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: AIV11228
Product Code: 2126.R0 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 Recombitek Lyme	298	42157A	☒ Recombinant
2 Imrab 3 TF	298	18127A	☒ Viral
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	Intrascapular	25	12/16/2010
2 1 ml	SQ	Intrascapular	25	12/16/2010
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	12/16/2010
Concurrent Drugs or Procedures:	Two vaccines together

Event Information

* Event description:	☒ Systemic
Explain the event and any treatment in a concise paragraph: 18 hours after vaccination, dog experienced myalgia, mild fever, and reluctance to move.	
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)	18 hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Wheaton Terrier	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	5 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	Tom Jatnieks	Name	(b)(6)
Address:	Weston Veterinary Hospital 6303 Schofield Avenue	Address	
City:	Weston	City	
State:	WI	State	
Zip:	54476	Zip	
*Phone:	715-359-4004(XXX-XXX-XXXX)	Phone	(b)(6) (XXX-XXX-XXXX)

FAX:	715-359-4022		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Tom
*Submitter's Last Name:	Jatnieks
*Submitter's Phone Number:	715-359-4004(XXX-XXX-XXXX)
*Today's Date:	01/20/2011(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 01/20/2011
Verified:yes
Reviewed:yes
Date Entered: 02/18/2011
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

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United States Department of Agriculture
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510 South 17th Street, Suite 104
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Phone: (515) 232-5785
FAX: (515) 232-7120

Record Number: AIV11161
Product Code: 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 Recombitek Lyme	298	42162A	☒ Recombinant
2			☒ [Click arrow for selections]
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L front	22	11/01/2010
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	11/08/2010
Concurrent Drugs or Procedures:	Intervet/SP Bordetella Vaccine

Event Information

* Event description:	☒ Systemic
Explain the event and any treatment in a concise paragraph: Approximately 8 hrs after being vaccinated, Otis was extremely lethargic, it was hard to rouse him, he had an elevated temp (102.3F) and was sore at the injection site. All but the soreness was resolved by 11/09/2010.	
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 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Recovered without treatment
Other:	

Animal Information

Case Identification:	10-116262	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pitbull Terrier	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	6 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): indoor dog, up to date on vaccines, on hwp/flea, never been vaccinated for Lyme before			

Personal Information

Veterinarian		Owner	
*Name:	Andrea Ballou	Name	
Address:	VCA Healthy Paws Medical Center 14840 Washington Street	Address	(b)(6)
City:	Haymarket	City	
State:	VA	State	
Zip:	20169	Zip	

*Phone:	703-754-4146(XXX-XXX-XXXX)	Phone:	(b)(6) (XXX-XXX-XXXX)
FAX:	703-754-1843		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	703-754-4146(XXX-XXX-XXXX)
*Today's Date:	11/09/2010(MM/DD/YYYY)
Relationship to animal:	☒ Owner
Other:	

Submit

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

Date Received: 11/09/2010
Verified:yes
Reviewed:yes
Date Entered: 02/18/2011
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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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: AIV11104

Product Code: 13D1.R1 1905.23 2126.R0 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 Recombitek C4	298	45289	☒ Recombinant
2 Imrab 3 TF	298	18123B	☒ Viral
3 Recombitek Lyme	298	42160	☒ Recombinant
4 Intra-Trac II	165A	53671A	☒ Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RF	25	10/05/2010
2 1 ml	SQ	RH	25	10/05/2010
3 1 ml	SQ	LH	25	10/05/2010
4 1 ml	SQ		25	10/05/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	10/05/2010
Concurrent Drugs or Procedures:	Phlebotomy

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Fever 104.4 Lethargy Anorexia, SQ swelling right front at site of vaccination. Painful to touch, toe touching lameness, muzzle swelling, Tx Dex Sp 8mg SQ, Rx Pred 7.5 mg BIDx3d, 5 mg BID x3 d	
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:	☒ Not Listed
*Outcome (select one):	☒ Other
Other:	Not Listed

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	15 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Healthy pet presented for annual vaccine boosters			

Personal Information

Veterinarian		Owner	
*Name:	Julie Cieplik	Name:	(b)(6)
Address:	Clinton Veterinary Hospital 93 Old Post Road	Address:	
City:	Clinton	City:	
State:	CT	State:	
Zip:	06413	Zip:	

*Phone:	860-669-5721(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)
FAX:	860-669-5824		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	Julie
*Submitter's Last Name:	Cieplik
*Submitter's Phone Number:	860-669-5721(XXX-XXX-XXXX)
*Today's Date:	10/06/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 10/08/2010
Verified:yes
Reviewed:yes
Date Entered: 02/15/2011
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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United States Department of Agriculture
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510 South 17th Street, Suite 104
Ames, IA 50010
Phone: (515) 232-5785
FAX: (515) 232-7120

Record Number: AIV11025
Product Code: 2126.R0 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 Recombitek Lyme	298	42151B	☒ Recombinant
2 Galaxy DA2PPv	165A	04009009A	☒ Viral
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LH leg	25	11/01/2010
2 1 ml	SQ	RF leg	25	07/12/2010
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/12/2010
Concurrent Drugs or Procedures:	pyrantel pamoate

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Developed angioedema approximately 1 hour post vaccine	
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 60 mins
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Belgian Malinois	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	9 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Had DHPLPCV at 6 weeks Fort Dodge with no reaction reported			

Personal Information

Veterinarian		Owner	
*Name:	Theresa Ford	Name:	
Address:	Bay Animal Hospital 3891 S Dupont Parkway	Address:	
City:	Townsend	City:	(b)(6)
State:	DE	State:	
Zip:	19734	Zip:	
*Phone:	302-279-1082(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)

FAX:	302-279-1086		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	Theresa
*Submitter's Last Name:	Ford
*Submitter's Phone Number:	302-279-1082(XXX-XXX-XXXX)
*Today's Date:	07/12/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/12/2010
Verified:yes
Reviewed:yes
Date Entered: 02/15/2011
CVB Reporter:
Acknowledgement:

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

Record Number: AIV11024

Product Code: 2668.05 2126.R0 15K5.20 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 Lepto Vax 4	112	045158B	☒ Bacterial
2 Recombitek Lyme	298	42148	☒ Recombinant
3 Nobivac Flu H3N8	165A	219113	☒ Viral
4 Recombitek KC2	124	DB593259	☒ Viral

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LR leg	25	07/02/2010
2 1 ml	SQ	LF leg	25	07/02/2010
3 1 ml	SQ	LF leg	25	07/02/2010
4 1 ml	IN	nostril	none	07/02/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/02/2010
Concurrent Drugs or Procedures:	Benedryl

Event Information

* Event description:	☒ Local
Explain the event and any treatment in a concise paragraph: The SQ injection on theLR leg swelled up to the size of a golf ball. The dog was given dexamethasone SP and the inflammation came down within 3 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)	mins
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Rottie/labrador retriver	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	3 yrs 6 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): vaccination			

Personal Information

Veterinarian		Owner	
*Name:	Amy Holford	Name:	
Address:	Univ of TN College of Vet Med 2407 River Dr.	Address:	
City:	Knoxville	City:	
State:	TN	State:	
Zip:	37996	Zip:	

*Phone:	865-974-8387(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	865-974-8387(XXX-XXX-XXXX)
*Today's Date:	07/06/2010(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	Veterinary Student

Submit

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

Date Received: 07/06/2010
Verified:yes
Reviewed:yes
Date Entered: 02/15/2011
CVB Reporter:
Acknowledgement:

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Adverse Event Report

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

Record Number: AIV10462

Product Code: 12X1.20 2126.R0 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	112484C	☒ Combination
2 Recombitek Lyme	298	42155A	☒ Recombinant
3 Imrab 3 TF	298	18111C	☒ Viral
4 Duramune Max 5	112	916538A	☒ Viral

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	Nares	Nose		07/06/2010
2 1 ml	SQ	L hip	22	07/06/2010
3 1 ml	SQ	R hip	22	07/06/2010
4 1 ml	SQ	L shoulder	22	07/06/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/06/2010
Concurrent Drugs or Procedures:	LCI-GP - 350265A - Code 2668.05

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: after 7 hrs of getting vaccines, dogs face swelled. Note: 4th product is combination product.	
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 hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.):			

Personal Information

Veterinarian		Owner	
*Name:	Patti Klein Manke	Name:	(b)(6)
Address:	Woodstock Veterinary Clinic 691 Lake Avenue	Address:	
City:	Woodstock	City:	
State:	IL	State:	

Zip:	60098	Zip:	(b)(6)
*Phone:	815-338-0132(XXX-XXX-XXXX)	Phone:	XXX-XXX-XXXX)
FAX:	815-338-9981		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	Patti
*Submitter's Last Name:	Klein Manke
*Submitter's Phone Number:	815-338-0132(XXX-XXX-XXXX)
*Today's Date:	07/07/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/08/2010
Verified:yes
Reviewed:yes
Date Entered: 09/30/2010
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

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

Record Number: AIV10458

Product Code: 13D1.29 2668.05 2126.R0 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	916520A	☒ Viral
2 LCI-GP	112	350265A	☒ Bacterial
3 Recombitek Lyme	298	42155A	☒ Recombinant
4 Naramune-2	124	104-607	☒ Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			05/17/2010
2 1 ml	SQ			05/17/2010
3 1 ml	SQ			
4 1 ml	Intranasal			

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/17/2010
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Some other event - Describe Below

Explain the event and any treatment in a concise paragraph:
Patient presented with facial swelling at home. Owner treaated with oral benadryl 25mg 1/2 tablet. Owner then brought pet in to the hospital when she recieved 1.75 ML Dexamethasone. Owner was instructed to observe at home and continue treatment with benadryl every 4 to 6 hours until swelling was gone.

