

October 17, 2005

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-20

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 July, August, and September 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
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus-Mannheimia Haemolytica- Pasteurella Multocida Vaccine, Modified Live Virus, Avirulent Live Culture	11A8.22	Intervet Inc., Est. 286	8/1/05
Bronchitis Vaccine, Georgia Type, Live Virus	1231.1J	Schering-Plough Animal Health Corp., Est. 226	7/21/05
West Nile Virus Vaccine, DNA	1995.D0	Wyeth, Est. 112	7/13/05
Arthrobacter Vaccine, Live Culture	1K11.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Aeromonas Salmonicida Bacterin	2035.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Aeromonas Salmonicida Bacterin	2035.01	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Aeromonas Salmonicida Bacterin	2035.02	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Autogenous Bacterin	2051.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05

True Name	Product Code	Establishment/ Permittee	Date
Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin	2138.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin	2138.01	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin	2138.02	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Edwardsiella Ictaluri Bacterin	2637.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Yersinia Ruckeri Bacterin	2638.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Erysipelothrix Rhusiopathiae Bacterin	2641.01	Schering-Plough Animal Health Corp., Est. 165A	7/12/05
Vibrio Anguillarum-Ordalii Bacterin	2858.03	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Flavobacterium Columnare Bacterin	2974.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Infectious Salmon Anemia Virus Vaccine, Killed Virus, Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin	4A45.20	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Babesia Caballi Antibody Test Kit, cELISA	501A.20	VMRD, Inc., Est. 332	8/16/05
Babesia Equi Antibody Test Kit, cELISA	501B.20	VMRD, Inc., Est. 332	8/16/05
Bovine Virus Diarrhea Antigen Test Kit	5A05.01	IDEXX Laboratories, Inc., Est. 313	8/5/05
Feline Panleukopenia Virus, Modified Live Virus	A561.20	Intervet Inc., Est. 286	9/8/05
Neospora Caninum, Killed Protozoa	AN15.20	Intervet Inc., Est. 286	8/31/05
Edwardsiella Ictaluri Bacterin	B637.00	Novartis Animal Health US, Inc., Permittee 303A	6/1/05
Porphyromonas Denticanis-Gulae-Salivosa, Killed Culture	B725.00	Pfizer Inc., Est. 189	8/24/05

U.S. Veterinary Biological Product Permit No. 303A was issued on June 1, 2005, to the following:

Novartis Animal Health US, Inc.
MAIL: Novartis Animal Health US, Inc.
1447 140th Street
Larchwood, Iowa 51241

The following product license for Wyeth, Est. 112, was terminated without prejudice on August 24, 2005:

Parvovirus Vaccine, Killed Virus, Code A8P5.21

The following product license for Boehringer Ingelheim Vetmedica, Inc., Est.124, was terminated without prejudice on August 24, 2005:

Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens
Types C & D Bacterin-Toxoid, Code 7160.01

The following product license for Boehringer Ingelheim Vetmedica, Inc., Est. 124 was terminated without prejudice on September 1, 2005:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus,
Haemophilus Somnus Bacterin, Code 44H5.20

The following product licenses for Lohmann Animal Health International, Est. 196, were terminated without prejudice on September 12, 2005:

Bronchitis Vaccine, Mass. and Ark. Types, Live Virus, Code 1231.13

Bronchitis Vaccine, Mass. and Conn. Types, Live Virus, Code 1231.14

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.16

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1232.10

Bronchitis Vaccine, Mass. Type, Killed Virus, Code 1235.10

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Killed Virus, Code 1245.40

Bursal Disease Vaccine, Killed Virus, Code 1275.01

Bursal Disease-Reovirus Vaccine, Killed Virus, Code 12D5.02

Bursal Disease-Reovirus Vaccine, Variant, Killed Virus, Code 12D5.41

Bronchitis-Bursal Disease-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12E5.4A

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

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

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12P5.41

Fowl Laryngotracheitis Vaccine, Live Virus, Code 1601.10

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. Type, Live Virus, Code 1761.18

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. Type, Live Virus, Code 1762.10

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

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass. and Ark. Types, Live Virus, Code 17A3.1M

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

Pigeon Pox Vaccine, Live Virus, Code 1881.11

Escherichia Coli Bacterin, Code 2648.46

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 and 3X4, Code 2704.00

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, and 4, Code 4635.40

Mycoplasma Gallisepticum Antigen, S-6 Serotype, Plate, Code 5071.00

Bronchitis Virus, Mass. Type, Live Virus, Code A231.12

Newcastle Disease Virus, B₁ Type, B₁ Strain, Live Virus, Code A711.11

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

Newcastle-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code A785.10

Pasteurella Multocida, Killed Culture, Avian Isolates, Types 1, 3, and 4,
Code B702.13

