Patient normal next day, following day not observed until evening, mildly depressed with increased resp. effort, died during night (~ 60 hr. post vax.)	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	48 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Died
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	2
(Other Species):	Number affected:	1
Breed: Chihuahua	Number vaccinated:	2
Sex: <input checked="" type="checkbox"/> Female	Number dead:	1
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 4 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): dogs, noPrivate home, 2 previous vax.		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Colyer Veterinary Service 8919 Skyway		Address: (b)(6)	
City: Paradise		City: (b)(6)	
State: CA		State: CA	
Zip: 95969		Zip: (b)(6)	
*Phone: 530-872-3246(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 530-872-3253			
E-mail: (b)(6)@sbcbglobal.net		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	530-872-3246(XXX-XXX-XXXX)
*Today's Date:	05/29/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/29/2009

Verified:yes

Reviewed:yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09295

Product Code: 14P5.20 2668.05 1081.00

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5 Cv-K	112	BB354A262A	<input checked="" type="checkbox"/> Viral
2 LCI-GP	112	0045141A	<input checked="" type="checkbox"/> Bacterial
3 Vanguard B (IN)	112	110264C	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Dorsal Shoulder	25	05/21/2009
2 1 ml	SQ	Dorsal Shoulder	25	05/21/2009
3 1 ml	Intranasal	Nose	None	05/21/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/21/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Swollen muzzle. Treated with Benadryl IM and Dexamethasone Sodium Phosphate Subcutaneously. Swelling resolved over 1 hour.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	Approx 2 hrs	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group:	
(Other Species):	Number affected:	
Breed: Chihuahua	Number vaccinated:	
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 14 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Hickory Grove Animal Hospital 5450 North Sharon Amity		Address:	
City: Charlotte		City:	
State: NC		State:	
Zip: 28215		Zip:	
*Phone: 704-563-5858(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	704-563-5858(XXX-XXX-XXXX)
*Today's Date:	05/28/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/28/2009

Verified:yes

Reviewed:yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09294

Product Code: 13D1.29 2100.02 1905.23

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916409A	<input checked="" type="checkbox"/> Viral
2 Bronchicine	189	A836743C	<input checked="" type="checkbox"/> Bacterial
3 Rabvac 3 TF	112	873177A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	
2 1 ml	SQ	LR	22	
3 1 ml	SQ	RR	22	
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/15/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
----------------------	--

Explain the event and any treatment in a concise paragraph:
 Owner called about 45 minutes after appt to say that Maggie had vomited once and, by the end of the conversation, looked like she was going to vomit again. Rec she bring Maggie up for anti-vaccine reaction injections just in case. Arrived around 4:45 pm. Not brought by owner. Person with her has been with her for about 20 minutes and Maggie's

not done any vomiting in that time. PE: BAR, wagging tail. Mucous membranes a little pale. HR = 100. Temp = 100.2
 Face not swollen; no trouble breathing. Tried for 10-15 minutes to get BP reading, but couldn't due to dog moving,
 small size, etc. Gave dex/ benedryl IM around 4:50 pm and kept for monitoring. Was BAR, ate treats.

If this adverse event involves a possible lack of efficacy with a rabies product please
 contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	45 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Yorkie	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	16 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Meadowbrook Animal Clinic 2905 Walton Blvd.	Address:	
City:	Rochester Hills	City:	
State:	MI	State:	
Zip:	48309	Zip:	
*Phone:	248-375-1440(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:	meadowbrookac@sbcglobal.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)

*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	248-375-1440(XXX-XXX-XXXX)
*Today's Date:	05/28/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	Practice Manager

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/28/2009

Verified:yes

Reviewed:yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09293

Product Code: 1905.23 13D1.29 2668.05

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18093A	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916425A,	<input checked="" type="checkbox"/> Viral
3 LCI-GP	112	350257A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	
2 1 ml	SQ	RR	22	
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/26/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Local
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Explain the event and any treatment in a concise paragraph:
 S. pm both dog's lethargic and swollen over area of dhpp vax O lethargic, color pink, heart and lungs normal, abdo palp normal, T 101 3 inch fluctuant swelling over right shoulder. A vax reaction P RX benedryl 12.5 mg / 5 ml give 2.5 ml po bid / mcp call back in morning

spt: see AIV09291 for related AER

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	8.5 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Chihuahua	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Male	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> No	
Age (i.e., 2 yrs or 2 mos):	18 wks	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Meadowbrook Animal Clinic 2905 Walton Blvd	Address:	(b)(6)
City:	Rochester Hills	City:	(b)(6)
State:	MI	State:	MI
Zip:	48309	Zip:	(b)(6)
*Phone:	248-375-1440(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:			
E-mail:	meadowbrookac@sbcglobal.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)

*Submitter's Phone Number:	248-375-1440(XXX-XXX-XXXX)
*Today's Date:	05/28/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	Practice Manager

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/28/2009

Verified:yes

Reviewed:yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09292

Product Code: 13D1.29 2100.02 1905.23

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916421A	<input checked="" type="checkbox"/> Viral
2 Bronchicine	189	A836743C	<input checked="" type="checkbox"/> Bacterial
3 Rabvac 3 TF	112	873177A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	
2 1 ml	SQ	LR	22	
3 1 ml	SQ	RR	22	
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/07/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
----------------------	--