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)	1-2 hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pug	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	1 yrs 6 mos		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):

Personal Information

Veterinarian		Owner	
*Name:	Marietta Walls	Name:	
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	
City:	Winchester	City:	
State:	VA	State:	

Zip:	22602	Zip:	
*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	07/02/2010(MM/DD/YYYY)
Relationship to animal:	☒ Not Listed
Other:	

Submit

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

Date Received: 07/02/2010
Verified:yes
Reviewed:yes
Date Entered: 09/30/2010
CVB Reporter:
Acknowledgement:

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United States Department of Agriculture
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510 South 17th Street, Suite 104
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Phone: (515) 232-5785
FAX: (515) 232-7120

Record Number: AIV10457

Product Code: 13D1.29 2668.05 2126.R0 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	916549A	☒ Viral
2 LCI-GP	112	350267A	☒ Bacterial
3 Recombitek Lyme	298	42155A	☒ Recombinant
4 Naramune-2	124	104-616	☒ Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			06/24/2010
2 1 ml	SQ			06/24/2010
3 1 ml	SQ			
4 1 ml	Intranasal		none	06/24/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/24/2010
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
Patient vomited before leaving appt. Dr. treated with inj. benadryl SQ as precaution. Latter that evening patient continued with vomiting and lethergy and was seen at their local emergency vet. They treated with Anzemet .8mg/kg and observaation.

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)	10-15 mins
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Shih-poo	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
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:	Holly Nightingale	Name:	
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	
City:	Winchester	City:	
State:	VA	State:	

Zip:	22602	Zip:	
*Phone:	540-647-0202(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	07/02/2010(MM/DD/YYYY)
Relationship to animal:	☒ Not Listed
Other:	

Submit

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

Date Received: 07/02/2010
Verified:yes
Reviewed:yes
Date Entered: 09/30/2010
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: AIV10456

Product Code: 13D1.29 1905.23 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 Duramune Max 5	112	916530A	☒ Viral
2 Imrab 3 TF	298	18103A	☒ Viral
3 Recombitek Lyme	298	42155A	☒ Recombinant
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			05/07/2010
2 1 ml	SQ			
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/07/2010
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: A couple hours after the patient recieved the vaccines he presented with swelling around the lips and eyes and shaking his head with a slightly elevated temp. Dr. treated with Benadryl IM .04 ML and observation	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Shih Tzu	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	6 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	Kim Arthur	Name:	
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	
City:	Winchester	City:	
State:	VA	State:	
Zip:	22602	Zip:	

*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	07/02/2010(MM/DD/YYYY)
Relationship to animal:	☒ Not Listed
Other:	

Submit

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

Date Received: 07/02/2010
Verified:yes
Reviewed:yes
Date Entered: 09/30/2010
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: AIV10442
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 LCI-GP	112	350267A	☒ Bacterial
2 Recombitek Lyme	298	42146	☒ Recombinant
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	23	06/19/2010
2 1 ml	SQ	L hip	23	06/19/2010
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/19/2010
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: normal exam, BAR, MM=pink, erythema with mild swelling noted periobitally bilaterally. gave benadryl inj (50 mg/ml) 2 cc IV along with Dex sp (4mg/ml) 1.5 cc IV, monitered for 20 minutes, swelling decreased. no resp. distress.	
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 mins
Attending veterinarian's level of suspicion that product caused event:	☒ Not Listed
*Outcome (select one):	☒ Other
Other:	not listed

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
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.): no previous reactions, on IAms all natural, indoor/outdoor, interceptor/frontline			

Personal Information

Veterinarian		Owner	
*Name:	Megan Hoelter	Name:	
Address:	Jefferson Animal Hospital & Emergency Ctr. 4504 Outer Loop	Address:	
City:	Louisville	City:	(b)(6)
State:	KY	State:	
Zip:	40219	Zip:	

*Phone:	502-966-4104(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)
FAX:	502-966-3904		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	502-966-4104(XXX-XXX-XXXX)
*Today's Date:	06/20/2010(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	vet tech

Submit

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

Date Received: 06/20/2010
Verified:yes
Reviewed:yes
Date Entered: 09/30/2010
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: AIV10385

Product Code: 13D1.29 2668.05 1905.23 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 Duramune Max 5	112	916478A	☒ Viral
2 LCI-GP	112	350263A	☒ Bacterial
3 Imrab 3 TF	298	18104B	☒ Viral
4 Recombitek Lyme	298	42153B	☒ Recombinant

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L dorsal shoulder	22	03/04/2010
2 1 ml	SQ	L dorsal shoulder	22	03/04/2010
3 1 ml	SQ	R dorsal shoulder	22	11/01/2010
4 1 ml	SQ	middle cranial dorsum	22	11/01/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/04/2010
Concurrent Drugs or Procedures:	Drontal Plus orally

Event Information

* Event description: ☒ Some other event - Describe Below Explain the event and any treatment in a concise paragraph: hypertrophic osteodytrophy	
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 days
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Great Dane	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.):			

Personal Information

Veterinarian		Owner	
*Name:	Suzanne M. Gerber	Name:	
Address:	Southwick Animal Hospital 498 College Highway	Address:	
City:	Southwick	City:	
State:	MA	State:	
Zip:	01077	Zip:	
*Phone:	413-569-3866(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)

FAX:	413-569-0791		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Suzanne
*Submitter's Last Name:	Gerber
*Submitter's Phone Number:	413-569-3866(XXX-XXX-XXXX)
*Today's Date:	04/30/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 04/30/2010
Verified:yes
Reviewed:yes
Date Entered: 09/23/2010
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: AIV10332

Product Code: 14M1.20 13D1.29 1905.23 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 Naramune-2	124	104-607	☒ Combination
2 Duramune Max 5	112	916499A	☒ Viral
3 Imrab 3 TF	298	18103A	☒ Viral
4 Recombitek Lyme	298	42151A	☒ Recombinant

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	Intranasal	Nose	none	03/25/2010
2 1 ml	SQ	Between shoulders	24	03/25/2010
3 1 ml	SQ	Between shoulders	24	03/25/2010
4 1 ml	SQ	Between shoulders	24	03/25/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/25/2010
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: patient had facial swelling and vomiting treated with benadryl	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	German Shorthair Pointer	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	1.5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): no history of vaccine reactions			

Personal Information

Veterinarian		Owner	
*Name:	Marietta Walls	Name:	(b)(6)
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	
City:	Winchester	City:	
State:	VA	State:	
Zip:	22602	Zip:	
*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):	☒ Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	03/25/2010(MM/DD/YYYY)
Relationship to animal:	☒ Not Listed
Other:	Assistant

Submit

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

Date Received: 03/26/2010
Verified:yes
Reviewed:yes
Date Entered: 09/08/2010
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: AIV10253
Product Code: 2126.R0 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 Recombitek Lyme	298	42151A	☒ Recombinant
2 Imrab 3 TF	298	18100A	☒ Viral
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1				
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	01/12/2010
Concurrent Drugs or Procedures:	none

Event Information

* Event description: ☒ Autoimmune	
Explain the event and any treatment in a concise paragraph: Dog's autoimmune system became hyperactive, causing fever, anerexia, lethargy, muscle pain, elevated white blood cell count, distal renal tubular acidosis. Condition required one week of hospitalization - two days at Veterinary Emergency & Specialty Center of New England in Waltham, Massachusetts, and five days at Tufts Cummings School of Veterinary Medicine in Grafton, Massachusetts - during which intensive supportive care was provided. Multiple tests were performed which ruled out disease, infection and other conditions. Therefore, suspicion is high that illness event was related to vaccines. The event has been reported to the manufacturer - Merial - and the case number is 10-4918.	
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 days 3 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Other
Other:	Dog is home and still recovering. She is weak and suffering from effects of distal renal tubular acidosis

Animal Information

Case Identification:		**For animals handled in a group (herd, litter, etc.)**	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	English Setter	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	5 yrs 2 wks		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
Got dog on July 17, 2009 from Grouse Ridge Kennels in Oxford, New York. Dog has no history of illness with the exception of a mild case of Lyme disease diagnosed on November 11, 2009, which she quickly recovered from with anitbiotic treatment. Has had rabies, parvo and distemper shots in past without adverse effects. January 12, 2010, was the first time she has had a Lyme vaccine.

