

April 10, 2006

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-10

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 2006. 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
Avian Influenza Vaccine, H5N2 Subtype, Killed Virus	10F5.10	Wyeth, Est. 112	2/24/06
Avian Influenza Vaccine, H5N9 Subtype, Killed Virus	10F5.11	Wyeth, Est. 112	2/24/06
Avian Influenza Vaccine, H7N2 Subtype, Killed Virus	10F5.12	Wyeth, Est. 112	2/24/06
Avian Influenza Vaccine, H7N3 Subtype, Killed Virus	10F5.13	Wyeth, Est. 112	2/24/06
Canine Distemper-Adenovirus Type 2 Vaccine, Modified Live Virus	13A1.20	Intervet Inc., Est. 286	3/23/06
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus-Rabies Vaccine, Modified Live & Killed Virus	13G9.20	Intervet Inc., Est. 286	3/10/06
Canine Distemper-Adenovirus Type 2-Parvovirus-Rabies Vaccine, Modified Live & Killed Virus	13H9.20	Intervet Inc., Est. 286	2/13/06
Coccidiosis Vaccine, Live Oocysts	1431.59	Viridus Animal Health, LLC, Est. 605	1/10/06
Newcastle Disease Vaccine, Subunit	1705.P0	Dow AgroSciences, LLC, Est. 642	1/27/06
Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Virus	1A82.50	Wyeth, Est. 112	3/31/06
Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus	1B82.50	Wyeth, Est. 112	3/31/06
Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.05	Pfizer Inc., Est. 189	3/23/06

True Name	Product Code	Establishment/ Permittee	Date
Mycoplasma Hyopneumoniae Bacterin	2775.02	Merial, Inc., Est. 298	1/5/06
Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.06	Pfizer Inc., Est. 189	3/23/06
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4461.22	Wyeth, Est. 112	3/7/06
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4465.20	Novartis Animal Health US, Inc., Est. 303	2/1/06
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44D7.22	Novartis Animal Health US, Inc., Est. 303	2/1/06
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.20	MVP Laboratories, Inc., Est. 301	3/10/06
Avian Influenza Virus Type A Antigen Test Kit	5180.50	Synbiotics Corp., Est. 312	1/24/06
Bovine Spongiform Encephalopathy-Scrapie Antigen Test Kit, EIA	5440.21	IDEXX Laboratories, Inc., Est. 313	2/14/06
Equine Infectious Anemia Virus Antibody Test Kit, ELISA	5515.00	VMRD, Inc., Est. 332	1/23/06
Allergenic Extract, Prescription Product	9531.00	Bio-Medical Services, Est. 627	1/3/06
Avian Influenza Virus Type A Antigen Test Kit	E180.50	Synbiotics Corp. Permittee 312B	1/24/06

U.S. Veterinary Biological Product Permit No. 312B was issued on January 24, 2006, to the following:

Synbiotics Corporation
 MAIL: Synbiotics Corporation
 11011 Via Frontera
 San Diego, California 92127

U.S. Veterinary Biologics Establishment License No. 627 was issued on January 3, 2006, to the following:

Bio-Medical Services
3921 Steck Avenue, Suite A-101
Austin, Texas 78759
MAIL: Bio-Medical Services
3921 Steck Avenue, Suite A-101
Austin, Texas 78759

U.S. Veterinary Biologics Establishment License No. 642 was issued on January 27, 2006, to the following:

Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, Indiana 46268
MAIL: Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, Indiana 46268

The following product license for Boehringer Ingelheim Vetmedica, Inc., Est. 124, was terminated without prejudice on March 20, 2006:

Tetanus Toxoid, Killed Culture, Code H601.00

The following product licenses for Pfizer Inc., Est. 189, were terminated without prejudice on March 31, 2006:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Code 1181.20

Erysipelothrix Rhusiopathiae Vaccine, Avirulent Live Culture, Code 1541.00

Parvovirus Vaccine, Modified Live Virus, Code 18M1.21

Actinobacillus Pleuropneumoniae-Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin, Code 2107.00

Bovine Virus Diarrhea Virus, Modified Live Virus, Code A201.21

Escherichia Coli Bacterin, Killed Culture, Code B648.04

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code D8C5.20

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code DBC5.20

The following product license for Heska Corporation, Est. 213, was terminated without prejudice on March 16, 2006:

Leptospira Canicola-Icterohaemorrhagiae-Pomona Bacterin, Code 2673.00

The following product licenses for Merial Select, Inc., Est. 279, were terminated without prejudice on March 31, 2006:

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

Bronchitis Vaccine, Ark. Type, Live Virus, Code 1231.22

Bursal Disease Vaccine, Live Virus, Code 1272.00

Bronchitis-Bursal Disease Vaccine, Mass. Type, Live Virus, Code 12F1.42

Bursal Disease-Newcastle Disease Vaccine, B₁ Type, B₁ Strain, Live Virus, Code 12G1.60

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

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. Type, Live Virus, Code 12J1.40

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. and Conn. Types, Live Virus, Code 1761.16

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

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. Type, Live Virus, Code 1761.19

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. and Conn. Types, Live Virus, Code 1761.1H

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. and Conn. Types, Live Virus, Code 1762.17

Hemorrhagic Enteritis Vaccine, Live Virus, Code 17E1.21

Escherichia Coli Bacterin, Code 2648.60

Bronchitis Virus, Mass. Type, Live Virus, Code A231.11

Bursal Disease Virus, Live Virus, Code A271.00

Bursal Disease Virus, Live Virus, Code A271.01

Marek's Disease Virus, Serotype 2, Live Virus, Code A631.00

Marek's Disease Virus, Serotype 3, Live Virus, Code A641.00

Marek's Disease Virus, Serotype 3, Live Virus, Code A641.01

Marek's Disease Virus, Serotype 1, Live Virus, Code A6L1.00

Newcastle Disease Virus, B₁ Type, B₁ Strain, Live Virus, Code A711.10

Newcastle Disease Virus, B₁ Type, LaSota Strain, Live Virus, Code A721.10

Newcastle Disease Virus, B₁ Type, LaSota Strain, Live Virus, Code A721.11

Bursal Disease Virus, Live Virus, Variant, Code A2B1.00

Bursal Disease Virus, Live Virus, Variant, Code A2B1.01

The following product licenses for Merial, Inc., Est. 298, were terminated without prejudice on February 24, 2006:

Feline Panleukopenia Vaccine, Killed Virus, Code 1565.20

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live and Killed Virus, Code 16D9.20

Parvovirus Vaccine, Killed Virus, Code 18P5.20

Bordetella Bronchiseptica Bacterin, Code 2100.01

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

Bordetella Bronchiseptica-Escherichia Coli Bacterin, Code 2112.01

Erysipelothrix Rhusiopathiae Bacterin, Code 2641.00

Escherichia Coli Bacterin, Code 2648.55

Actinobacillus Pleuropneumoniae Bacterin, Code 2657.00

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona-Pasteurella Multocida Bacterin, Code 4915.20

The Permit for Distribution and Sale of the following products for Lasher Associates, Inc., Permittee No. 305, was terminated without prejudice on March 9, 2006:

Mycoplasma Gallisepticum-Synoviae Antibody Test Kit, Code 5074.00

Newcastle-Bronchitis Virus Antibody Test Kit, Code 5081.00

Newcastle-Bursal Disease Virus Antibody Test Kit, Code 5082.00

The establishment license and the following product licenses for Bioport Corporation, Est. 308, were terminated without prejudice on March 9, 2006:

Clostridium Botulinum Type B Toxoid, Code 8010.00

Tetanus Toxoid, Code 8601.00

The following product licenses for IDEXX Laboratories, Inc., Est. 313, were terminated without prejudice on March 21, 2006:

Pseudorabies Virus Antibody Test Kit, Code 5110.03

Porcine Reproductive and Respiratory Syndrome Virus Antibody Test Kit, Code 59S5.00

The establishment license and the following product licenses for Kadel Vaccine Company, Est. 323, were terminated without prejudice on January 25, 2006:

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

Pasteurella Multocida Vaccine, Avirulent Live Culture, Bovine Isolate, Code 1871.06

Autogenous Bacterin, Code 2051.00

The establishment license and the following product license for Custom Dried Foods, Est. 400, were terminated without prejudice on March 9, 2006:

Bovine IgG, Code C606.00

/s/ Byron E. Rippke for

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