

July 14, 2004

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-14

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 April, May and June 2004. 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 and Killed Virus	1187.25	Pfizer Inc., Est. 189	6/14/04
Bovine Virus Diarrhea Vaccine, Killed Virus	1205.25	Pfizer Inc., Est. 189	6/14/04
Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass Type, Killed Virus	12M5.43	Lohmann Animal Health International, Est. 196	6/29/04
Equine Influenza Vaccine, Modified Live Virus	1501.10	Heska Corp., Est. 213	5/18/04
Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus	1679.32	United Vaccines, Inc., Est. 245	4/21/04
Hemorrhagic Enteritis Vaccine, Live Virus	17E1.20	Biomune Co., Est. 368	5/25/04
Autogenous Bacterin	2051.B0	SolidTech Animal Health, Inc., Est. 604	5/11/04
Autogenous Bacterin	2051.I0	SolidTech Animal Health, Inc., Est. 604	5/11/04
Haemophilus Paragallinarum Bacterin	2658.12	Lohmann Animal Health International, Est. 196	06/29/04
Mycoplasma Hypopneumoniae Bacterin	2775.01	Novartis Animal Health US, Inc., Est. 303	5/20/04

True Name	Product Code	Establishment/ Permittee	Date
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4469.25	Pfizer Inc., Est.189	6/14/04
Bovine Virus Diarrhea Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4595.25	Pfizer Inc., Est. 189	6/14/04
Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	48C5.21	Intervet Inc., Est. 286	5/19/04
Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus, Salmonella Enteritidis Bacterin	48D6.10	Intervet Inc., Est. 286	6/9/04
Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Clostridium Botulinum Type C Bacterin-Toxoid	4929.32	United Vaccines, Inc., Est. 245	4/21/04
Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Clostridium Botulinum Type C-Pseudomonas Aeruginosa Bacterin-Toxoid	4949.32	United Vaccine, Inc., Est. 245	4/21/04
Canine Heartworm Antigen Test Kit	5018.02	Heska Corp., Est. 213	6/14/04
Canine Heartworm Antigen Test Kit	5018.03	Heska Corp., Est. 213	6/14/04
Pasteurella Multocida Antibody Test Kit	5130.01	Synbiotics Corporation, Est. 312	4/27/04
Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA	5430.20	Abbott Laboratories, Permittee 460B	4/7/04
Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA	5430.20	Pierce Biotechnology, Inc., Est. 625	4/7/04
Bovine Spongiform Encephalopathy Antigen Test Kit, Western Blot	5430.70	Roche Diagnostics, Permittee 626A	4/7/04
Allergenic Extract, Pythium Insidiosum	9540.00	Nelco Laboratories, Inc., Est. 359	5/24/04

True Name	Product Code	Establishment/ Permittee	Date
Bursal Disease Virus, Variant Strain, Live	A2B9.40	Charles River Laboratories, Inc. Est. 344	5/19/04
Autogenous Killed Culture	B051.00	Newport Laboratories, Inc., Est. 455	5/11/04
Mycobacterium Bovis Gamma Interferon Test Kit for Cervids	EA64.10	Biocor Animal Health Inc., Permittee 462A	4/7/04
Clostridium Botulinum Type C, Killed Culture	G010.00	Heska Corp., Est. 213	3/10/04

U.S. Veterinary Biological Product Permit No. 460B was issued on April 7, 2004, to the following:

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064

U.S. Veterinary Biologics Establishment License No. 625 was issued on April 7, 2004, to the following:

Pierce Biotechnology, Inc.
3747 North Meridian Road
Rockford, Illinois 61101
MAIL: Pierce Biotechnology, Inc.
P.O. Box 117
Rockford, Illinois 61105

U.S. Veterinary Biological Product Permit No. 626A was issued on April 7, 2004, to the following:

Roche Diagnostics
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

The establishment license for Kirkegaard and Perry Laboratories, Inc., Est. No. 350, and the following product licenses were terminated without prejudice on April 26, 2004:

Avian Influenza Virus Antibody Test Kit, Code 5004.00
Avian Encephalomyelitis Virus Antibody Test Kit, Code 5006.00
Avian Leukosis Virus Antigen Test Kit, Code 5007.00

Avian Reovirus Antibody Test Kit, Code 5008.00

Bordetella Avium Antibody Test Kit, Code 5015.00

Infectious Bronchitis Virus Antibody Test Kit, Code 5030.00

Infectious Bursal Disease Virus Antibody Test Kit, Code 5040.00

Mycoplasma Gallisepticum Antibody Test Kit, Code 5070.00

Mycoplasma Gallisepticum Antibody Test Kit, Code 5070.01

Mycoplasma Gallisepticum-Synoviae Antibody Test Kit, Code 5074.00

Newcastle Disease Virus Antibody Test Kit, Code 5080.00

Newcastle Disease Virus Antibody Test Kit, Code 5080.01

Avian Encephalomyelitis-Bronchitis-Bursal Disease-Newcastle Disease-Reovirus Antibody Test Kit, Code 5106.00

Pasteurella Multocida Antibody Test Kit, Code 5130.00

Pasteurella Multocida Antibody Test Kit, Code 5130.01

Infectious Bursal Disease Virus Antibody Test Kit, Code 5040.01

Mycoplasma Meleagridis Antibody Test Kit, Code 5172.00

Mycoplasma Synoviae Antibody Test Kit, Code 5173.00

Mycoplasma Synoviae Antibody Test Kit, Code 5173.01

Fowl Laryngotracheitis Virus Antibody Test Kit, Code 5601.00

Hemorrhagic Enteritis Virus Antibody Test Kit, Code 57E1.00

The following product licenses for Pfizer Inc., Est. 189, were terminated without prejudice on June 22, 2004:

Bovine Rhinotracheitis Vaccine, Modified Live Virus, Code 1101.20

Bovine Rhinotracheitis-Parainfluenza₃ Vaccine, Modified Live Virus, Code 1121.20

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Code 1151.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Code 1171.20

Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Code 11A1.20

Bovine Rhinotracheitis-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Code 11B1.20

Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Modified Live Virus, Code 19H1.20

Leptospira Bratislava Bacterin, Code 2679.00

Bovine Rhinotracheitis-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4277.20

Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4367.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4461.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4560.21

Equine Rhinopneumonitis-Influenza Vaccine-Tetanus Toxoid, Modified Live and Killed Virus, Code 4885.20

Equine Influenza Vaccine-Tetanus Toxoid, Killed Virus, Code 4895.20

Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Modified Live Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid, Code 49B1.20

/s/ Richard E. Hill, Jr.

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