Personal Information

Veterinarian		Owner		
*Name:	Daria Smith	Name:		
Address:	Lexington Veterinary Associates 511 Waltham Street	Address:		
City:	Lexington	City:	(b)(6)	
State:	MA	State:		
Zip:	02421	Zip:		
*Phone:	781-862-1127(XXX-XXX-XXXX)	Phone:		XX-XXXX)
FAX:	781-862-9012			
E-mail:		E-mail:	(b)(6)	com

This event has been reported to the manufacturer(s):	☒ Yes	
*Submitter's First Name	(b)(6)	
*Submitter's Last Name		
*Submitter's Phone Number		XX-XXX-XXXX)
*Today's Date:	01/25/2010(MM/DD/YYYY)	
Relationship to animal:	☒ Owner	
Other:		

Submit

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

Date Received: 01/26/2010
Verified:yes
Reviewed:yes
Date Entered: 06/09/2010
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: AIV10131
Product Code: 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 Recombitek Lyme	298	42148	☒ Recombinant
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LH leg	25	09/10/2009
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/10/2009
Concurrent Drugs or Procedures:	see form

Event Information

* Event description: ☒ Local	
Explain the event and any treatment in a concise paragraph: owner noted in am 9/11/09 not weight bearing in right hind and on exam noted high normal temp, swelling in right hock and 4/4 lame in RH. sedated - no boney changes noted, arthrocentesis gave large vol of turbid yellow fluid. culture - negative, cytology - consistent with acute (sterile) arthritis. treated with rimadyl and added doxycycline. was previously positive for lyme antibody on idexx snap test. spt: note injection site is listed as LH leg, not RH 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)	approx. 18 hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Golden Retriever	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	5 yrs 5 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): well kept pet dog. vaccinated yearly. history of otitis externa & pyoderma. Treat symptomatically no major medical issues.			

Personal Information

Veterinarian		Owner	
*Name:	Kathryn Stoltzfus	Name:	(b)(6)
Address:	Talleyville Veterinary Hospital	Address:	

	3001 Concord Pike		
City:	Wilmington	City:	
State:	DE	State:	
Zip:	19803	Zip:	(b)(6)
*Phone:	302-478-0648(XXX-XXX-XXXX)	Phone:	XX-XXX-XXXX)
FAX:	302-478-7868		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Kathryn
*Submitter's Last Name:	Stoltzfus
*Submitter's Phone Number:	302-478-0648(XXX-XXX-XXXX)
*Today's Date:	10/27/2009(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 10/28/2009
Verified:yes
Reviewed:yes
Date Entered: 02/11/2010
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: AIV10101
Product Code: 2126.R0 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 Recombitek Lyme	298	42149	☒ Recombinant
2 Duramune Max 5	112	916467A	☒ Viral
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	24	09/30/2009
2 1 ml	SQ	R shoulder	24	09/30/2009
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/30/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Facial Swelling and itching an hour after 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)	1 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Lab Retrevier	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.):			

Personal Information

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

FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	10/01/2009(MM/DD/YYYY)
Relationship to animal:	☒ Not Listed
Other:	

Submit

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

Date Received: 10/01/2009
Verified:yes
Reviewed:yes
Date Entered: 01/19/2010
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: AIV10093
Product Code: 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 Recombitek Lyme	298	42147	☒ Recombinant
2			☒ [Click arrow for selections]
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LH leg	22	09/22/2009
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/22/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: lethargy, vomiting, inappetance within 3 hours of vaccination. Presented to hospital 4 hours later and was active, febrile	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	Cookie Johnson	**For animals handled in a group (herd, litter, etc.)**	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Shih Tzu x Bichon	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	1.5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Had lyme vaccination last year and did not have an adverse reaction.			

Personal Information

Veterinarian		Owner	
*Name:	Patricia Ware	Name	(b)(6)
Address:	Chesapeake Veterinary Hospital 102 Country Day Road	Address:	
City:	Chester	City:	
State:	MD	State:	
Zip:	21619-2631	Zip:	

*Phone:	410-643-3101(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	Patricia
*Submitter's Last Name:	Ware
*Submitter's Phone Number:	410-643-3101(XXX-XXX-XXXX)
*Today's Date:	09/23/2009(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 09/23/2009
Verified:yes
Reviewed:yes
Date Entered: 01/19/2010
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: AIV10078
Product Code: 1331.R1 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 Recombitek C3	298	47012	☒ Recombinant
2 Recombitek Lyme	298	42148	☒ Recombinant
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	shoulder region	23	09/11/2009
2 1 ml	SQ	shoulder region	23	09/11/2009
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/11/2009
Concurrent Drugs or Procedures:	topical ear medication

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
Puppy presented for evaluation of an ear infection and vaccine boosters. Vaccines were administered and client left with patient. Client returned to clinic within a half hour. Puppy had significant facial swelling and generalized hives. Treatment consisted of IM injections of Diphenhydramine and Dexamethasone.

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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Bosten Terrier	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
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:	Diane Zilker	Name:	
Address:	Token Creek Veterinary Clinic 3790 State Road 19	Address:	
City:	Sun Prairie	City:	
State:	WI	State:	

Zip:	53590	Zip:	
*Phone:	608-834-9700(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	Diane
*Submitter's Last Name:	Zilker
*Submitter's Phone Number:	608-834-9700(XXX-XXX-XXXX)
*Today's Date:	09/15/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 01/15/2010
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: AIV10069

Product Code: 1331.20 2668.00 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 Duramune Adult 3	112	1867115A	☒ Viral
2 Vanguard L4	189	A839157B	☒ Bacterial
3 Recombitek Lyme	298	42148	☒ Recombinant
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R Coxofemoral region	25	09/03/2009
2 1 ml	SQ	R Coxofemoral region	25	09/03/2009
3 1 ml	SQ	L Coxofemoral Region	25	09/03/2009
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/03/2009
Concurrent Drugs or Procedures:	85 mg DIPHENHYDRAMINE IM

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Dog examined and found to be apparently healthy. Pre-treated with 85mg (body weight) diphenhydramine Im which is s.o.p. Approximately 60 seconds after vaccination, dog vomited and collapsed. was obtunded with in 10 minutes. 20ga iv catheter installed and 0.9% NaCl administered @ 95ml/hr. 16mg dexamethasone sodium phosphate administered IV and anothe 50mg diphenhydramine IV. Approximately 1 hour 15 minutes post reaction dog became responsive. within 2 hours standing in cage. 2 hours later vomiting/diarrhea blood - D.I.C. Dog transferred to emergency clinic and has been hospitalized/supported until 9/10/2009. Still serious condition, but stable.	
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)	60 sec
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Other
Other:	Still recovering with intense treatment

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Greater Swiss Mountain	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.): No medical history, last vaccinated 2007, family pet			

Personal Information

Veterinarian		Owner	
*Name:	Robert Guasto	Name:	(b)(6)
Address:	Rocky Shores Animal Hospital	Address:	

	341 Route 25a		
City:	Rocky Point	City	
State:	NY	State	
Zip:	11778	Zip	
*Phone:	631-209-2035(XXX-XXX-XXXX)	Phone	XXX-XXX-XXXX)
FAX:	631 209-2417		
E-mail:	rguasto@hotmail.com	E-mail:	

(b)(6)

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Robert
*Submitter's Last Name:	Guasto
*Submitter's Phone Number:	631-209-2035(XXX-XXX-XXXX)
*Today's Date:	09/10/2009(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 09/10/2009
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

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: 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	☒ Recombinant
2 Recombitek Lyme	298	42147	☒ Recombinant
3 Duramune LCI/GP	112	045153A	☒ Bacterial
4			☒ [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:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/13/2009
Concurrent Drugs or Procedures:	No

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :		Number vaccinated:	1
Sex:	☒ Not Listed	Number dead:	0
Neutered:	☒ 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:	Diane Zilker	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):	☒ No
*Submitter's First Name:	Diane
*Submitter's Last Name:	Zilker
*Submitter's Phone Number:	608-834-9700(XXX-XXX-XXXX)
*Today's Date:	08/14/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 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	☒ Recombinant
2 Vanguard L4	189	A838205C	☒ 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:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/14/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ 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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Toy Poodle	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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:	Jane Sayler	Name:	(b)(6)
Address:	West Frederick Veterinary Hospital, PC 6902 Bowers Road	Address:	
City:	Frederick	City:	
State:	MD	State:	
Zip:	21702	Zip:	
*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):	☒ No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	301-473-4478(XXX-XXX-XXXX)
*Today's Date:	07/17/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: AIV09331
Product Code: 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 Recombitek Lyme	298	42135	☒ Recombinant
2			
3			
4			

Administration of products.

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

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/28/2008
Concurrent Drugs or Procedures:	

Event Information

* Event description: ☒ Some other event - Describe Below	
Explain the event and any treatment in a concise paragraph: drooling & diarrhea immediately, lethargic & not wanting to play since vaccine given. 1-2 hrs after vacine was given started diarrhea and drooling. cleared up 24 hrs after vaccine was given. 7-8 days after vaccine given, he started to make snorting/smacking noises and moving his head in jerking motions. jerking & mouth noises have progressively gotten worse.	
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)	1-2 hrs post vax
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*Outcome (select one):	☒ Recovered with treatment
Other:	placed on seizure medication

Animal Information

Case Identification:	Chester	**For animals handled in a group (herd, litter, etc.)**	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Lab X	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	2.3 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): healthy pet prior			

Personal Information

Veterinarian		Owner	
*Name:	Darlene Cook	Name	
Address:	The Bluffs Pet Clinic 2518 Old West Main Street	Address	(b)(6)
City:	Red Wing	City	

State:	MN	State:	MN
Zip:	55066	Zip:	55066
*Phone:	651-388-1103(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	651-388-9527		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	651-388-1103(XXX-XXX-XXXX)
*Today's Date:	06/20/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: AIV09322
Product Code: 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 Recombitek Lyme	298	42143	☒ Recombinant
2			
3			
4			

Administration of products.

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

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/06/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description: ☒ Some other event - Describe Below Explain the event and any treatment in a concise paragraph: lethargic and hiding in kennel since vaccine was given. started making a "smacking" noise with her mouth and once daily she would make jerking motions. activity has progressively gotten worse and 3 days ago (7-8 days post vax) she started the smacking noise & jerking motion more often. yesterday she was continously snapping in the air and making jerking motions. placed on herbal antiseizure medication.	
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)	1-2 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*Outcome (select one):	☒ Recovered with treatment
Other:	see hard copy

Animal Information

Case Identification:	Kodi	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Weimaraner X	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	2.5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	Darlene Cook	Name	
Address:	The Bluffs Pet Clinic 2518 Old West Main Street	Address	(b)(6)
City:	Red Wing	City	

State:	MN	State:	MN
Zip:	55066	Zip:	55066
*Phone:	651-388-9527(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	651-388-9527		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ 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:	06/17/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 09/11/2009
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	☒ Combination
2 Imrab 3 TF	298	18093C	☒ Viral
3 Recombitek Lyme	298	42145	☒ Recombinant
4 LeptoVax 4	112	045147A	☒ 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:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/26/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ 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 immunosuppresive 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:	☒ High
*Outcome (select one):	☒ Died
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Dachshund	Number vaccinated:	1
Sex:	☒ Male	Number dead:	1
Neutered:	☒ 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, fortdodge 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: Merical 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:	Summer Matsinger	Name:	
Address:	Northern Rhode Island Animal Hospital 152 School Street, P.O. 129	Address:	
City:	Forestdale	City:	(b)(6)
State:	RI	State:	
Zip:	02824	Zip:	
*Phone:	401-762-2400(XXX-XXX-XXXX)	Phone:	X-XXX-XXXX)
FAX:	401-765-7679		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Summer
*Submitter's Last Name:	Matsinger
*Submitter's Phone Number:	401-762-2400(XXX-XXX-XXXX)
*Today's Date:	06/09/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 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	☒ Viral
2 Recombitek Lyme	298	42144	☒ Recombinant
3 LeptoVax 4	112	045151A	☒ 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:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/06/2009
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ 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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Collie	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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:	Rose Broglio	Name:	(b)(6)
Address:	Nassau Veterinary Clinic 3930 US Rte 2, P.O. Box 400	Address:	
City:	Nassau	City:	
State:	NY	State:	

Zip:	12123	Zip:	(b)(6)
*Phone:	518-766-2636(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	518-766-3934		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Rose
*Submitter's Last Name:	Broglio
*Submitter's Phone Number:	518-766-2636(XXX-XXX-XXXX)
*Today's Date:	06/09/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 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	☒ Bacterial
2 Recombitek Lyme	298	42145	☒ 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:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/06/2009
Concurrent Drugs or Procedures:	no others

Event Information

* Event description: ☒ Anaphylaxis/Hypersensitivity	
Explain the event and any treatment in a concise paragraph: allergic reaction - 1 hour post vaccation, 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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Swiss Mountain Dog	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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:	Beth Ann Shane	Name	
Address:	Nassau Veterinary Clinic 3930 US Rt. 20	Address	(b)(6)
City:	Nassau	City	
State:	NY	State	

Zip:	12123	Zip	(b)(6)
*Phone:	518-766-2636(XXX-XXX-XXXX)	Phone	XXX-XXX-XXXX)
FAX:	518-766-3934		
E-mail:	www.nassauvet.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	518-766-2636(XXX-XXX-XXXX)
*Today's Date:	06/08/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 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	☒ Recombinant
2 Duramune Adult 3	112	1867111A	☒ Viral
3 LeptoVax 4	112	045147A	☒ Bacterial
4			☒ [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:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/08/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ 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:	☒ [Click arrow for selections]
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Boston Terrier	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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:	Holly Bradshaw	Name:	
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	
City:	Winchester	City:	(b)(6)
State:	VA	State:	
Zip:	22602	Zip:	
*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone:	

FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	05/13/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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.<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	☒ Viral
2 Recombitek Lyme	298	42141	☒ Recombinant
3 LeptoVax 4	112	045147A	☒ 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:	☒ 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:	☒ High
*Outcome (select one):	☒ Other
Other:	too soon to determine

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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:	Heide Meier	Name	
Address:	Truesdell Animal Care Hospital 4214 Milwaukee Street	Address	(b)(6)
City:	Madison	City	
State:	WI	State	

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):	☒ Yes
*Submitter's First Name:	Heide
*Submitter's Last Name:	Meier
*Submitter's Phone Number:	608-244-2555(XXX-XXX-XXXX)
*Today's Date:	04/29/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: 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	☒ Bacterial
2 Recombitek Lyme	298	42143	☒ Recombinant
3 Imrab 3 TF	298	18088B	☒ Viral
4 Naramune-2	124	567	☒ 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:	☒ 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:	☒ High
*Outcome (select one):	☒ Other
Other:	partial recovery

Animal Information

Case Identification:	Kelsey Holsclaw	**For animals handled in a group (herd, litter, etc.)**	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Golden Retriever	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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:	Holly Bradshaw	Name	(b)(6)
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address	
City:	Winchester	City	

State:	VA	State:	
Zip:	22602	Zip:	(b)(6)
*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Holly
*Submitter's Last Name:	Bradshaw
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	04/10/2009(MM/DD/YYYY)
Relationship to animal:	☒ 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: AIV09164

Product Code: 1905.23 2126.R0 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	18000B	☒ Viral
2 Recombitek Lyme	298	42138	☒ Recombinant
3 Duramune Max 5	112	916365A	☒ Viral
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	25	02/26/2009
2 1 ml	SQ	Between shoulders	25	02/26/2009
3 1 ml	SQ	L shoulders	25	02/26/2009
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	02/26/2009
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: facial swelling and redness	
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 3 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ Not Listed
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Chihuahua	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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:	Marietta Walls	Name:	
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	
City:	Winchester	City:	
State:	VA	State:	
Zip:	22602	Zip:	
*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):	☒ Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	02/27/2009(MM/DD/YYYY)
Relationship to animal:	☒ Not Listed
Other:	

Submit

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

Date Received: 02/27/2009
Verified:yes
Reviewed:yes
Date Entered: 04/20/2009
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: AIV09127
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 Duramune LCI-GP	112	045143A	☒ Bacterial
2 Recombitek Lyme	298	42141	☒ Recombinant
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LF	25	01/13/2009
2 1 ml	SQ	LH	25	01/13/2009
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	01/13/2009
Concurrent Drugs or Procedures:	physical exam & oral Strongid 1.1 ml

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
appointment (initial) was at 2:45 p.m. - owner brought pet back to practice @ 5:20 p.m. for severe facial swelling, erythema, prunitis. Temp 101, pulse 120, respiratory rate 60, mucous membranes pink. given 0.2 ml benadryl (50 mg/ml) IM, dexamethasone SP (4 mg/ml) 0.27 ml SQ, and SQ fluids (normosol) 100 ml.