Explain the event and any treatment in a concise paragraph:
 S: Presented for exam. Started vomiting yesterday after appointment; owner isn't sure when; vomited three times last night and twice this morning. Yellow, fluid. Normal attitude. Had diarrhea also but owner isn't sure if it was before or after appt. O: PE: BAR. Temp = 101.3. Mucous membranes pink, moist, CRT < 1.5 seconds. Abdominal palpation;

palpated several instances; flinched once but didn't react other than that. Heart murmur. P: Treated with dex/benedryl; owner not to give food or water for a few hours, then try a little bit of i/d. If vomiting/ diarrhea continues and/or attitude/ appetite decreases, return to work up GI other than vacc rxn. -- pm

<p>If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.</p>	
Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:		Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	13 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Meadowbrook Animal Clinic 2905 Walton Blvd.	Address:	
City:	Rochester Hills	City:	
State:	MI	State:	
Zip:	48309	Zip:	
*Phone:	248-375-1440(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:	meadowbrookac@sbcglobal.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)

*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	248-375-1440(XXX-XXX-XXXX)
*Today's Date:	05/28/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/28/2009

Verified:yes

Reviewed:yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09291

Product Code: 13D1.29 1905.23 2668.05

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916425A	<input checked="" type="checkbox"/> Viral
2 Imrab 3 TF	298	18093A	<input checked="" type="checkbox"/> Viral
3 LCI-GP	112	350257A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	
2 1 ml	SQ	RR	22	
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/26/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Local
Explain the event and any treatment in a concise paragraph: . pm, both dog's lethargic with swelling over right shoulders where dhpp given O T 101.2 color pink, heart and lungs normal, 2 " soft swelling over right shoulder A vax reaction/ localizedP Rx benadryl 12.5 mg. / 5 ml. give 2.5 ml q 12 hrs. pm. call back in am./mcp	

spt: see AIV09293 for related AER

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	8.5 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):	Number affected: 1
Breed: Chihuahua	Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0
Neutered: <input checked="" type="checkbox"/> No	
Age (i.e., 2 yrs or 2 mos): 18 wks	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):	

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Meadowbrook Animal Clinic 2905 Walton Blvd	Address:	(b)(6)
City:	Rochester Hills	City:	(b)(6)
State:	MI	State:	MI
Zip:	48309	Zip:	(b)(6)
*Phone:	248-375-1440(XXX-XXX-XXXX)	Phone:	(b)(6) XX-XXX-XXXX
FAX:			
E-mail:	meadowbrookac@sbcglobal.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)

*Submitter's Phone Number:	248-375-1440(XXX-XXX-XXXX)
*Today's Date:	05/28/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	Practice Manager

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/28/2009

Verified:yes

Reviewed:yes

Date Entered: 08/07/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09288

Product Code: 13D1.20 14M1.20 1905.24

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Galaxy DA2PPvL	165A	212379B	<input checked="" type="checkbox"/> Viral
2 Intra-Trac II	165A	53659	<input checked="" type="checkbox"/> Combination
3 Defensor 1	189	S831726B	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LR	22	05/22/2009
2 1 ml	Intranasal	Nose	No needle	05/22/2009
3 1 ml	SQ	RR	22	05/22/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/22/2009
Concurrent Drugs or Procedures:	On Heartworm Medication

Event Information

* Event description: Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:

Patient presented for routine vaccinations. Vaccinations were administered on 5/22/09 at approx. 10:30 am. Patient then left the clinic and on the way home started to vomit and was lateral recumbent. Owners returned to the clinic around 11:00 am and patient presented with anaphylaxis. Set I.V catheter and administered Dexamethasone and

Benadryl, Administered fluids and observed.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): Roughly 30 mins
(Include Units: mins, hrs, days, wks, mos, yrs)

Attending veterinarian's level of suspicion that product caused event: High

*Outcome (select one): Recovered with treatment

Other:

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Bichon		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Rainbow Vet Clinic 2636 Noble Road		Address:	
City: Cleveland Heights		City:	
State: OH		State:	
Zip: 44121		Zip:	
*Phone: 216-291-3931 (XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
	480-304-2312 (XXX-XXX-XXXX)

*Submitter's Phone Number:	
*Today's Date:	05/22/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	Veterinary Staff

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/22/2009

Verified:yes

Reviewed:yes

Date Entered: 08/06/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09287

Product Code: 2668.05 1331.20 14M1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045145B	<input checked="" type="checkbox"/> Bacterial
2 Duramune Adult 3	112	1867111A	<input checked="" type="checkbox"/> Viral
3 Recombitek KC2	124	104-584	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	25	11/01/2009
2 1 ml	SQ	R shoulder	25	05/13/2009
3 1 ml	Intranasal	Nose	n/a	05/13/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/13/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Patient was vaccinated after Annual Exam. About two hours after came back with swollen muzzle and eyes. Dr. Gave Diphenhydramine 1.0 ml IM and Dexamethasone NaP 1.0 ml IV. went home with prescription of benadryl oral to continue if needed.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	about 2 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	2009-us-02986	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Golden Retriever	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	1 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): P had duramune max5 before several times before but not the duramune adult3, however, Dr. is very confident that the cause of the reaction is Lepto vaccine.			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	4500 NE Cornell Road	Address:	(b)(6)
City:	Hillsboro	City:	(b)(6)
State:	OR	State:	OR
Zip:	97124	Zip:	(b)(6)
*Phone:	503-648-1643(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	503-648-2003		
E-mail:	clientservices@frontiervet.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	503-648-1643(XXX-XXX-XXXX)

*Today's Date: 05/21/2009(MM/DD/YYYY)	
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/21/2009

Verified: yes

Reviewed: yes

Date Entered: 08/06/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09286

Product Code: 1905.23 2100.02 13D1.29 46E5.21

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab3 TF	298	18084C	<input checked="" type="checkbox"/> Viral
2 Bronchicine CAe	189	A836743C	<input checked="" type="checkbox"/> Bacterial
3 Duramune Max 5	112	916346A	<input checked="" type="checkbox"/> Viral
4 CvK/LCI-GP	112	094227A	<input checked="" type="checkbox"/> Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R leg	22	11/01/2009
2 1 ml	SQ	R hip	22	11/01/2009
3 1 ml	SQ	L hip	22	05/19/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/19/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Dog started vomiting 10 min after vaccinated. Owner returned to clinic. Temp 103, slowed down. Gave Diphenhydramine 0.3mL & Dexamethasone 0.3mL IM, Metoclopramide 0.5mL SQ.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	10 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Trevor	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	JRT	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Male	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	18 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Suburban Animal Clinic 640 North Wilson Road	Address:	(b)(6)
City:	Columbus	City:	(b)(6)
State:	OH	State:	OH
Zip:	43204	Zip:	(b)(6)
*Phone:	614-276-5479(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	614-276-9989		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	614-276-5479(XXX-XXX-XXXX)
*Today's Date:	05/20/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/20/2009

Verified:yes

Reviewed:yes

Date Entered: 08/06/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09285
 Product Code: 13D1.29 2100.02

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916327A	<input checked="" type="checkbox"/> Viral
2 Bronchicine CAe	189	A835550	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	04/22/2009
2 1 ml	SQ	L shoulder	22	04/22/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/22/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: facial swelling, angioedema, periocular and muzzle, hives on abdomen, swollen feet	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	approx 1 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	2851	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:1	
(Other Species):		Number affected:1	
Breed :	Labrador	Number vaccinated:1	
Sex:	<input checked="" type="checkbox"/> Male	Number dead:0	
Neutered:	<input checked="" type="checkbox"/> Not Listed		
Age (i.e., 2 yrs or 2 mos):	8 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name	(b)(6)
Address:	Town & Country Animal Clinic 3095 Genesee Street	Address	(b)(6)
City:	Cheektowaga	City	(b)(6)
State:	NY	State:	NY
Zip:	14225	Zip:	(b)(6)
*Phone:	716-896-2424(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	716-896-2424(XXX-XXX-XXXX)
*Today's Date:	05/20/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/20/2009

Verified:yes

Reviewed:yes

Date Entered: 08/06/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09277

Product Code: 1905.23 12X1.20 13D1.29

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Rabvac 3 TF	112	873178A	<input checked="" type="checkbox"/> Viral
2 Bronchi-Shield III	112	112436B	<input checked="" type="checkbox"/> Combination
3 Duramune Max 5	112	916402A	<input checked="" type="checkbox"/> Viral
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RR leg	25	05/08/2009
2 1 ml	Intranasal	IN		05/08/2009
3 1 ml	SQ	R shoulder	25	05/08/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/08/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Urticaria - dog returned 2-4 hours after vaccination for treatment of facial swelling.	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	2 - 4 hrs	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Pomeranian		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Not Listed		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Not Listed		
Age (i.e., 2 yrs or 2 mos): 7 yrs 10 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): pet owned, no travel history		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Newport Harbor Animal Hospital 125 Mesa Drive		Address: (b)(6)	
City: Costa Mesa		City: (b)(6)	
State: CA		State: CA	
Zip: 92627		Zip: (b)(6)	
*Phone: 949-631-1030(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX)	
FAX: 949-631-3354			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	949-631-1030(XXX-XXX-XXXX)
*Today's Date:	05/16/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/16/2009

Verified:yes

Reviewed:yes

Date Entered: 08/05/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09276

Product Code: 13D1.29 2668.05 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916391A	<input checked="" type="checkbox"/> Viral
2 LCI-GP	112	350254A	<input checked="" type="checkbox"/> Bacterial
3 Bronchi-Shield III	112	112442B	<input checked="" type="checkbox"/> Combination
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RF shoulder	22	05/14/2009
2 1 ml				05/14/2009
3 1 ml	IN	IN		05/14/2009
4				

Administered by: <input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY) 05/14/2009
Concurrent Drugs or Procedures: none

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: 2 mins post vaccination, Ella vomited 3 times, her eyelids started swelling, she developed a rash under her chin & she was intensely pruritic.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	2 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Springer Spaniel	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Female	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 12 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): 4/2/09 - given DHPPC Schering-Plough by breeders vet (no reaction, stated).		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Ames Pet Hospital 1400 Dickinson Avenue, P.O. Box 1596		Address: (b)(6)	
City: Ames		City: (b)(6)	
State: IA		State: IA	
Zip: 50014		Zip: (b)(6)	
*Phone: 515-292-8885(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 515-292-3033			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	515-292-8885(XXX-XXX-XXXX)
*Today's Date:	05/14/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/14/2009

