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:

Product Code: 2126.01

* 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 Nobivac Lyme	165A/286	216110	
2			
3			
4			

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	LT	22	02/20/2010
2				
3				
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	02/02/2010
Concurrent Drugs or Procedures:	Heartworm/Lyme/Ehrilichia/Anaplasma bloodwork (40x)

Event Information

* Event description: ☒ Some other event - Describe Below

Explain the event and any treatment in a concise paragraph:
02/24/10 patient returned to hospital weak with 105 temp. Bloodwork showed mild ALP elevation & mild increase WBC count with left shift. Abdominal radiograhs unremarkable. Patient responded to fluids, antibotics and steroids

and was released.

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
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*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 :	Labrador	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	11.5 yrs		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
Hx of mild laryngeal paralysis oplenectomy 12/08 due to splenic himatoma

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Grayslake Animal Hospital 1490 E Belvidare	Address:	
City:	Graplate	City:	
State:	IL	State:	
Zip:	60030	Zip:	
*Phone	(b)(6) XXX-XXX-XXXX)	Phone:	X-XXXX)
FAX:	847-223-8625		
E-mail:	(b)(6)	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:	
*Today's Date:	07/19/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 08/20/2010
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

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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: AIV10371
Product Code: 2126.01
* 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 Nobivac Lyme	286	216113	☒ Bacterial
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 hip	22	04/19/2010
2				
3				
4				

Administered by:	☒ Non-veterinarian
*Date of Product Use:(MM/DD/YYYY)	04/19/2010
Concurrent Drugs or Procedures:	none

Event Information

* Event description: ☒ Local

Explain the event and any treatment in a concise paragraph:
Vaccination (booster from 3/29 initial) given @ 2pm 4/19. At 6:40 pm vet paged by owner for swelling around the left hip area. It was advised to ice the area & to give 25 mg benadryl (had 25mg earlier for allergies..routinely gets 25 mg BID during the season). Rechecked today & while still swollen, it is less per owner. Vitals ok. Advised to continue

ice, benadryl & monitor.

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)	4.5 hrs
Attending veterinarian's level of suspicion that product caused event:	☒ Medium
*Outcome (select one):	☒ Recovered with treatment
Other:	

Animal Information

Case Identification:	Chase Robbins	**For animals handled in a group (herd, litter, etc.)**	
*Species:	☒ Canine (Dog)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Maltese mix	Number vaccinated:	1
Sex:	☒ Male	Number dead:	0
Neutered:	☒ Yes		
Age (i.e., 2 yrs or 2 mos):	11 yrs		

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

Personal Information

Veterinarian		Owner	
*Name:	(b)(6)	Name:	(b)(6)
Address:	Grayslake Animal Hospital 1490 East Belvidere Road	Address:	
City:	Grayslake	City:	
State:	IL	State:	
Zip:	60030	Zip:	
*Phone	(b)(6) XXX-XXX-XXXX)	Phone:	
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:	
*Today's Date:	04/20/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 04/20/2010
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

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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: AIV10300

Product Code: 13D1.29 2126.01 1905.24 12X1.20

* Required Fields

Product Information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (Est. No.) or Manufacturer Name	Serial (lot) Number	Type of Product
1 Duramune Max 5	112	916504A	☒ Viral
2 Nobivac Lyme	165A	216113	☒ Bacterial
3 Imrab 1 TF	298	22024C	☒ Viral
4 Intra-Trac 3	165A	54210A	☒ Combination

Administration of products.

Dose	Route	Site	Needle Size	Date Reconstituted
1 1 ml	SQ	R shoulder	22	03/02/2010
2 1 ml	SQ	LR leg	22	03/02/2010
3 1 ml	SQ	RR leg	22	03/02/2010
4 1 ml	IN	intranasal		03/02/2010

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	03/02/2010
Concurrent Drugs or Procedures:	physical exam, heartworm test

Event Information

* Event description: ☒ Systemic

Explain the event and any treatment in a concise paragraph:
pain, lethargy, trembling. dog was seen & treated at local emergency hospital. presenting complaints were marked pain in left rear leg, lethargy, & trembling. presented night of vaccination. attending clinician administered diphenhydramine & anti-inflammatory 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)	5-6 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 :	Shihtzu	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.):
acquired as puppy from breeder. housed with another dog. has been vaccinated previously (annually & puppy boosters). this is 1st time vaccinated with Nobivac product (Lyme), used LymeVax from Ft. Dodge previously.

Personal Information

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

*Today's Date:	03/03/2010(MM/DD/YYYY)
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 03/03/2010
Verified:yes
Reviewed:yes
Date Entered: 08/18/2010
CVB Reporter:
Acknowledgement: yes

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