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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Brussels Griffon	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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.):
from Kentucky - a rescue group; previously given rabies (merial), DHPP & corona vaccine (unknown brand) and neutered by rescue group. was on pedigree diet.

Personal Information

Veterinarian		Owner	
*Name:	Jennifer Dauphin	Name	(b)(6)
Address:	Northern Rhode Island Animal Hospitals, Inc. 152 School Street, P.O. Box 129	Address	
City:	Forestdale	City	

State:	RI	State:		
Zip:	02824	Zip:	(b)(6)	
*Phone:	401-762-2400(XXX-XXX-XXXX)	Phone:		XXX-XXX-XXXX)
FAX:	401-765-7679			
E-mail:		E-mail:		

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Jennifer
*Submitter's Last Name:	Dauphin
*Submitter's Phone Number:	401-762-2400(XXX-XXX-XXXX)
*Today's Date:	01/23/2009(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 01/23/2009
Verified:yes
Reviewed:yes
Date Entered: 03/06/2009
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: AIV09069

Product Code: 1905.24 13D1.22 108100 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 Defensor 3	189	S724896D	☒ Viral
2 Vanguard Plus 5	189	A829624	☒ Viral
3 Bronch-Shield	112	110259A	☒ Bacterial
4 Recombitek Lyme	298	42135	☒ Recombinant

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RR leg	22	11/06/2008
2 1 ml	SQ	L lumbar	22	11/06/2008
3 0.5 mls	IN	Nostrils	n/a	11/06/2008
4 1 ml	SQ	LR	22	11/06/2008

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	11/06/2008
Concurrent Drugs or Procedures:	no

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Vomited several times following her vaccines and lethargy.	
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:	☒ High
*Outcome (select one):	☒ Recovered without treatment
Other:	

Animal Information

Case Identification:	20986 "Precious"	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Dachsund Mix	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	4 yrs & 8 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	Scott McCall	Name:	
Address:	Animal Care Centers 1851 Acton Highway	Address:	
City:	Granbury	City:	(b)(6)
State:	TX	State:	
Zip:	76049	Zip:	
*Phone:	817-573-5003(XXX-XXX-XXXX)	Phone:	

FAX:	817-573-2210		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	817-573-5003(XXX-XXX-XXXX)
*Today's Date:	11/19/2008(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	Technician

Submit

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

Date Received: 11/19/2008
Verified:yes
Reviewed:yes
Date Entered: 01/02/2009
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: AIV09064
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	045142A	☒ Bacterial
2 Recombitek Lyme	298	42138	☒ Recombinant
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LF shoulder	25	10/31/2008
2 1 ml	SQ	LH hip	25	10/31/2008
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	10/31/2008
Concurrent Drugs or Procedures:	annual exam, 4Dx Heartworm test (blood draw)

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
A few minutes after vaccines were administered pet shrieked when owner tried to lift off table. A few minutes later patient was in sternal recumbancy/nonresponsive. Treated with oxygen, dexamethasone sodium phospate (IV), Bendaryl (IM), Epinephrine (IV). Intravenous fluids - needed multiple doses of dexamethasone and bendryl. Lateral radiograph taken once patient had increased respiratory effort (prior to IV fluids) indicated very mild pleural effusion. Referred to 24 hour emergency care facility for overnight supportive care and observation.

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 5 mins
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	SOBE	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pug	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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.):
Indoor only dog - goes outside to urinate/defecate only. Diet - Eukaneuba lamb & rive, no contact with other dogs, no history of vaccine reactions, no history of medical issues to date. **Has received Merial Imrab rabies, LeptoVax FD, Merial Recombitek Lyme in 2005; received FD LeptoVax & Intervet Lyme 11/7/06; received Galaxy DA2PP & LeptoVax, Intervet Lyme, Merial rabies Imrab on 10/23/07.

Personal Information

Veterinarian	Owner

*Name:	Jennifer Dauphin	Name:	Wayne Martin
Address:	Northern R.I. Animal Hospital 1525 School Street, P.O. Box 129	Address:	(b)(6)
City:	Forestdale	City:	
State:	RI	State:	
Zip:	02824	Zip:	(b)(6)
*Phone:	401-762-2400(XXX-XXX-XXXX)	Phone:	X-XXX-XXXX)
FAX:	401-765-7679		
E-mail:	jennifer.dauphin@charter.net	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Jennifer
*Submitter's Last Name:	Dauphin
*Submitter's Phone Number:	401-762-2400(XXX-XXX-XXXX)
*Today's Date:	11/13/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 11/13/2008
Verified:yes
Reviewed:yes
Date Entered: 01/02/2009
CVB Reporter: Page
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: AIV09041

Product Code: 1905.24 13D1.22 1081.00 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 Defensor 3	189	S724896D	☒ Viral
2 Vanguard Plus 5	189	A829624	☒ Viral
3 Bronchi-Shield	112	110257B	☒ Bacterial
4 Recombitek Lyme	298	42135	☒ Recombinant

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RR hip	22	10/08/2008
2 1 ml	SQ	L lumbar	22	10/08/2008
3 1 ml	IN	Nostrils	n/a	10/08/2008
4 1 ml	SQ	LR hip	22	10/08/2008

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	10/08/2008
Concurrent Drugs or Procedures:	no

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Vomiting uncontrolably, could barely walk. Vomited apr. 12-13 times in a matter of a couple hours. Patient also had a bowel movement in the house.	
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)	hrs
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	26365 "Tucker"	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Medium Mix	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	2 yrs & 2 days		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	Kathleen Wallace	Name:	(b)(6)
Address:	Hood County Animal Clinic 1851 Acton Highway	Address:	
City:	Granbury	City:	
State:	TX	State:	
Zip:	76049	Zip:	

*Phone:	817-573-5003(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	817-573-2210		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	817-573-5003(XXX-XXX-XXXX)
*Today's Date:	10/22/2008(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	Technician

Submit

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

Date Received: 10/22/2008
Verified:yes
Reviewed:yes
Date Entered: 12/09/2008
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: AIV09012

Product Code: 1331.20 2668.05 2126.R0 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	1867108A	☒ Viral
2 LeptoVax 4	112	045141A	☒ Bacterial
3 Recombitek Lyme	298	42136	☒ Recombinant
4 Naramune-2	124	552	☒ Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	shoulder	23	09/23/2008
2 1 ml	SQ	shoulder	23	09/23/2008
3 1 ml	SQ	LR leg	23	09/23/2008
4 1 ml	SQ	nostrils	NA	09/28/2088

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	09/23/2008
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
local; patient received vaccines at 2:30 p.m. vomited in the car on the way home & vomited again at home. His face & ears were pruritic and his face started to swell. He vomited on the way to the emergency clinic and again once he arrived at 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)	20 mins
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Yorkie/Poo	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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:	Richard Armstrong	Name	(b)(6)
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address	
City:	Winchester	City	
State:	VA	State	

Zip:	22602	Zip:	(b)(6)
*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone:	XX-XXX-XXXX)
FAX:	540-678-1409		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name	
*Submitter's Last Name	(b)(6)
*Submitter's Phone Numbe	XXX-XXX-XXXX)
*Today's Date:	09/23/2008(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	

Submit

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

Date Received: 09/23/2008
Verified:yes
Reviewed:yes
Date Entered: 10/24/2008
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: AIV08433

Product Code: 1905.23 2126.R0 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	18078A	☒ Viral
2 Recombitek Lyme	298	42132A	☒ Recombinant
3 Duramune Max 5	112	916332A	☒ Viral
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	RR leg	22	08/22/2008
2 1 ml	SQ	LR leg	22	08/22/2008
3 1 ml	SQ	scruff area	22	02/22/2008
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/22/2008
Concurrent Drugs or Procedures:	nail trim, exam

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Vaccines given about 4:30 pm. Presented to the emergency service at 7 pm for facial swelling and pruritis. Patient (male 17 week old minature dachshund) was given DexNaPhos 2 mg IV and Diphenhydramine 8 mg IM. Owner continued benadryl at home every 8 hours. He is now back to 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)	within 3 hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Mini Dachshund	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	17 wks		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): indoor pet; was given DAPP July 2, 2008 and DAPP, bordetella, and Lyme on 7/23/2008.			