Verified:yes

Reviewed:yes

Date Entered: 08/05/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09275

Product Code: 2126.R0 1331.20 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Recombitek Lyme	298	42145	<input checked="" type="checkbox"/> Recombinant
2 Duramune Adult 3	112	1867111A	<input checked="" type="checkbox"/> Viral
3 LeptoVax 4	112	045147A	<input checked="" type="checkbox"/> Bacterial
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml				
2 1 ml				
3 1 ml				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use: (MM/DD/YYYY)	05/08/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: The patient presented with a swollen face, pink skin and welts all over his head.	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	within 1-4 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> [Click arrow for selections]
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Boston Terrier	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 6 yrs 10 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Apple Valley Animal Hospital 1207 Cedar Creek Grade		Address: (b)(6)	
City: Winchester		City: (b)(6)	
State: VA		State: VA	
Zip: 22602		Zip: (b)(6)	
*Phone: 540-678-0202(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	05/13/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other: Veterinary Assistant

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/13/2009

Verified: yes

Reviewed: yes

Date Entered: 08/05/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB website. [CVB Home Page](http://www.aphis.usda.gov/vs/cvb/ic/adverseeventreport.htm)

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09270

Product Code: 13D1.29

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916411A	<input checked="" type="checkbox"/> Viral
2			<input checked="" type="checkbox"/> [Click arrow for selections]
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	intrascapular	25	05/11/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/11/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Patient developed facial and foot edema following vaccination.	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	<30 mins	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:	Administered dex SP 0.5mg/kg SC, diphenhydramine 0.5mg/kg IM; discharged on Benadryl PO	

Animal Information

Case Identification:	Thor	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	English Bulldog	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Male	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> No	
Age (i.e., 2 yrs or 2 mos):	11 wks	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Previous vaccination (Galaxy 5-way) 4/19/09 by breeder, no problems reported. Presented 4/30/09 for facial edema and urticaria (responsive to dex and diphenhydramine); presumed allergic reaction, unknown cause. Otherwise healthy puppy.		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Cypress Veterinary Hospital 2037 Main Street	Address:	
City:	Oakley	City:	
State:	CA	State:	
Zip:	94561	Zip:	
*Phone:	925-625-5330(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	925-625-5330(XXX-XXX-XXXX)

*Today's Date:	05/13/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/13/2009

Verified:yes

Reviewed:yes

Date Entered: 08/05/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09269

Product Code: 13D1.29

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916393A	<input checked="" type="checkbox"/> Viral
2			<input checked="" type="checkbox"/> [Click arrow for selections]
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	05/13/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/13/2009
Concurrent Drugs or Procedures:	wellness exam and vaccinate

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Dr. Caid gave vaccine, Owner got home and dog started to vomit. Vomitted 4-5 times and gums were very pale. Owner brought back in, Dr. Caid gave it 0.12mls benadryl SQ. Dog has been monitored over the last 4 hours and is doing fine. No more vomiting.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	45 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Medium
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification: 2009-US-02758	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Lhasa/Bichon mix	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Female	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 14 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Valley Veterinary Hospital 3210 Main Avenue		Address: (b)(6)	
City: Fargo		City: (b)(6)	
State: ND		State: ND	
Zip: 58103		Zip: (b)(6)	
*Phone: 701-232-3391 (XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX: 701-293-6477			
E-mail: tech@valleyveterinary.net		E-mail: na	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	701-232-3391 (XXX-XXX-XXXX)

*Today's Date:	05/13/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	Vet Tech

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/13/2009

Verified:yes

Reviewed:yes

Date Entered: 08/05/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB website. [CVB Home Page](http://www.aphis.usda.gov/vs/cvb/ic/adverseeventreport.htm)

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09262

Product Code: 1905.23 13D1.29 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Rabvac 3 TF	112	873175A	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916353A	<input checked="" type="checkbox"/> Viral
3 Bronchi-Shield III	112	112432A	<input checked="" type="checkbox"/> Combination
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	25	05/05/2009
2 1 ml	SQ	L shoulder	25	05/05/2009
3 1 ml	Intranasal	Nose		05/05/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/05/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: swelling of the face developed	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	6 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	5316-1	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Daschund	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	4 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): normal dog			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Tates Creek Animal Hospital 4101 Tates Creek Centre Dr. Ste 146	Address:	
City:	Lexington	City:	
State:	KY	State:	
Zip:	40517	Zip:	
*Phone:	859-273-1933(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	859-273-1933(XXX-XXX-XXXX)
*Today's Date:	05/08/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Veterinarian
Other:

