



October 14, 2008

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-17

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Subject: Issuance of Licenses

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

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 2008. 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	1171.24	Pfizer Inc., Est. 189	8/12/08
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.23	Pfizer Inc., Est. 189	8/12/08
Marek's Disease Vaccine, Serotypes 1 & 3, Live Herpesvirus Chimera	1631.R0	Schering-Plough Animal Health Corp., Est. 165A	9/29/08
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus	19A5.23	Pfizer Inc., Est. 189	8/1/08
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus	19A5.29	Pfizer Inc., Est. 189	8/1/08
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae Bacterin	4993.21	Pfizer Inc., Est. 189	8/1/08
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hypopneumoniae Bacterin	4994.23	Pfizer Inc., Est. 189	8/1/08
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hypopneumoniae Bacterin	4994.24	Pfizer Inc., Est. 189	8/1/08



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Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Mycoplasma Hypopneumoniae Bacterin	4995.25	Pfizer Inc., Est. 189	8/1/08
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Mycoplasma Hypopneumoniae Bacterin	4995.26	Pfizer Inc., Est. 189	8/1/08
Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49F6.23	Pfizer Inc., Est. 189	7/24/08
Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49F6.24	Pfizer Inc., Est. 189	8/1/08
Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49G6.23	Pfizer Inc., Est. 189	7/24/08
Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49G6.24	Pfizer Inc., Est. 189	8/1/08
Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector, Mycoplasma Hypopneumoniae Bacterin	49K5.R1	Boehringer Ingelheim Vetmedica, Inc., Est. 124	7/22/08
Canine Heartworm Antigen Test Kit	5018.00	SafePath Laboratories LLC, Est. 430	7/25/08
Avian Influenza Virus Type A Antigen Test Kit	5180.50	Inverness Medical Innovations, Est. 330	7/23/08
Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA	5430.22	Bio-Rad Laboratories, Est. 624	8/22/08
Canine Parvovirus, Modified Live Virus	A8M1.23	Intervet Inc., Est. 286	8/21/08

The Establishment License and following product for Merck Sharp & Dohme, Est. No. 3, were terminated on July 29, 2008:

Rubeola Virus, Live Virus, Code A661.00

The Establishment License and following product for Immune Modulators, LLC, Est. No. 606, were terminated on August 13, 2008:

Bacterial Immunomodulator, Killed Bacteria, Code 9200.00

The Permit for Distribution and Sale of the following products for Abbott Laboratories, Permittee No. 460A, was terminated without prejudice on August 21, 2008:

Feline Leukemia Virus Antigen Test Kit, Code 5028.00

Canine Parvovirus Antigen Test Kit, Code 5024.00

The Permit for Distribution and Sale of the following product for Abbott Laboratories, Permittee No. 460B, was terminated on August 21, 2008:

Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA, Code 5430.20

The following product license for Wyeth, Est. 112, was terminated without prejudice on September 29, 2008:

Sarcocystis Neurona Vaccine, Code 1SN5.20

The following product licenses for Pfizer Inc., Est. 189, were terminated without prejudice on July 24, 2008:

Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus, Code 1091.21

Bovine Rhinotracheitis Vaccine, Modified Live Virus, Code 1101.22

Bovine Rhinotracheitis-Parainfluenza3 Vaccine, Modified Live Virus,
Code 1121.22

Bovine Rhinotracheitis-Parainfluenza3 Vaccine, Modified Live Virus,
Code 1121.23

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus,
Code 1151.25

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live and Killed Virus, Code 1157.22

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

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Code 1187.22

Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Code 11A1.25

Bovine Virus Diarrhea Vaccine, Killed Virus, Code 1205.22

Bordetella Bronchiseptica Bacterin, Code 2100.01

Erysipelothrix Rhusiopathiae Bacterin, Code 2641.00

Actinobacillus Pleuropneumoniae Bacterin, Code 2657.02

Leptospira Hardjo Bacterin, Code 26M7.00

Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin, Code 40A6.20

Bovine Rhinotracheitis-Parainfluenza3 Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin, Code 4139.20

Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4367.25

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3 Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin, Code 44H9.30

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Bordetella Bronchiseptica Bacterin, Code 46E9.21

Canine Parainfluenza Vaccine, Modified Live Virus, Bordetella Bronchiseptica Bacterin, Code 47A1.20

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4975.20

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida
Bacterin-Toxoid, Code 7054.00

The following product license for Lohmann Animal Health International, Est. 196, was terminated without prejudice on July 16, 2008:

Marek's Disease Vaccine, Serotype 2, Live Virus, Code 1631.00

The following product licenses for Lohmann Animal Health International, Est. 196, were terminated without prejudice on September 22, 2008:

Avian Reovirus Vaccine, Killed Virus, Code 1045.00

Bursal Disease Vaccine, Standard & Variant, Killed Virus, Code 12B5.40

The following product licenses for Merial Select, Inc., Est. 279, were terminated without prejudice on August 14, 2008:

Bursal Disease-Marek's Disease Vaccine, Standard & Variant, Serotypes 2 & 3,
Live Virus, Code 12C8.41

Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus, Code 1711.11

Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus, Code 1721.10

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Conn Types, Live
Virus, Code 1761.1X

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass Type, Live Virus,
Code 1771.18

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on August 7, 2008:

Bursal Disease Virus, Killed Virus, Code A275.00

Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture,
Code A861.00

Bursal Disease Vaccine, Killed Virus, Code 1275.00

Bursal Disease Vaccine, Killed Virus, Code 1275.10

Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code 12B5.40

Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus,
Code 12D5.00

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.10

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.40

Bursal Disease-Newcastle Disease Vaccine, Standard and Variant, Killed Virus,
Code 12G5.41

Bursal Disease-Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus,
Code 12J5.40

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard and Variant,
Mass. Type, Killed Virus, Code 12J5.60

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and
Variant, Mass. Type, Killed Virus, Code 12M5.00

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass. Type,
Killed Virus, Code 12M5.10

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant,
Killed Virus, Code 12P5.40

Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture,
Code 1861.00

The following product licenses for Intervet Inc., Est. 286, were terminated without
prejudice on September 17, 2008:

Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.23

Fusobacterium Necrophorum Bacterin, Code 2556.00

Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona
Bacterin, Code 2665.00

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-
Icterohaemorrhagiae-Pomona Bacterin, Code 2863.00

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western, and
Venezuelan, Killed Virus, Tetanus Toxoid, Code 4847.31

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The following product license for IDEXX Laboratories, Inc., Est. 313, was terminated without prejudice on September 26, 2008:

Bovine Leukemia Virus Antibody Test Kit, Code 5505.20

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics