

April 18, 2005

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-09

Subject: Issuance of Licenses

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
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 January, February and March 2005. 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
Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.20	Intervet Inc., Est. 286	3/17/05
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.22	Intervet Inc., Est. 286	3/29/05
Mink Distemper Vaccine, Modified Live Virus	1451.02	United Vaccines, Inc., Est. 245	3/15/05
Escherichia Coli Vaccine, Avirulent Live Culture	1551.02	ARKO Laboratories Ltd., Est. 337	3/4/05
Marek's Disease Vaccine, Serotype 3, Live Virus	1641.06	Intervet Inc., Est. 286	1/10/05
Newcastle Disease Vaccine, Killed Virus	1705.13	Wyeth Est. 112	1/24/05
Flavobacterium Columnare Vaccine Avirulent Live Culture	17F1.00	Intervet Inc., Est. 286	3/24/05
Escherichia Coli Bacterin	2648.63	Schering-Plough Animal Health Corp., Est. 165A	3/30/05
Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.01	Schering-Plough Animal Health Corp., Est. 165A	3/29/05
Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.01	Intervet Inc., Est. 286	3/31/05
Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.01	Intervet Inc., Est. 286	3/29/05

True Name	Product Code	Establishment/ Permittee	Date
Bovine IgG	3606.00	Land O'Lakes Animal Health Milk Products Company, Permittee 612A	3/31/05
Bovine Rhinotracheitis-Virus Diarrhea- Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo- Icterohaemorrhagiae-Pomona Bacterin	4461.20	Schering-Plough Animal Health Corp., Est. 165A	3/29/05
Bovine Rhinotracheitis Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin- Toxoid	45H5.20	Texas Vet Lab, Inc., Est. 290	3/30/05
Encephalomyelitis-Rhinopneumonitis- Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid	4847.31	Intervet Inc., Est. 286	2/2/05
Canine Parvovirus Antigen Test Kit	5024.05	Synbiotics Corp., Est. 312	2/23/05
Scrapie Antigen Test Kit, ELISA	5410.20	Bio-Rad Laboratories, Est. 624	3/4/05
Swine Influenza Virus Antibody Test Kit, H3N2	59A5.01	IDEXX Laboratories, Inc., Est. 313	2/9/05
Clostridium Perfringens Type A Toxoid	8081.00	Schering-Plough Animal Health Corp., Est. 165A	1/19/05
Allergenic Extract Prescription Product	9531.00	Pet Allergy Laboratory, Inc., Est. 643	2/8/05
Canine Coronavirus Vaccine, Killed Virus	A4P5.20	VacciCel, Inc., Est. 292	12/14/04
Leptospira Canicola-Grippotyphosa-Hardjo- Icterohaemorrhagiae-Pomona Bacterin	B665.03	Pfizer Inc., Est. 189	3/29/05
Canine Parvovirus Antigen Test Kit	E024.05	Synbiotics Corp., Permittee 312C	2/23/05
Canine Parvovirus Antigen Test Kit	E024.05	LMD Agro-Vet LLC, Est. 430	2/23/05
Clostridium Perfringens Type A Toxoid	H081.00	Schering-Plough Animal Health Corp., Permittee 311	1/19/05

U.S. Veterinary Biologics Permit No. 612A was issued on March 31, 2005, to the following:

Land O'Lakes Animal Milk Products Company
MAIL: Land O'Lakes Animal Milk Products Company
1080 County Road F West
Shoreview, Minnesota 55126

U.S. Veterinary Biologics Establishment License No. 643 was issued on February 8, 2005, to the following:

Pet Allergy Laboratory, Inc.
13581 Pond Springs Road, Suite 303
Austin, Texas 78729
MAIL: Pet Allergy Laboratory, Inc.
13581 Pond Springs Road, Suite 303
Austin, Texas 78729

U.S. Veterinary Biologics Permit No. 189C was issued on February 7, 2005, to the following:

Pfizer Inc.
MAIL: Pfizer Animal Health
601 West Cornhusker Highway
Lincoln, Nebraska 68521

Due to the acquisition of Bayer Healthcare LLC, Permittee No. 52B, by Pfizer Inc., Permittee No. 189C, the following product listed on Permit 52B has been reissued on Permit 189C:

Parapox Ovis Immunomodulator, Code 9330.00

The following product licenses for Wyeth, Est. 112, were terminated without prejudice on March 8, 2005:

Avian Encephalomyelitis-Fowl Pox Vaccine, Live Virus, Code 10M1.11

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus, Code 1175.21

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1185.21

Bursal Disease Vaccine, Killed Virus, Code 1275.01

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.11

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.13

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 12J5.42

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Code 13D1.24

Canine Coronavirus Vaccine, Modified Live Virus, Code 14P1.20

Canine Coronavirus-Parvovirus Vaccine, Modified Live and Killed Virus, Code 14R7.21

Feline Leukemia-Rhinotracheitis-Calici Vaccine, Killed Virus, Code 15L5.20

Feline Leukemia-Rhinotracheitis-Calici Vaccine, Modified Live Virus and Killed Virus, Code 15L9.21

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

Feline Rhinotracheitis-Calici Vaccine, Killed Virus, Code 16C5.20

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Rabies Vaccine, Modified Live Virus & Killed Virus, Code 16S9.20

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. Type, Live Virus, Code 1761.12

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

Parvovirus Vaccine, Killed Virus, Code 18P5.00

Transmissible Gastroenteritis Vaccine, Modified Live Virus, Code 1961.20

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin, Code 2106.01

Borrelia Burgdorferi Bacterial Extract, Code 2126.02

Leptospira Canicola-Icterohaemorrhagiae Bacterin, Code 2671.02

Escherichia Coli Bacterin, Code 26R8.E2

Streptococcus Equi Bacterin, Code 2855.00

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4435.20

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4638.31

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 46J9.22

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 46J9.24

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid, Code 4865.21

Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus, Mycoplasma Galliepticum-Synoviae Bacterin, Code 48C6.10

Transmissible Gastroenteritis Vaccine, Modified Live Virus, Clostridium Perfringens Type C Toxoid, Code 49M9.20

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Ehrlichia Risticii-Tetanus Bacterin-Toxoid, Code 4B35.40

Pullorum Antigen, Stained Antigen K Polyvalent, Code 5206.00

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin-Toxoid, Code 7054.01

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid, Code 7060.01

Clostridium Perfringens Type C. Toxoid, Code 8101.00

The following product license for Boehringer Ingelheim Vetmedica, Inc., Est. 124, was terminated without prejudice on February 7, 2005:

Bovine Rhinotracheitis-Parainfluenza₃ Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin, Code 4165.00

The following product licenses for Synbiotics Corporation, Est. 312, were terminated without prejudice on January 28, 2005:

Brucella Abortus Antibody Test Kit, Code 5013.00

Bovine Leukemia Antibody Test Kit, Code 5505.21

The following product licenses for ALK-Abello, Inc., Est. 259, were terminated without prejudice on February 28, 2005:

Allergenic Extract, Flea Antigen, Code 9525.00

Allergenic Extract, Intradermal Test Kit, Code 9532.00

The following product license for International Duck Research Cooperative, Inc., Est. 268, was terminated without prejudice on February 2, 2005:

Riemerella Anatipestifer Bacterin, Code 2698.00

The following product licenses for IDEXX Corporation, Est. 313, were terminated without prejudice on January 28, 2005:

Canine Parvovirus Antigen Test Kit, Code 5024.01

Feline Infectious Peritonitis Antibody Test Kit, Code 5029.01

/s/ Richard E. Hill, Jr.

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