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/12/2009

Verified:yes

Reviewed:yes

Date Entered: 08/04/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09260

Product Code: 1905.24 13D1.29 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Defensor 1	189	S833963	<input checked="" type="checkbox"/> Viral
2 Duramune Max 5	112	916393A	<input checked="" type="checkbox"/> Viral
3 Intra-Trac 3	165A	54190B	<input checked="" type="checkbox"/> Combination
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RR		
2 1 ml	SQ	LR		
3	Intranasal	nares		
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/05/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Vaccinations given at wellness exam, approximately 2 hours later moderate to severe facial swelling, especially the right side of face. Sophie also seem more lethargic on the car ride back to the clinic.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	2 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Labrador Retriever		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Female		Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 1 yr 7 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Valley Veterinary Hospital 3212 Main Avenue		Address:	
City: Fargo		City:	
State: ND		State:	
Zip: 58103		Zip:	
*Phone: 701-232-3391 (XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	701-232-3391 (XXX-XXX-XXXX)
*Today's Date:	05/05/2009 (MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	vet tech

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/05/2009

Verified:yes

Reviewed:yes

Date Entered: 08/04/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09257

Product Code: 2668.00 2100.02 1905.23

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Vanguard L4	189	A833410A	<input checked="" type="checkbox"/> Bacterial
2 Bronchicine CAe	189	A831582	<input checked="" type="checkbox"/> Bacterial
3 Imrab 3 TF	298	18092A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L scapular area	22	05/01/2009
2 1 ml	SQ	LR	22	05/01/2009
3 1 ml	SQ	RR	22	05/01/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/01/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: @ & 1/2 hours after vaccinations given, Annie's muzzle & face swelled up. The owner opted to treat at home with 50mg of benadryl 1st & monitor & this seems to have done the trick	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	2.5 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Medium
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Annie Turner	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	10 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Stable history, has received all these vaccines before without incident. Did have allergic reactions in the past to previcox & to cephalixin (oral medications)			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Grayslake Animal Hospital 1490 East Belvidere Road	Address:	(b)(6)
City:	Grayslake	City:	(b)(6)
State:	IL	State:	IL
Zip:	60030	Zip:	(b)(6)
*Phone:	847-223-8612(XXX-XXX-XXXX)	Phone:	(b)(6) (XX-XXX-XXXX)
FAX:	847-223-8625		
E-mail:	djglah@aol.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	847-223-8612(XXX-XXX-XXXX)

*Today's Date:	05/01/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 05/01/2009

Verified:yes

Reviewed:yes

Date Entered: 07/29/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09250

Product Code: 1905.23 2126.R0 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18089B	<input checked="" type="checkbox"/> Viral
2 Recombitek Lyme	298	42141	<input checked="" type="checkbox"/> Recombinant
3 LeptoVax 4	112	045147A	<input checked="" type="checkbox"/> Bacterial
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	04/21/2009
2 1 ml	SQ	Between shoulders	22	04/21/2009
3 1 ml	SQ	L shoulder	22	04/21/2009
4				

Administered by: <input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY) 04/21/2009
Concurrent Drugs or Procedures: none

Event Information

* Event description: Some other event - Describe Below

Explain the event and any treatment in a concise paragraph:
 The pet owner called 4/29/09 to report that her dog began coughing 4/28/09. He had not been boarded or visited a dog park. He awakened every 2-3 hours at night coughing. He coughs so hard that he vomits. The owner declined a physical exam. Doxycycline and Tussigon were prescribed.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	7 days
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Other
Other:	too soon to determine

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)		Number in group: 1
(Other Species):		Number affected: 1
Breed: Labrador		Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male		Number dead: 0
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 2 yrs 11 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Truesdell Animal Care Hospital 4214 Milwaukee Street		Address: (b)(6)	
City: Madison		City: (b)(6)	
State: WI		State: WI	
Zip: 53714		Zip: (b)(6)	
*Phone: 608-244-2555(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	608-244-2555(XXX-XXX-XXXX)

*Today's Date: 04/29/2009(MM/DD/YYYY)	
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/29/2009

Verified: yes

Reviewed: yes

Date Entered: 07/29/2009

CVB Reporter:

Acknowledgement: yes

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09247

Product Code: 2668.05 2100.02

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045146A	<input checked="" type="checkbox"/> Bacterial
2 Bronchicine CAe	189	A836743C	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L hip	22	
2 1 ml	SQ	R hip	22	
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/25/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: About 90 minutes after vaccines were given, Sofia started shaking and felt hot to owner. Vomited in car en route back to the clinic. Temp on arrival was 102 F. Dr. Shardy treated with Diphenhydramine 0.2mL/Dexamethasone 0.2mL IM. Recommend owner give Children's Benedryl 1/2 tsp orally that evening.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	90 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Sofia	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Yorkshire Terrier	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos):	3.5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Suburban Animal Clinic 640 North Wilson Road	Address:	(b)(6)
City:	Columbus	City:	(b)(6)
State:	OH	State:	OH
Zip:	43204	Zip:	(b)(6)
*Phone:	614-276-5479(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	614-276-9989		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	614-276-5479(XXX-XXX-XXXX)

*Today's Date: 04/27/2009(MM/DD/YYYY)	
Relationship to animal:	<input checked="" type="checkbox"/> Other
Other:	RVT

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/27/2009

Verified: yes

Reviewed: yes

Date Entered: 07/27/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09246

Product Code: 13D1.29 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916411A	<input checked="" type="checkbox"/> Viral
2 LeptoVax 4	112	045151A	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	25	04/22/2009
2 1 ml	SQ	L shoulder	25	04/22/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/22/2009
Concurrent Drugs or Procedures:	Venipuncture for HWT and Anal Gland Expression