Personal Information

Veterinarian		Owner	
*Name:	Holly Bradshaw	Name:	
Address:	Apple Valley Animal Hospital 1207 Cedar Creek Grade	Address:	(b)(6)
City:	Winchester	City:	
State:	VA	State:	

Zip:	22602	Zip:	22603
*Phone:	540-678-0202(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	540-678-0419		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Holly
*Submitter's Last Name:	Bradshaw
*Submitter's Phone Number:	540-678-0202(XXX-XXX-XXXX)
*Today's Date:	08/25/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 08/25/2008
Verified:yes
Reviewed:yes
Date Entered: 09/22/2008
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: AIV08408
Product Code: 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 Recombitek Lyme	298	42135	☒ Recombinant
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L thigh	22	07/31/2008
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/31/2008
Concurrent Drugs or Procedures:	rabies vaccine, DHPP, Leptospirosis

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Angioedema - 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)	within 8 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pitbull Terrier	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	4 yrs 7 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): current on all vaccines			

Personal Information

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

FAX:	301-473-4036		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Erin
*Submitter's Last Name:	Frey
*Submitter's Phone Number:	301-473-4478(XXX-XXX-XXXX)
*Today's Date:	08/04/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 08/04/2008
Verified:yes
Reviewed:yes
Date Entered: 09/22/2008
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: AIV08406
Product Code: 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 Recombitek Lyme	298	42135	☒ Recombinant
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L thigh	22	08/01/2008
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/01/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: vomiting, lethargy, trembling - systemic; trembling & vomited, no angioedema or urticaria	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	3239-2	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Shitzu	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	15 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Purchased; current on rabies, DHPOP, lepto vacc, only dog in house, no medical problems.			

Personal Information

Veterinarian		Owner	
*Name:	Erin Frey	Name:	
Address:	West Frederick Veterinary Hospital, P.C. 6902 Bowers Road	Address:	(b)(6)
City:	Frederick	City:	
State:	MD	State:	
Zip:	21702	Zip:	
*Phone:	301-473-4478(XXX-XXX-XXXX)	Phone:	(b)(6) (XXX-XXX-XXXX)

FAX:	301-473-4036		
E-mail:	petdoc@westfredvet.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Erin
*Submitter's Last Name:	Frey
*Submitter's Phone Number:	301-473-4478(XXX-XXX-XXXX)
*Today's Date:	08/01/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 08/01/2008
Verified:yes
Reviewed:yes
Date Entered: 09/22/2008
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: AIV08402
Product Code: 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 Recombitek Lyme	298	42135	☒ Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R thigh	22	07/25/2008
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/25/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
vomiting - vaccine administered at 3:00 p.m., 5:37 p.m. vomited 2x, lethargy; 0.22 ml (11 mg) diphenhydramine Im at 6:07 p.m. 100 ml SQ LRS, vomited at 6:10 p.m. and 2x overnight, 12.5 mg diphenhydramine PO every 8 hours.

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:	☒ High	
*Outcome (select one):	☒ Recovered with treatment	
Other:		

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Jack Russel Terrier	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	8 mos		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
obtained Jan 2008, DHPP 12/28/07, 1/18/08, 2/8/08, 3/7/08; rabies 3/7/08, lepto 4 vaccine 1/18/08, 2/8/08, 3/7/08.

Personal Information

Veterinarian		Owner	
*Name:	Erin Frey	Name:	(b)(6)
Address:	West Frederick Veterinary Hospital 6902 Bowers Road	Address:	
City:	Frederick	City:	
State:	MD	State:	
Zip:	21702	Zip:	

*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):	☒ Yes
*Submitter's First Name:	Erin
*Submitter's Last Name:	Frey
*Submitter's Phone Number:	301-473-4478(XXX-XXX-XXXX)
*Today's Date:	07/30/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/30/2008
Verified:yes
Reviewed:yes
Date Entered: 08/28/2008
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: AIV08399
Product Code: 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 Recombitek Lyme	298	42135	☒ Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LR leg	22	07/21/2008
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/21/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Approximately 2 hrs post lyme vax pet vomited, was trembling & lethargic.	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Papillonx	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.): Pet came in for lyme booster vaccination (last given 8/18/07)			

Personal Information

Veterinarian		Owner	
*Name:	Abby Strobbe	Name:	(b)(6)
Address:	Medomak Veterinary Service 14 Atlantic Highway	Address:	
City:	Waldoboro	City:	
State:	ME	State:	
Zip:	04572	Zip:	
*Phone:	207-563-7786(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)

FAX:	207-563-2235		
E-mail:	www.medomakvet.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Abby
*Submitter's Last Name:	Strobbe
*Submitter's Phone Number:	207-563-7786(XXX-XXX-XXXX)
*Today's Date:	07/28/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/28/2008
Verified:yes
Reviewed:yes
Date Entered: 08/28/2008
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: AIV08398
Product Code: 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 Recombitek Lyme	298	42135	☒ Recombinant
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LR leg	22	07/25/2008
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/25/2008
Concurrent Drugs or Procedures:	None

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Approx. 2 hrs post lyme vax pet vomited, was trembling & lethargic.	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Boston Terrier	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
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:	Abby Strobbe	Name:	(b)(6)
Address:	Medomak Veterinary Service 14 Atlantic Highway	Address:	
City:	Waldoboro	City:	
State:	ME	State:	
Zip:	04572	Zip:	
*Phone:	207-563-7786(XXX-XXX-XXXX)	Phone:	(b)(6) (XXX-XXX-XXXX)

FAX:	507-563-2235		
E-mail:	www.medomakvet.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Abby
*Submitter's Last Name:	Strobbe
*Submitter's Phone Number:	207-563-7786(XXX-XXX-XXXX)
*Today's Date:	07/28/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/28/2008
Verified:yes
Reviewed:yes
Date Entered: 08/28/2008
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: AIV08365

Product Code: 2126.R0 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 Recombitek Lyme	298	42134A	☒ Bacterial
2 Duramune Max 5	112	916238A	☒ Viral
3 Bronchi-Shield III	112	112391A	☒ Combination
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L back leg	22	06/23/2008
2 1 ml	SQ	R shoulder	22	06/23/2008
3 1 ml	IN			06/23/2008
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/23/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Presented to an emergence clinic several hours later for facial swelling without vomiting or diarrhea. Given dexamethasone and diphenhydramine injections. Recovered well	
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)	unknown -- within several hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Lab	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ No		
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:	Karen Hoersch/Diane Zilker	Name:	
Address:	Token Creek Veterinary Clinic 3790 State Road 19	Address:	
City:	Sun Prairie	City:	(b)(6)
State:	WI	State:	
Zip:	53590	Zip:	

*Phone:	608-834-9700(XXX-XXX-XXXX)	Phone (b)(6)	XXX-XXX-XXXX)
FAX:	608-834-0700		
E-mail:	doczilker@tokencreekvet.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	Diane
*Submitter's Last Name:	Zilker
*Submitter's Phone Number:	608-834-9700(XXX-XXX-XXXX)
*Today's Date:	07/02/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/02/2008
Verified:yes
Reviewed:yes
Date Entered: 08/07/2008
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: AIV08307

Product Code: 1905.23 2126.R0 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	18071C	☒ Viral
2 Recombitek Lyme	298	42129B	☒ Bacterial
3 Duramune Max 5	112	916276A	☒ Viral
4 LeptoVax 4	112	045136A	☒ Bacterial

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R hip	25	05/12/2008
2 1 ml	SQ	L hip	25	05/12/2008
3 1 ml	SQ	R shoulder	25	05/12/2008
4 1 ml	SQ	L shoulder	25	05/12/2008

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/12/2008
Concurrent Drugs or Procedures:	None

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
Dog started vomiting 10 minutes after vaccination, then defecated a few minutes later and became very lethargic. MM were very pale and heart rate was elevated. An IV catheter was placed. He was given 8 mg of Dexamethasone Sodium Phosphate, 50 mg of diphenhydramine and 250 cc of IV fluids. W/in 30 minutes he was nearly normal and was discharged for further observation at home. Owners continued administering diphenhydramine for an additional 36 hours.

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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Lab X	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.):
She was vaccinated with all of these antigens a year ago, although we do not know the manufacturer of the vaccines. She had no apparent reaction then.

Personal Information

Veterinarian		Owner	
*Name:	Kerrie Burns	Name:	(b)(6)
Address:	All Paws Animal Hospital	Address:	

	5225 Excelsior Blvd			
City:	St. Louis Park	City:		
State:	MN	State:		
Zip:	55416	Zip:	(b)(6)	
*Phone:	952-848-0913(XXX-XXX-XXXX)	Phone:		X-XXX-XXXX)
FAX:	952-848-0896			
E-mail:	webburns@frontiernet.net	E-mail:		

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Kerrie
*Submitter's Last Name:	Burns
*Submitter's Phone Number:	952-848-0913(XXX-XXX-XXXX)
*Today's Date:	05/14/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 05/14/2008
Verified:yes
Reviewed:yes
Date Entered: 05/19/2008
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: AIV08234
Product Code: 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 Recombitek Lyme	298	42131A	☒ Bacterial
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	neck	23	03/18/2008
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/18/2008
Concurrent Drugs or Procedures:	Dexamethasone SQ, Combiten SQ

Event Information

* Event description:	☒ Systemic

Explain the event and any treatment in a concise paragraph:
When getting home from the trip to the vet's office, the dog vomited several times and then was standing with his head down. Tx - IV fluids, 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)	30 mins
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pekinese	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	7 yrs		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
n/o sialocele - found 10/10/07. last vaccines were 5/4/07 - received vaccines for lyme, DA2PP and rabies. Lyme vaccine was same manufacturer (merial) same brand.

