



October 7, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-22

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
P.O. Box 844
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/ Byron E. Rippke, for
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 July, August, and September 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
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live Virus	1171.27	Pfizer Inc., Est. 189	8/28/09
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.28	Pfizer Inc., Est. 189	8/28/09
Bronchitis Vaccine, Conn Type, Live Virus	1231.15	Merial Select, Inc., Est. 279	9/3/09
Bronchitis Vaccine, Georgia Type, Live Virus	1231.1J	Wyeth, Est. 112	9/1/09
Autogenous Bacterin	2051.00	ProtaTek International, Inc., Est. 329	9/1/09
Autogenous Bacterin	2051.04	Newport Laboratories, Inc., Est. 455	8/5/09
Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.06	Pfizer Inc., Est. 189	8/28/09



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-22

Page 2

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 & 4 & 3X4	2703.19	Lohmann Animal Health International, Est. 196	8/4/09
Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.07	Pfizer Inc., Est. 189	8/28/09
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4469.24	Pfizer Inc., Est. 189	9/9/09
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44B1.23	Pfizer Inc., Est. 189	9/9/09
Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46E5.24	Wyeth, Est. 112	9/28/09
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Hardjo Bacterin	4L49.20	Pfizer Inc., Est. 289	9/9/09
Tetanus Antitoxin, Equine Origin	6302.01	Colorado Serum Company, Est. 188	8/31/09
Allergenic Extract, Mixed Trees	9522.02	Allergy Laboratories, Inc., Est. 629	8/7/09
Allergenic Extract, Mixed Weeds	9522.04	Allergy Laboratories, Inc., Est. 629	8/7/09
Allergenic Extract, Mixed Molds	9523.00	Allergy Laboratories, Inc., Est. 629	8/7/09
Allergenic Extract, Mixed Inhalants	9524.00	Allergy Laboratories, Inc., Est. 629	8/4/09

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-22

Page 3

Autogenous Killed Culture	B051.00	ProtaTek International, Inc., Est. 329	8/5/09
---------------------------	---------	--	--------

The establishment license and following product for Quadraspec, Inc., Est. No. 583, were terminated without prejudice on September 15, 2009:

Canine Heartworm Antigen Test Kit, Code 5018.00

The Permit for Distribution and Sale of the following product for Diagnostic Chemicals Limited (USA), Permittee No. 610, was terminated without prejudice on September 29, 2009:

Canine Parvovirus Antigen Test Kit, Blot Test, Code 5024.50

The following product licenses for Schering-Plough Animal Health Corporation, Est. 165A, were terminated without prejudice on July 1, 2009:

Bordetella Avium, Avirulent Live Culture, Code A021.00

Avian Encephalomyelitis-Fowl Pox Vaccine, Live Virus, Code 10M1.10

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Code 1171.21

Bursal Disease Vaccine, Live Virus, Code 1271.10

Escherichia Coli Vaccine, Avirulent Live Culture, Avian Isolate, Code 1551.01

Fowl Laryngotracheitis Vaccine, Modified Live Virus, Code 1601.11

Fowl Laryngotracheitis Vaccine, Live Virus, Code 1601.12

Fowl Pox Vaccine, Live Virus, Code 1621.10

Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus, Code 1711.10

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. Type, Live Virus, Code 1761.11

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Conn. Type, Live Virus, Code 1761.13

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-22

Page 4

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Conn. Types, Live Virus, Code 1761.17

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass. Type, Live Virus, Code 1771.12

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass. and Conn. Types, Live Virus, Code 1771.17

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Ark. Types, Live Virus, Code 17A1.1M

Pasteurella Multocida Vaccine, Avirulent Live Culture, Avian Isolate, Code 1871.01

Pasteurella Multocida Vaccine, Avirulent Live Culture, Avian Isolate, Code 1871.02

Pigeon Pox Vaccine, Live Virus, Code 1881.10

Pseudorabies-Swine Influenza Vaccine, Modified Live and Killed Virus, Code 1899.R0

Swine Influenza Vaccine, Killed Virus, Code 19A5.10

Swine Influenza Vaccine, H1N1, Killed Virus, Code 19A5.13

Swine Influenza Vaccine, H3N2, Killed Virus, Code 19A5.25

Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Code 19A5.42

Porcine Rotavirus Vaccine, Killed Virus, Code 19E5.20

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin, Code 2101.00

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin, Code 2108.00

Ehrlichia Risticii Bacterin, Code 2639.00

Escherichia Coli Bacterin, Code 2648.62

Actinobacillus Pleuropneumoniae-Erysipelothrix Rhusiopathiae-Haemophilus Parasuis Bacterin, Code 264C.00

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-22

Page 5

Actinobacillus Pleuropneumoniae- Haemophilus Parasuis Bacterin,
Code 2A74.00

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus
Toxoid, Code 4835.20

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid,
Code 4865.00

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Ehrlichia Risticii-
Tetanus Bacterin-Toxoid, Code 4866.20

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira
Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin,
Code 48C5.20

Swine Influenza Vaccine, Killed Virus, Mycoplasma Hyopneumoniae Bacterin,
Code 4995.00

Porcine Rotavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-
Escherichia Coli Bacterin-Toxoid, Code 49C5.20

Porcine Reproductive and Respiratory Syndrome-Parvovirus Vaccine,
Reproductive Form, Modified Live and Killed Virus, Erysipelothrix
Rhusiopathiae-Leptospira Bratislava-Canicola-Grippytyphosa-Hardjo-
Icterohaemorrhagiae-Pomona Bacterin, Code 49S1.20

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus,
Ehrlichia Risticii-Tetanus Bacterin-Toxoid, Code 4A35.40

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira
Bratislava-Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona
Bacterin, Code 4BC5.20

Porcine Reproductive and Respiratory Syndrome-Parvovirus Vaccine,
Reproductive Form, Modified Live and Killed Virus, Erysipelothrix
Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-
Pomona Bacterin, Code 4PS9.20

The following product licenses for Lohmann Animal Health International, Est. 196, were
terminated without prejudice on September 10, 2009:

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.00

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.01

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-22

Page 6

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.02

Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 1651.01

Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 1651.02

Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 1651.03

Marek's Disease Vaccine, Serotype 1, Live Virus, Code 16L1.00

Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Code 16L1.02

Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Code 16L1.05

ARCHIVED