Event Information

* Event description: Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
 Duramune and Leptospirosis were given SQ in different sites. Within 10 minutes she began having marked Gastrointestinal tract signs (vomiting and defecating). She collapsed and her gums were very pale. We placed an IV

Catheter and started her on IV fluids. Dexamethasone Sodium Phosphate 1.8mg was given IV followed by diphenhydramine 25mg given IV. During IV administration of the diphenhydramine the dog started seizing and vocalizing, so diazepam was administered in 2.5mg alloquotes for a total of 12.5mg over the next 45 minutes. Within 15 minutes her color and strength improved dramatically. IV fluids were run for several more hours (total 500mls). At this point the dog was discharged to the owner. She was still a little anxious but her vital signs were stable. By mid-afternoon of the following day she was normal.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	10 mins
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	None Given	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Mini Schauzner	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Female	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	Approx 4 yrs	

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
 Owner acquired this dog in the week preceding the event. She was a puppy mill rescue dog. Previous vaccination history is not available.

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	All Paws Animal Hospital 5225 Excelsior Blvd	Address:	(b)(6)
City:	St. Louis Park	City:	(b)(6)
State:	MN	State:	MN
Zip:	55416	Zip:	(b)(6)
*Phone:	952-848-0913(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)
FAX:	952-848-0986		
E-mail:	(b)(6)@allpawsvets.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	952-848-0913(XXX-XXX-XXXX)
*Today's Date:	04/27/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit!

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/27/2009

Verified:yes

Reviewed:yes

Date Entered: 07/27/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09245

Product Code: 2668.05

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LeptoVax 4	112	045146A	<input checked="" type="checkbox"/> Bacterial
2			<input checked="" type="checkbox"/> [Click arrow for selections]
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 vial	SQ	L lateral thigh	22	04/27/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/27/2009
Concurrent Drugs or Procedures:	n/a

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: 1mg/kg Benadryl & 2mg/kg Dex SP IV
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 hr
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	Melanie Wilson	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Mini Dachshund	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	2 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name	(b)(6)
Address:	Companion Animal Hospital 2930 Tazewell Pike	Address	(b)(6)
City:	Knoxville	City	(b)(6)
State:	TN	State:	TN
Zip:	37918	Zip	(b)(6)
*Phone:	865-689-2719(XXX-XXX-XXXX)	Phone	(b)(6) XXX-XXX-XXXX
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	865-689-2719(XXX-XXX-XXXX)
*Today's Date:	04/27/2009(MM/DD/YYYY)
Relationship to animal:	

	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/27/2009

Verified:yes

Reviewed:yes

Date Entered: 07/27/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB website. <http://www.aphis.usda.gov/vs/cvb/ic/adverseeventreport.htm>>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09242
 Product Code: 13D1.29 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916361A	<input checked="" type="checkbox"/> Viral
2 LCI-GP	112	350251A	<input checked="" type="checkbox"/> Bacterial
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder		
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/31/2009
Concurrent Drugs or Procedures:	received two other vaccines in two other locations

Event Information

* Event description:	<input checked="" type="checkbox"/> Local
Explain the event and any treatment in a concise paragraph: 3 cm lump at vaccine site	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?) (Include Units:mins, hrs, days, wks, mos, yrs)	about 3 wks
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Did not recover
Other:	Lump is still there

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Yellow Lab	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Female	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos): 3 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Bath Animal Hospital 15 Congress Avenue		Address:	
City: Bath		City:	
State: ME		State:	
Zip: 04530		Zip:	
*Phone: 207-443-9006(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	207-443-9006(XXX-XXX-XXXX)
*Today's Date:	04/24/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/24/2009

Verified:yes

Reviewed:yes

Date Entered: 07/27/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09235
 Product Code: 1905.23 2668.05

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18088A	<input checked="" type="checkbox"/> Viral
2 Duramune LCI-GP	112	916330A/350247A	<input checked="" type="checkbox"/> Viral
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R hip	23	04/20/2009
2 1 ml	SQ	R shoulder	23	04/20/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/20/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: lethargic, itchy and swollen eyes	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 hr
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	9581	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Bichon Mix	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	18 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	
Address:	Animal Medical Clinic 234 Snelling Avenue South	Address:	
City:	St. Paul	City:	
State:	MN	State:	
Zip:	55105	Zip:	
*Phone:	651-690-1564(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	651-698-9595		
E-mail:	amc234@goldengate.net	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	651-690-1564(XXX-XXX-XXXX)
*Today's Date:	04/21/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other:CVT

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/21/2009

Verified:yes

Reviewed:yes

Date Entered: 06/19/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09231

Product Code: 13D1.29 1905.24

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916328A	<input checked="" type="checkbox"/> Viral
2 Diluent for Duramune	112	090830A	<input checked="" type="checkbox"/> Other
3 Imrab 1 TF	298	22018A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder		
2 1 ml	SQ	R shoulder		
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/14/2009
Concurrent Drugs or Procedures:	no

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: At ER: reoccurring facial edema, hives, paratis, lethergy. Tx: IV dexamethazone, 1mg, 25 mg difin, 150 ml lactoringers - NEXT day at clinic treated again, resolved after three days.	