Personal Information

Veterinarian		Owner	
*Name:	Karen Kahn	Name:	
Address:	Rocky Point Animal Hospital 526A Route 25A	Address:	
City:	Rocky Point	City:	
State:	NY	State:	

Zip:	11778	Zip:	
*Phone:	631-744-8882(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:	KKrpah@optonline.net	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Karen
*Submitter's Last Name:	Kahn
*Submitter's Phone Number:	631-744-8882(XXX-XXX-XXXX)
*Today's Date:	03/19/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 03/19/2008
Verified:yes
Reviewed:yes
Date Entered: 04/02/2008
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: AIV08202

Product Code: 2668.00 2126.R0 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	045131A	☒ Bacterial
2 Recombitek Lyme	298	42129A	☒ Bacterial
3 Bronchicine CAe	189	A718719	☒ Bacterial
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L rear	22	02/20/2008
2 1 ml	SQ	L shoulder	22	02/20/2008
3 1 ml	SQ	R shoulder	22	02/20/2008
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	02/20/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: 3 hours post vaccination owner noticed puritic, generalized hives, swollen lips & muzzle. Treated with 2 cc Recover & 4 cc (8 mb) dexamethasone IM LR.	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Lab	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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.): has had all of these exact vaccines before			

Personal Information

Veterinarian		Owner	
*Name:	Tami Fourez	Name:	(b)(6)
Address:	Grayslake Animal Hospital 1490 East Belvidere Road	Address:	
City:	Grayslake	City:	
State:	IL	State:	
Zip:	60030	Zip:	

*Phone:	847-223-8612(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)
FAX:	847-223-8625		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	(b)(6)
*Submitter's Last Name:	
*Submitter's Phone Number:	847-223-8612(XXX-XXX-XXXX)
*Today's Date:	02/20/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 02/20/2008
Verified:yes
Reviewed:yes
Date Entered: 03/26/2008
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: AIV08197

Product Code: 2668.00 2126.R0 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	045131A	☒ Bacterial
2 Recombitek Lyme	298	42129A	☒ Recombinant
3 Bronchicine CAe	189	A718719	☒ Combination
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L rear	22	02/20/2008
2 1 ml	SQ	L shoulder	22	02/20/2008
3 1 ml	SQ	R shoulder	22	02/20/2008
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	02/20/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Three hours post-vaccination the owner noticed puritis, generalized hives, swollen lips and muzzle. Treated with 2cc Rexxxx and 4 cc (8 mg) dexamethasone IM in left rear 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)	3 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ Not Listed
*Outcome (select one):	☒ Other
Other:	not listed

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever	Number vaccinated:	1
Sex:	☒ Not Listed	Number dead:	0
Neutered:	☒ Not Listed		
Age (i.e., 2 yrs or 2 mos):	5 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): Has had all of these exact vaccines before.			

Personal Information

Veterinarian		Owner	
*Name:	Jami Fourez	Name:	
Address:	Grayslake Animal Hospital 1490 East Belvidere Road	Address:	
City:	Grayslake	City:	
State:	IL	State:	
Zip:	60030	Zip:	

(b)(6)

*Phone:	847-223-8612(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)
FAX:	847-223-8625		
E-mail:	djglah@aol.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	847-223-8612(XXX-XXX-XXXX)
*Today's Date:	02/20/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 02/21/2008
Verified:yes
Reviewed:yes
Date Entered: 03/25/2008
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: AIV08141

Product Code: 2668.00 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 Duramune LCI/GP	112	045131A	☒ Viral
2 Recombitek Lyme	298		☒ Bacterial
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L shoulder	22	01/07/2008
2 1 ml	SQ	L thigh	22	01/07/2008
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	01/07/2008
Concurrent Drugs or Procedures:	none

Event Information

* Event description: ☒ Anaphylaxis/Hypersensitivity	
Explain the event and any treatment in a concise paragraph: 3 hours post vaccination dog developed facial swelling & uticaria.	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Lab	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.): has had leptovax twice before, 1st time for lymes vacc.			

Personal Information

Veterinarian		Owner	
*Name:	Susan Sallee	Name:	
Address:	Grayslake Animal Hospital 1490 East Belvidere Road	Address:	
City:	Grayslake	City:	
State:	IL	State:	
Zip:	60030	Zip:	
*Phone:	847-223-8612(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)

(b)(6)

FAX:	847-223-8625		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	Susan
*Submitter's Last Name:	Sallee
*Submitter's Phone Number:	847-223-8612(XXX-XXX-XXXX)
*Today's Date:	01/08/2008(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 01/08/2008
Verified:yes
Reviewed:yes
Date Entered: 02/13/2008
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: AIV08100

Product Code: 2126.R0 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 Recombitek Lyme	298	42129A	☒ Recombinant
2 Bronchicine	189	A718474A	☒ Bacterial
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

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

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	12/13/2007
Concurrent Drugs or Procedures:	heart worm test blood draw

Event Information

* Event description: ☒ Some other event - Describe Below	
Explain the event and any treatment in a concise paragraph: reacted for a couple of minutes; disoriented and shook 2 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?): (Include Units:mins, hrs, days, wks, mos, yrs)	2 days
Attending veterinarian's level of suspicion that product caused event:	☒ Low
*Outcome (select one):	☒ Recovered without treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Airedale	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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:	Sarah Wormwood	Name	
Address:	Limerick Mills Animal Hospital P.O. Box 537	Address	(b)(6)
City:	Limerick	City	
State:	ME	State	
Zip:	04048	Zip	
*Phone:	207-793-4493(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)

FAX:	207-793-2873		
E-mail:	limerickmillsanimalhospital@yahoo.com	E-mail:	avaznis@yahoo.com

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	Sarah
*Submitter's Last Name:	Wormwood
*Submitter's Phone Number:	207-793-4493(XXX-XXX-XXXX)
*Today's Date:	12/17/2007(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 12/17/2007
Verified:yes
Reviewed:yes
Date Entered: 01/23/2008
CVB Reporter: Schierer
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: AIV07371

Product Code: 13D1.R1 2126.R0 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 Recombitek C 4	298	45173B-32075B	☒ Recombinant
2 Recombitek Lyme	298	42126	☒ Recombinant
3 Imrab3 TF	298	18056B	☒ Viral
4			☒ Other

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	08/09/2007
2 1 ml	SQ	L hip	22	08/09/2007
3 1 ml	SQ	R hip	22	08/09/2007
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	08/09/2007
Concurrent Drugs or Procedures:	Drontal Plus 22.7mg #2 PO

Event Information

* Event description:	☒ Systemic

Explain the event and any treatment in a concise paragraph:
Vomiting 4 times since vaccination. Administered diphenhdramine IM, dexamethasone IV, famotidine IM, rx'd I/D and carafate.

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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	Chestnut	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever Mix	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
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:	Robert Taeubel	Name:	
Address:	Eastwood Animal Hospital 1513 South Alafaya Trail	Address:	
City:	Orlando	City:	
State:	FL	State:	
Zip:	32828	Zip:	

(b)(6)

*Phone:	407-447-9444(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:	407-447-5998		
E-mail:	roberttaeubel@msn.com	E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	407-447-9444(XXX-XXX-XXXX)
*Today's Date:	08/10/2007(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	Hospital manager

Submit

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

Date Received: 08/10/2007
Verified:yes
Reviewed:yes
Date Entered: 08/28/2007
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: AIV07346

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	42125A	☒ Bacterial
2 Leptovax 4	112	045118A	☒ Bacterial
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			07/26/2007
2 1 ml	SQ			07/26/2007
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	07/26/2007
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: facial swelling responded to dexamethasone epinephrine and benadryl	
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:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Mini Dachshund	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	3 mos		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.): first lyme,lepto vaccine on 7/11/2007			

Personal Information

Veterinarian		Owner	
*Name:	Agata Thompson	Name:	
Address:	Kingston Animal Hospital 192 Main Street	Address:	
City:	Kingston	City:	
State:	MA	State:	
Zip:	02364	Zip:	
*Phone:	781-585-6525(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)

FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Agata
*Submitter's Last Name:	Thompson
*Submitter's Phone Number:	781-585-6525(XXX-XXX-XXXX)
*Today's Date:	07/26/2007(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 07/26/2007
Verified:yes
Reviewed:yes
Date Entered: 08/28/2007
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: AIV07318

Product Code: 13D1. R1 2126.R0 14M1.20 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 Recombitek C4	298	45171B/32073B	☒ Recombinant
2 Recombitek Lyme	298	42125B	☒ Recombinant
3 Recombitek KC2	124	536A	☒ Recombinant
4 Imrab 3 TF	298	18061B	☒ Viral

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R front shoulder	22	06/20/2007
2 1 ml	SQ	L hip	22	
3 0.5 ml	IN	Intranasal	none	06/20/2007
4 1 ml	SQ	R hip	22	

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/20/2007
Concurrent Drugs or Procedures:	None

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
Vaccines were given, pet went home, had a bath dues to fleas, O returned about 2 hours after initial exam and noted facial swelling, especially upper lip.

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 2 hrs
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pug	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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.):
This was first visit to our clinic, had been vaccinated in Florida at previous vet, did not receive Lepto vaccines previously.

Personal Information

Veterinarian		Owner	
*Name:	Christine Calvert	Name	
Address:	Calvert Veterinary Center 4193 Mountain Road	Address	
City:	Pasadena	City	(b)(6)
State:	MD	State	
Zip:	21122	Zip	

*Phone:	410-360-7297(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	Christine
*Submitter's Last Name:	Calvert
*Submitter's Phone Number:	410-360-7297(XXX-XXX-XXXX)
*Today's Date:	06/26/2007(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 06/26/2007
Verified:yes
Reviewed:yes
Date Entered: 07/11/2007
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: AIV07301
Product Code: 2126.R0 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 Recombitek Lyme	298	42123	☒ Recombinant
2 Vanguard Plus 5	189	A610925B	☒ Viral
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L hip	25	06/14/2007
2 1 ml	SQ	R shoulder	25	06/14/2007
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	06/14/2007
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
Drooling, crying, ears back, swollen muzzle, spitting up. gave benadryl 50mg/ml - .24 mls SQ dexamethasone 2mg/ml -1.0 ml 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)	3 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	Lincoln	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pomeranian	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ 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.):

Personal Information

Veterinarian		Owner	
*Name:	Darlene Cook	Name:	(b)(6)
Address:	The Bluffs of Red Wing 2518 Old West Main Street	Address:	
City:	Redwing	City:	
State:	MN	State:	
Zip:	55066	Zip:	

*Phone:	651-388-1103(XXX-XXX-XXXX)	Phone:	(b)(6) XXX-XXX-XXXX)
FAX:	651-388-9527		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	651-388-1103(XXX-XXX-XXXX)
*Today's Date:	06/14/2007(MM/DD/YYYY)
Relationship to animal:	☒ Other
Other:	certifed veterinary technician

Submit

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

Date Received: 06/14/2007
Verified:yes
Reviewed:yes
Date Entered: 06/15/2007
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: AIV07294

Product Code: 13D1.R1 2126.R0 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 Recombitek C4	298	45168	☒ Recombinant
2 Recombitek Lyme	298	42125A	☒ Recombinant
3 Recombitek KC2	124	536A	☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	05/30/2007
2 1 ml	SQ	L hip	22	05/30/2007
3 1 ml	IN	nose	none	05/30/2007
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	05/30/2007
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: While pet was still in hospital we noted swollen face/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)	15 mins
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:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Pug	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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:	Christine Calvert	Name:	
Address:	Calvert Veterinary Center 4193 Mountain Road	Address:	
City:	Pasadena	City:	
State:	MD	State:	
Zip:	21122	Zip:	
*Phone:	410-360-7297(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)

FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ No
*Submitter's First Name:	Christine
*Submitter's Last Name:	Calvert
*Submitter's Phone Number:	410-360-7297(XXX-XXX-XXXX)
*Today's Date:	06/06/2007(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 06/06/2007
Verified:yes
Reviewed:yes
Date Entered: 06/15/2007
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: AIV07231
Product Code: 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 Recombitek Lyme	298	42122B	☒ Recombinant
2			
3			
4			

Administration of products.

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

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/24/2007
Concurrent Drugs or Procedures:	

Event Information

* Event description:	☒ Systemic

Explain the event and any treatment in a concise paragraph:
repeated vomiting, lethargy, anorexia. Tx :dexamethasone 2mg/ml - 3.5 mls SQ; diphenzydramine - 50 mg/ml - 1.4 mls 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)	24 hrs	
Attending veterinarian's level of suspicion that product caused event:	☒ Not Listed	
*Outcome (select one):	☒ Other	
Other:	not listed	

Animal Information

Case Identification:		For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Labrador Retriever	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	2.5 yrs		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):

Personal Information

Veterinarian			Owner
*Name:	Denise Hodge	Name	
Address:	The Bluffs of Red Wing 2518 Old West Main Street	Address	
City:	Red Wing	City	(b)(6)
State:	MN	State	
Zip:	55066	Zip	

*Phone:	651-388-1103(XXX-XXX-XXXX)	Phone:	(XXX-XXX-XXXX)
FAX:			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name:	Denise
*Submitter's Last Name:	Hodge
*Submitter's Phone Number:	651-388-1103(XXX-XXX-XXXX)
*Today's Date:	04/25/2007(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 05/07/2007
Verified:yes
Reviewed:yes
Date Entered: 05/21/2007
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: AIV07222
Product Code: 2668.00 2126.R0 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 Lepto Vax 4	112	045118A	☒ Bacterial
2 Recombitek Lyme	298	42121A	☒ Recombinant
3 Intra Trac 2	165A	53635	☒ Combination
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	L scapula area	22	04/14/2007
2 1 ml	SQ	L hip area	22	04/14/2007
3 1 ml	Intranasal	nares	none	04/14/2007
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/14/2007
Concurrent Drugs or Procedures:	none

Event Information

* Event description:	☒ Local

Explain the event and any treatment in a concise paragraph:
Owner noticed a large lump at Leptospirosis vaccine site 1 week following the vaccine. She has had this vaccine a number of times in the past. I aspirated for cytology and directed the owners to apply warm compresses.

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:	☒ High
*Outcome (select one):	☒ Other
Other:	The mass has started to decrease in size, we are monitoring to be sure it fully resolves.

Animal Information

Case Identification:	"Kiwi" Caviezel	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Golden Retriever	Number vaccinated:	1
Sex:	☒ Female	Number dead:	0
Neutered:	☒ 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.):
Presented for annual exam. Indoor dog. One other dog in the household.

Personal Information

Veterinarian		Owner	
*Name:	Lisa Lindesmith	Name	(b)(6)
Address:	5225 Excelsior Blvd.	Address	
City:	St. Louis Park	City	
State:	MN	State	
Zip:	55416	Zip	

*Phone:	952-848-0913(XXX-XXX-XXXX)	Phone:	(b)(6) (X-XXX-XXXX)
FAX:	952-848-0896		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	Lisa
*Submitter's Last Name:	Lindesmith
*Submitter's Phone Number:	952-848-0913(XXX-XXX-XXXX)
*Today's Date:	04/24/2007(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 04/24/2007
Verified:yes
Reviewed:yes
Date Entered: 05/02/2007
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: AIV05169

Product Code: 2126.R0 13D1.25

* 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	42105	☒ Bacterial
2 Duramune Max 5	112	116750A	☒ Viral
3			☒ [Click arrow for selections]
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ			04/05/2005
2 1 ml	SQ			04/05/2005
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	04/05/2005
Concurrent Drugs or Procedures:	Premed with Dex Na P

Event Information

* Event description:	☒ Anaphylaxis/Hypersensitivity
Explain the event and any treatment in a concise paragraph: Pruritus began within 1 hour after vaccines given, tx with 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)	Within 1 hour
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	423-4	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Siberian Husky	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Not Listed		
Age (i.e., 2 yrs or 2 mos):	6 yrs		
History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):			

Personal Information

Veterinarian		Owner	
*Name:	Peter Sakas	Name:	
Address:	Niles Animal Hospital, 7278 N. Milwaukee Ave	Address:	
City:	Niles	City:	(b)(6)
State:	IL	State:	
Zip:	60714	Zip:	
*Phone:	847-647-9325(XXX-XXX-XXXX)	Phone	(b)(6) (XXX-XXX-XXXX)

FAX:	847-647-8498		
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Not Listed
*Submitter's First Name	(b)(6)
*Submitter's Last Name	
*Submitter's Phone Number:	847-647-9325(XXX-XXX-XXXX)
*Today's Date:	04/26/2005(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 04/26/2005
Verified:
Reviewed:
Date Entered:
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