

January 9, 2003

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-01

Subject: Issuance of Licenses

To: Biologics Licenses, 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 October, November and December 2002. 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 Vaccine, Modified Live Virus	1181.23	Boehringer Ingelheim Vetmedica, Inc. Est. 124	10/09/02
Bronchitis Vaccine, Ark. Type, Live Virus	1231.1M	Wyeth, Est. 112	12/10/02
Coccidiosis Vaccine, Live Oocysts	1431.58	Viridus Animal Health, Est. 605	11/26/02
Canine Coronavirus-Parvovirus Vaccine, Modified Live and Killed Virus	14R7.29	Wyeth, Est. 112	12/10/02
Marek's Disease Vaccine, Serotype 3, Live Virus	1641.02	Lohmann Animal Health Intl., Est. 196	12/10/02
Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus	1651.03	Lohmann Animal Health Intl., Est. 196	12/10/02
Newcastle Disease Vaccine, Killed Virus	1705.14	Lohmann Animal Health Intl., Est. 196	11/20/02
Parvovirus Vaccine, Modified Live Virus	18M1.29	Wyeth, Est. 112	12/10/02
Rabies Vaccine, Killed Virus	1905.23	Merial, Inc., Est. 298	10/07/02
Swine Influenza Vaccine, H3N2, Killed Virus	19A5.25	Schering-Plough Animal Health Corp., Est. 165A	11/08/02

True Name	Product Code	Establishment/ Permittee	Date
Swine Influenza Vaccine, H1N1 and H3N3, Killed Virus	19A5.26	Pfizer Inc., Est. 189	11/07/02
Mycoplasma Bovis Bacterin	2760.01	Texas Vet Lab., Inc., Est. 290	10/28/02
Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	2A41.00	Intervet Inc. Est. 286	12/05/02
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4145.21	Heska Corp., Est. 213	10/04/02
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4469.23	Boehringer Ingelheim Vetmedica, Inc. Est. 124	12/26/02
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Campylobacter Fetus- Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44B9.21	Heska Corp., Est. 213	10/04/02
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin	44C9.23	Boehringer Ingelheim Vetmedica, Inc., Est. 124	10/09/02
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44D9.23	Boehringer Ingelheim Vetmedica, Inc. Est. 124	10/09/02
Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae Bacterin	4906.20	Novartis Animal Vaccines, Inc. Est. 303	12/18/02
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Mycoplasma Hyopneumoniae Bacterin	4995.22	Schering-Plough Animal Health Corp., Est. 165A	10/01/02

True Name	Product Code	Establishment/ Permittee	Date
Parvovirus-Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	46F6.22	Pfizer Inc., Est. 189	11/07/02
Parvovirus-Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49G6.22	Pfizer Inc., Est. 189	11/07/02
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49L6.22	Pfizer Inc., Est. 189	11/07/02
Pseudorabies Virus gpI Antibody Test Kit	5113.02	IDEXX Laboratories, Inc., Est. 313	12/20/02
Chronic Wasting Disease Antigen Test Kit, ELISA	5420.20	Bio-Rad Laboratories Permit No. 624	10/31/02
Neospora Caninum Antibody Test Kit, cELISA	5N05.20	VMRD, Inc. Est. 332	10/18/02
Bacterial Immunomodulator, Killed Bacteria	9200.00	Immune Modulators, Inc. Est. 606	10/04/02

U. S. Veterinary Biological Product Permit No. 624 was issued on October 31, 2002, to the following:

Bio-Rad Laboratories
 Life Science Group
 2000 Alfred Nobel Drive
 Hercules, California 94547

U. S. Veterinary Biological Establishment License No. 606 was issued on October 4, 2002, to the following:

Immune Modulators, Inc.
 85 Hunter Road
 Cataula, Georgia 31804
 MAIL: Immune Modulators, Inc.
 85 Hunter Road
 Cataula, Georgia 31804

U. S. Veterinary Biological Establishment License No. 605 was issued on November 26, 2002, to the following:

Viridus Animal Health, LLC
520 W. Industrial Lake Drive
Lincoln, Nebraska 68528
MAIL: Viridus Animal Health, LLC
520 W. Industrial Lake Drive
Lincoln, Nebraska 68528

The following product licenses for Texas Vet Labs, Inc., Est. 290, were terminated without prejudice on December 2, 2002:

Haemophilus Somnus-Pasteurella Haemolytica-Multocida Bacterin,
Code 2660.00

Haemophilus Somnus-Pasteurella Haemolytica-Multocida-Salmonella
Typhimurium Bacterin, Code 2677.00

Pasteurella Haemolytica-Multocida Salmonella Typhimurium Bacterin,
Code 2708.00

The following product licenses for Merial Select Inc., Est. 279, were terminated without prejudice on November 5, 2002:

Bronchitis Vaccine, Mass Type, Live Virus, Code 1231.18

Fowl Pox Vaccine, Live Virus, Code 1621.00

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Conn Type, Live Virus,
Code 1761.1A

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass Type, Live Virus,
Code 1761.1M

Newcastle-Bronchitis Vaccine, B₁ Type, LaSota Strain, Mass Type, Live Virus,
Code 1771.19

Newcastle-Bronchitis Vaccine, B₁ Type, B₁ Strain, Mass & Ark Types, Live
Virus, Code 17A1.2M

Tenosynovitis Vaccine, Modified Live Virus, Code 1951.01

Tenosynovitis Vaccine, Modified Live Virus, Code 1951.02

Turkey Pox Vaccine, Live Virus, Code 19G1.10

The following product licenses for Schering-Plough Animal Health Corp., Est. 314, were terminated without prejudice on November 25, 2002:

Bovine Rhinotracheitis Vaccine, Killed Virus, Code 1105.R0

Bovine Rhinotracheitis-Parainfluenza₃ Vaccine, Modified Live Virus,
Code 1121.31

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

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

Newcastle Disease-Fowl Pox Vaccine, Live Fowl Pox Vector, Code 17C1.R0

Pseudorabies Vaccine, Modified Live Virus, Code 1891.R0

Pseudorabies Vaccine, Modified Live Virus, Code 1891.R2

Pseudorabies Vaccine, Modified Live Virus, Code 1891.R3

Pseudorabies Vaccine, Killed Virus, Code 1895.R0

Pseudorabies Vaccine, Killed Virus, Code 1895.R1

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

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

Swine Influenza Vaccine, Killed Virus, Code 19A5.11

Mycoplasma Hyopneumoniae Bacterin, Code 2775.00

/s/Richard E. Hill, Jr.

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

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