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	4-6 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment
Other:	

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):	Number affected: 1
Breed: Chihuahua-Doxin mix	Number vaccinated: 1
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0
Neutered: <input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos): 2 yrs	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): treatment - 2.4 mg dexamethazone, IV - oral benadryl, prednisalone	

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Heartlend Animal Hospital 1051 West Stearns Road		Address:	
City: Bartlett		City:	
State: IL		State:	
Zip: 60310		Zip:	
*Phone: 630-372-2000(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	630-372-2000(XXX-XXX-XXXX)
*Today's Date:	04/20/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/20/2009

Verified:yes

Reviewed:yes

Date Entered: 06/19/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09228
 Product Code: 1905.23 1331.20

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18086A	<input checked="" type="checkbox"/> Viral
2 Duramune Adult 3	112	1867110A	<input checked="" type="checkbox"/> Viral
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RH leg	25	11/01/2009
2 1 ml	SQ	FR leg	25	01/30/2009
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	01/30/2009
Concurrent Drugs or Procedures:	No

Event Information

* Event description: <input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph:
If this adverse event involves a possible lack of efficacy with a rabies product please

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1 hr	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:	Merial 09-23525/FortDodge 2009-US-02077	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed:	Italian Greyhound	Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> Yes		
Age (i.e., 2 yrs or 2 mos):	4 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Patient returned in about 1 hr with Swollen face, erythema & urticaria. treated With Benadryl & Dexamethasone SP IV. P Monitored for several hours then went home with Rx for Benadryl. O didn't give any and P came back 1.5 hrs later with worsened symptoms and was sent to the ER hosp. for ON monitoring and IV fluids.			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Frontier Veterinary Hospital 4500 NE Cornell Road	Address:	(b)(6)
City:	Hillsboro	City:	(b)(6)
State:	OR	State:	OR
Zip:	97124	Zip:	(b)(6)
*Phone:	503-648-1643(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	503-648-2003		
E-mail:	clientservices@frontiervet.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number:	503-648-1643(XXX-XXX-XXXX)

*Today's Date:	04/18/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/18/2009

Verified:yes

Reviewed:yes

Date Entered: 06/19/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09227

Product Code: 1905.23 14M1.20 1331.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Imrab 3 TF	298	18090A	<input checked="" type="checkbox"/> Viral
2 Recombitek KC2	124	104585	<input checked="" type="checkbox"/> Viral
3 Duramune Adult 3	112	1867111A	<input checked="" type="checkbox"/> Viral
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RH leg	25	11/01/2009
2 1 ml	Intranasal	Nose	n/a	04/13/2009
3 1 ml	SQ	FR leg	25	04/13/2009
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/13/2009
Concurrent Drugs or Procedures:	No

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Swollen face after Vaccination	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	2 to 4 hrs	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:	Merial=09-23517 / FD 2009-US-02071	For animals handled in a group (herd, litter, etc.)	
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :		Number vaccinated:	1
Sex:	<input checked="" type="checkbox"/> Female	Number dead:	0
Neutered:	<input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos):	1 yr 6 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Vaccination			

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Frontier Veterinary Hospital 4500 NE Cornell Road	Address:	(b)(6)
City:	Hillsboro	City:	(b)(6)
State:	OR	State:	OR
Zip:	97124	Zip:	(b)(6)
*Phone:	503-648-1643(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX
FAX:	503-648-2003		
E-mail:	clientservices@frontiervet.com	E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	503-648-1643(XXX-XXX-XXXX)
*Today's Date:	04/17/2009(MM/DD/YYYY)

Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/17/2009

Verified:yes

Reviewed:yes

Date Entered: 06/19/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09220

Product Code: 13D1.20

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Galaxy DA2PPvL	165A	212362B	<input checked="" type="checkbox"/> Combination
2			<input checked="" type="checkbox"/> [Click arrow for selections]
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	injection	back	18	04/08/2009
2				
3				
4				

Administered by:	<input checked="" type="checkbox"/> Non-veterinarian
*Date of Product Use:(MM/DD/YYYY)	04/08/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: hives in 3 of 9 puppies	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	1st in 2 hrs, 2nd in 2 days, 3rd in 4 days	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Not Listed	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 9	
(Other Species):	Number affected: 3 so far	
Breed: American Bulldog	Number vaccinated: 9	
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> No		
Age (i.e., 2 yrs or 2 mos): 13 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): 1st set of shots, house dogs, born in my home from female I own, no health problems, eat dry kibble same brand as always		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name: (b)(6)	
Address: Canal Road Animal Hospital 22640 Canal Road		Address: (b)(6)	
City: Orange Beach		City: (b)(6)	
State: AL		State: AL	
Zip: 36561		Zip: (b)(6)	
*Phone: 251-968-7387(XXX-XXX-XXXX)		Phone: (b)(6) XXX-XXX-XXXX	
FAX:			
E-mail:		E-mail: (b)(6)@yahoo.com	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	(b)(6)
*Submitter's Phone Number	(b)(6) XXX-XXX-XXXX
*Today's Date:	04/13/2009(MM/DD/YYYY)
Relationship to animal:	

<input type="checkbox"/> Owner
Other:

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/13/2009

Verified:yes

Reviewed:yes

Date Entered: 06/15/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website.<p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09218

