



July 22, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-13

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
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Ames, IA 50010

(515) 337-6100

TO: VS Management Team (VSMT)
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS

FROM: Richard E. Hill, Jr. /s/ Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

SUBJECT: Issuance of Licenses

The purpose of this notice is to bring to the attention of interested parties licenses issued and terminated during the months of April, May, and June 2009. These do not include those licenses reissued to update pertinent information. A product license or permit for distribution and sale has been issued for each of the following:

True Name	Product Code	Establishment/ Permittee	Date
Autogenous Vaccine, Killed Virus	1015.10	Hygieia Biological Laboratories, Est. 407	04/02/09
Bursal Disease Vaccine, Live Virus	1271.01	Biomune Company, Est. 368	05/27/09
Bursal Disease Vaccine, Live Virus	1271.16	Schering-Plough Animal Health Corporation, Est. 226	04/20/09
Equine Influenza Vaccine, Killed Virus	1505.28	Wyeth, Est. 112	04/03/09
Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus	1515.2A	Wyeth, Est. 112	04/03/09
Feline Leukemia-Rhinotracheitis-Calici- Panleukopenia Vaccine, Killed Virus	15B5.21	Wyeth, Est. 112	06/29/09



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Canine Influenza Vaccine, H3N8, Killed Virus	15K5.20	Schering-Plough Animal Health Corporation, Est. 165A	05/27/09
Fowl Laryngotracheitis-Marek's Disease Vaccine, Serotypes 2 & 3, Modified Live & Live Marek's Disease Vector	16J1.R2	Intervet, Inc., Est. 286	06/08/09
West Nile Virus Vaccine, Killed Virus	1995.22	Wyeth, Est. 112	05/11/09
Borrelia Burgdorferi Bacterin	2126.01	Schering-Plough Animal Health Corporation, Est. 165A	05/08/09
Haemophilus Parasuis-Mycoplasma Hypopneumoniae Bacterin	2565.00	Pfizer Inc., Est. 189	06/29/09
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.10	Hygieia Biological Laboratories, Est. 407	04/02/09
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterial Extract	4639.28	Wyeth, Est. 112	06/29/09
Encephalomyelitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4835.24	Wyeth, Est. 112	04/03/09
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4845.24	Wyeth, Est. 112	04/03/09
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4847.24	Wyeth, Est. 112	04/03/09
Encephalomyelitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4875.24	Wyeth, Est. 112	04/03/09
Chronic Wasting Disease Antigen Test Kit, ELISA	5420.22	Bio-Rad Laboratories, Est. 624	05/27/09
Allergenic Extract, House Dust	9521.00	Allergy Laboratories, Inc., Est. 629	06/08/09

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Allergenic Extract, Mixed Ragweed	9522.01	Allergy Laboratories, Inc., Est. 629	05/08/09
Allergenic Extract, Mixed Epidermals	9527.00	Allergy Laboratories, Inc., Est. 629	06/08/09
Allergenic Extract, Mixed Insects	9528.00	Allergy Laboratories, Inc., Est. 629	06/08/09
Allergenic Extract, Mixed Mites	95A1.00	Allergy Laboratories, Inc., Est. 629	05/08/09
Bursal Disease Virus, Live Virus	A271.50	Charles River Laboratories, Inc., Est. 344	05/27/09
Clostridium Sordellii, Killed Culture	GC90.00	Pfizer Inc., Est. 189	06/08/09

Prionics USA, Inc., Est. No. 582A (Permittee), acquired the following product from Pfizer Inc., Est. No. 189, on May 26, 2009:

Mycobacterium Tuberculosis Gamma Interferon Test Kit, For Non-Human Primates, Code 5A64.20

The establishment license and following product license for CAVL (a division of Walco International, Inc.), Est. No. 364, were terminated without prejudice on May 27, 2009:

Autogenous Bacterin, Code 2051.00

The establishment license and following product license for Dow AgroSciences, LLC, Est. No. 642, were terminated without prejudice on April 1, 2009:

Newcastle Disease Vaccine, Subunit, Code 1705.P0

The following product licenses for Wyeth, Est. 112, were terminated without prejudice on April 30, 2009:

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.12

Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus, Code 1331.22

Canine Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Code 1441.27

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Equine Influenza Vaccine, Killed Virus, Code 1505.22

Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.24

Giardia Lamblia Vaccine, Killed Protozoa, Code 18G5.01

Parvovirus Vaccine, Modified Live Virus, Code 18M1.22

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid, Code 4835.21

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid, Code 4845.21

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid, Code 4847.21

Encephalomyelitis-Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid, Code 4875.21

The following product licenses for United Vaccines, Inc., Est. 245, were terminated without prejudice on June 8, 2009:

Mink Distemper Vaccine, Modified Live Virus, Code 1451.02

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Code 1679.30

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Code 1679.32

Mink Enteritis Vaccine, Killed Virus, Code 1685.20

Mink Enteritis Vaccine, Killed Virus, Code 1685.22

Pseudomonas Aeruginosa Bacterin, Code 2735.02

Mink Distemper Vaccine, Modified Live Virus, Clostridium Botulinum Type C Bacterin-Toxoid, Code 4919.00

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Clostridium Botulinum Type C Bacterin-Toxoid, Code 4929.30

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Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus,
Clostridium Botulinum Type C Bacterin-Toxoid, Code 4929.32

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus,
Clostridium Botulinum Type C-Pseudomonas Aeruginosa Bacterin-Toxoid,
Code 4949.30

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus,
Clostridium Botulinum Type C-Pseudomonas Aeruginosa Bacterin-Toxoid,
Code 4949.32

Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C Bacterin-
Toxoid, Code 4955.20

Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C Bacterin-
Toxoid, Code 4955.22

Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C-
Pseudomonas Aeruginosa Bacterin-Toxoid, Code 49A5.20

Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C-
Pseudomonas Aeruginosa Bacterin-Toxoid, Code 49A5.22

Aleutian Disease Virus Counterelectrophoresis Antigen, Code 5001.02

Aleutian Disease Virus Counterelectrophoresis Antigen, Mink Origin,
Code 5005.00

Clostridium Botulinum Type C Bacterin-Toxoid, Code 7010.02

Clostridium Botulinum Type C-Pseudomonas Aeruginosa Bacterin-Toxoid,
Code 7020.00

The following product license for IDEXX Laboratories, Inc., Est. 313, was terminated
without prejudice on April 13, 2009:

Pseudorabies Virus Antibody Test Kit, Code 5110.01

The following product license for Binax, Inc., Est. 330, was terminated without prejudice
on May 27, 2009:

Canine Heartworm Antigen Test Kit, Code 5018.01