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: AIV10120
Product Code: 1515.2A 4865.00 1991.R1
* 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 Calvenza EIV/EHV	124	326015A	☒ Viral
2 Encevac-T with Havlogen	286	06689901B	☒ Viral
3 PreveNile	286	07968007	☒ Viral
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Rec
1 2 ml	IM	neck	20	10/14/200
2 1 ml	IM	neck	20	10/14/200
3 1 ml	IM	neck	20	10/14/200
4				

Administered by:	☒ Veterinarian (or veterinary staff)
*Date of Product Use:(MM/DD/YYYY)	10/14/2009
Concurrent Drugs or Procedures:	3 vaccines, no other drugs or procedures

Event Information

* Event description: ☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
5 year old paint horse, no known vaccine history, first time treating horse, horse bright and alert on arrival, gave all three vaccines in the muscle on the left side of the neck, it was raining at the time, so gave vaccines under mane in triangle region because it was the only dry region of the horse, pulled back on each syringe no blood so adminstered in the muscle, horse did not react to needles, vet and three others with horse for 5 minutes after administering vaccines, horse bright and alert when leaving horse, one hour later horse found dead near the location that we left the horse, no outer signs of distress on horse when found dead.

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.

All redactions on this page are pursuant to (b)(6).

Onset (How long after product use did the event begin?): (Include Units:mins, hrs, days, wks, mos, yrs)	within an hour
Attending veterinarian's level of suspicion that product caused event:	☒ Not Listed
*Outcome (select one):	☒ Died
Other:	

Animal Information

Case Identification:	Lakota	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Equine (Horse)	Number in group:	1
(Other Species):		Number affected:	1
Breed :	Paint horse	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.):
no known vaccine history, first time for us to vaccinate horse, owner has owned horse for the last 10 months, in dirt lot pastu
trail horse, alfalfa diet

Personal Information

Veterinarian		Owner	
*Name:		Name	
Address:		Address	
City:		City	
State:		State	
Zip		Zip	
*Phone		Phone	
FAX			
E-mail:		E-mail:	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name	
*Submitter's Last Name	
*Submitter's Phone Number	
*Today's Date	
Relationship to animal:	☒ Veterinarian
Other:	

Submit

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

Date Received: 10/16/2009
Verified:yes
Reviewed:yes
Date Entered: 02/01/2010
CVB Reporter:
Acknowledgement:

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: AIV10312
Product Code: 1905.23 4845.33 1991.R1
* 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 EquiRab with Havlogen	286	91698901B	☒ Viral
2 Prestige V with Havlogen	286	09998902B	☒ Combination
3 PreveNile	286	07969006	☒ Viral
4			☒ [Click arrow for selections]

Administration of products.

Dose	Route	Site	Needle Size	Date Rec
1 1 ml	IM	R neck	20	11/01/201
2 1 ml	IM	L neck	20	11/01/201
3 1 ml	IM	L neck	20	03/04/201
4				

Administered by:	☒ Non-veterinarian
*Date of Product Use:(MM/DD/YYYY)	03/04/2010
Concurrent Drugs or Procedures:	none (3 vaccines only)

Event Information

* Event description: ☒ Anaphylaxis/Hypersensitivity

Explain the event and any treatment in a concise paragraph:
1 minute after administration of vaccines horse fell down. Veterinarian was on site, and administered epinephrine (4 cc IM) immediately. The horse died less than 30 seconds later.

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 mins
Attending veterinarian's level of suspicion that product caused event:	☒ High
*Outcome (select one):	☒ Died

All redactions on this page are pursuant to (b)(6).

Other:	

Animal Information

Case Identification:	Little Bit	For animals handled in a group (herd, litter, etc.)	
*Species:	☒ Equine (Horse)	Number in group:	85
(Other Species):		Number affected:	1
Breed :	Appendix	Number vaccinated:	6
Sex:	☒ Female	Number dead:	1
Neutered:	☒ No		
Age (i.e., 2 yrs or 2 mos):	4 yrs		

History and Environment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc.):
Healthy young horse, stabled, died after receiving vaccination

Personal Information

Veterinarian		Owner	
*Name:		Nam	
Address:		Addres	
City:		Cit	
State:		Stat	
Zip		Zi	
*Phone		Phon	
FAX			
E-mail:		E-ma	

This event has been reported to the manufacturer(s):	☒ Yes
*Submitter's First Name:	
*Submitter's Last Name:	
*Submitter's Phone Number:	
*Today's Date:	
Relationship to animal:	
Other:	

Submit

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

Date Received: 03/08/2010
Verified:yes
Reviewed:yes
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