Product Code: 2668.05 2126.R0 1905.23 14M1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 LCI-GP	112	350249A	<input checked="" type="checkbox"/> Bacterial
2 Recombitek Lyme	298	42143	<input checked="" type="checkbox"/> Recombinant
3 Imrab 3 TF	298	18088B	<input checked="" type="checkbox"/> Viral
4 Naramune-2	124	567	<input checked="" type="checkbox"/> Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder		
2 1 ml	SQ	LR leg		
3 1 ml	SQ	RR leg		
4 1 ml	IN	Intranasal		

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/21/2009
Concurrent Drugs or Procedures:	Benazepril

Event Information

* Event description: Some other event - Describe Below

Explain the event and any treatment in a concise paragraph:
 Beginning about 24 hours.

spt: see faxed history...this dog has been having a history of seizures for the past 2 years and vaccination appears to

have aggravate the problem.

If this adverse event involves a possible lack of efficacy with a rabies product please contact the Center for Disease Control (CDC) at (404) 639-1050.	
Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	24 hrs
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> High
*Outcome (select one):	<input checked="" type="checkbox"/> Other
Other:	partial recovery

Animal Information

Case Identification:	Kelsey Holsclaw	For animals handled in a group (herd, litter, etc.)
*Species:	<input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1
(Other Species):		Number affected: 1
Breed:	Golden Retriever	Number vaccinated: 1
Sex:	<input checked="" type="checkbox"/> Female	Number dead: 0
Neutered:	<input checked="" type="checkbox"/> Yes	
Age (i.e., 2 yrs or 2 mos):	4 yrs	
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name	(b)(6)
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address	(b)(6)
City:	Winchester	City	(b)(6)
State:	VA	State:	WV
Zip:	22602	Zip	(b)(6)
*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone	(b)(6) (XXX-XXX-XXXX)
FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
	540-678-0202(XXX-XXX-XXXX)

*Submitter's Phone Number:	
*Today's Date:	04/10/2009(MM/DD/YYYY)
Relationship to animal:	<input checked="" type="checkbox"/> Veterinarian
Other:	

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/10/2009

Verified:yes

Reviewed:yes

Date Entered: 06/15/2009

CVB Reporter:

Acknowledgement:

This confirms that your Adverse Event Report has been received by the Center for Veterinary Biologics (CVB). Thank you for submitting this information in your Adverse Event Report. It is information such as this that enables the CVB to monitor the performance of veterinary biologics used in field conditions. If you have additional questions regarding Adverse Event Reporting for veterinary biological products, please visit the CVB. website. <p>CVB Home Page

Adverse Event Report

Pharmacovigilance
 United States Department of Agriculture
 Center for Veterinary Biologics
 510 South 17th Street, Suite 104
 Ames, IA 50010
 Phone: (515) 232-5785
 FAX: (515) 232-7120

Record Number: AIV09216

Product Code: 13D1.29 12X1.20

*** Required Fields**

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916393A	<input checked="" type="checkbox"/> Viral
2 Intra-Trac III	165A	54186B	<input checked="" type="checkbox"/> Combination
3			<input checked="" type="checkbox"/> [Click arrow for selections]
4			<input checked="" type="checkbox"/> [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			
2	IN			
3				
4				

Administered by:	<input checked="" type="checkbox"/> Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/23/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	<input checked="" type="checkbox"/> Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Twenty minutes after vaccines, Rio vomited once. About 5 minutes later he vomited 3 times.	
If this adverse event involves a possible lack of efficacy with a rabies product please	

contact the Center for Disease Control (CDC) at (404) 639-1050.

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	20 mins	
Attending veterinarian's level of suspicion that product caused event:	<input checked="" type="checkbox"/> Not Listed	
*Outcome (select one):	<input checked="" type="checkbox"/> Recovered with treatment	
Other:		

Animal Information

Case Identification:	For animals handled in a group (herd, litter, etc.)	
*Species: <input checked="" type="checkbox"/> Canine (Dog)	Number in group: 1	
(Other Species):	Number affected: 1	
Breed: Labrador Retriever	Number vaccinated: 1	
Sex: <input checked="" type="checkbox"/> Male	Number dead: 0	
Neutered: <input checked="" type="checkbox"/> Not Listed		
Age (i.e., 2 yrs or 2 mos): 12 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):		

Personal Information

Veterinarian		Owner	
*Name: (b)(6)		Name:	
Address: Valley Veterinary Hospital 3210 Main Street		Address:	
City: Fargo		City:	
State: ND		State:	
Zip: 58103		Zip:	
*Phone: 701-232-3391(XXX-XXX-XXXX)		Phone: (XXX-XXX-XXXX)	
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	<input checked="" type="checkbox"/> Not Listed
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	(b)(6)
*Submitter's Phone Number:	701-232-3391(XXX-XXX-XXXX)
*Today's Date:	04/08/2009(MM/DD/YYYY)
Relationship to animal:	

<input checked="" type="checkbox"/> Other
Other: Vet Tech

Submit

Contact Scott Taylor if you have any questions regarding adverse events.

Date Received: 04/08/2009

Verified: yes

Reviewed: yes

Date Entered: 06/15/2009

CVB Reporter:

Acknowledgement:

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