Bronchitis Virus, Killed Virus, Code E235.11

Bursal Disease Virus, Killed Virus, Code E275.10

Newcastle Disease Virus, B₁ Type, LaSota Strain, Killed Virus, Code E725.10

The following product license for Heska Corporation, Est. 213, was terminated without prejudice on August 16, 2005:

Transmissible Gastroenteritis Vaccine, Modified Live Virus, Bordetella
Bronchiseptica-Clostridium Perfringens Type C-Escherichia Coli-Pasteurella
Multocida Bacterin-Toxoid, Code 49J9.00

The following product license for Heska Corporation, Est. 213, was terminated without prejudice on August 24, 2005:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live
Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona
Bacterin, Code 4439.00

The following product license for Schering-Plough Animal Health, Est. 226, was terminated without prejudice on September 20, 2005:

Fowl Laryngotracheitis Vaccine, Modified Live Virus, Code 1601.11

The establishment license and the following product license for Aventis Pasteur, Inc., Est. 287, were terminated without prejudice on July 15, 2005:

Borrelia Burgdorferi Antigen, Code A026.R0

The establishment license and the following product licenses for Microbiological Associates, Inc., Est. 299, were terminated without prejudice on September 2, 2005:

Canine Distemper Virus Antibody Test Kit, Code 5020.00

Feline Leukemia Virus Antibody Test Kit, Code 5026.00

Feline Leukemia Virus Antigen Test Kit, Code 5028.00

Feline Infectious Peritonitis Antibody Test Kit, Code 5029.01

Mouse Hepatitis Virus Antibody Test Kit, Code 5061.00

Mycoplasma Pulmonis Antibody Test Kit, Code 5065.00

Mycoplasma Pulmonis Antibody Test Kit, Code 5065.01

Pneumonia Virus of Mice Antibody Test Kit, Code 5090.00

Pneumonia Virus of Mice Antibody Test Kit, Code 5090.01

Rat Coronavirus Sialodacryoadenitis Virus Antibody Test Kit, Code 5240.00

Sendai Virus Mouse Antibody Test Kit, Code 5280.00

Sendai Virus Rat Antibody Test Kit, Code 5280.01

Toxoplasma Gondii Antibody Test Kit, Code 5285.00

The following product license for Novartis Animal Health US, Inc., Permittee 303A, was terminated without prejudice on August 3, 2005:

Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin,
Code 2138.01

The following product license for Novartis Animal Health US, Inc., Permittee 303A, was terminated without prejudice on August 15, 2005:

Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin,
Code 2138.00

The following product licenses for Synbiotics Corporation, Est. 312, were terminated without prejudice on September 12, 2005:

Canine Heartworm Antigen Test Kit, Code 5018.03

Feline Leukemia Virus Antigen Test Kit, Code 5028.02

The following product license for ProtaTek International, Inc., Est. 329, was terminated without prejudice on August 22, 2005:

Ehrlichia Canis Antibody Test Kit, Code 5037.00

The establishment license and the following product licenses for Syracuse Bioanalytical, Inc., Est. 354, were terminated without prejudice on September 14, 2005:

Bovine Virus Diarrhea Antigen Test Kit, Code 5A05.01

Bovine Coronavirus Antigen Test Kit, Code 5C05.00

The establishment license and the following product license for Gull Laboratories, Inc., Est. 382, were terminated without prejudice on September 2, 2005:

Canine Borrelia Burgdorferi Antibody Test Modules, Code E017.00

The establishment license and the following product license for Alk Laboratories, Est. 416, were terminated without prejudice on July 28, 2005:

Allergenic Extract, Prescription Product, Code 9531.00

The establishment license and the following product licenses for ImmunoMed Corporation, Est. 421, were terminated without prejudice on September 2, 2005:

Rabies Vaccine, Killed Virus, Code 1905.51

Rabies Vaccine, Killed Virus, Code 1905.55

Rabies Virus, Killed Virus, Code A905.51

Rabies Virus, Killed Virus, Code A905.52

The Permit for Distribution and Sale of the following product for Roche Diagnostics Corporation, Permittee 626A, was terminated without prejudice on September 1, 2005:

Bovine Spongiform Encephalopathy Antigen Test Kit, Western Blot,
Code 5430.70

/s/ Richard E. Hill, Jr.

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