

November 4, 2004

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-18**

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 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
Autogenous Vaccine, Killed Virus	1015.10	Wyeth Est. 112	7/21/04
Autogenous Vaccine, Killed Virus	1015.20	MVP Laboratories, Inc., Est. 301	9/13/04
Lawsonia Intracellularis Vaccine, Avirulent Live Culture	10L1.02	Boehringer Ingelheim Vetmedica, Inc., Est. 124	9/23/04
Bovine Virus Diarrhea Vaccine, Killed Virus	1205.21	Novartis Animal Health US, Inc., Est. 303	7/8/04
Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Mass. Type, Killed Virus	12J5.43	Lohmann Animal Health International, Est. 196	8/24/04
Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.25	Wyeth Est. 112	9/17/04
Canine Parainfluenza Vaccine, Modified Live Virus	1421.21	Wyeth Est. 112	9/17/04
Feline Leukemia Vaccine, Live Canarypox Vector	1555.R3	Merial, Inc., Est. 298	9/20/04
Feline Panleukopenia Vaccine, Modified Live Virus	1561.23	Heska Corp., Est. 213	8/4/04
Feline Rhinotracheitis-Calici Vaccine, Modified Live Virus	16C1.22	Heska Corp., Est. 213	8/4/04
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus	16D1.22	Heska Corp., Est. 213	8/4/04

True Name	Product Code	Establishment/ Permittee	Date
Autogenous Bacterin	2051.00	Hennessy Research Assoc., LLC, Est. 597	9/13/04
Feline Leukemia Virus Antigen Test Kit	5028.05	Synbiotics Corp., Est. 312	8/23/04
Mycoplasma Gallisepticum Antigen	5071.02	Charles River Laboratories, Inc., Est. 344	7/15/04
Bovine Spongiform Encephalopathy Antigen Test Kit, Immunohistochemistry	5430.40	VMRD, Inc. Est. 332	8/5/04
Bovine Spongiform Encephalopathy-Scrapie Antigen Test Kit, ELISA	5440.20	Pierce Biotechnology, Inc., Est. 625	9/1/04
Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	7935.00	Merial, Inc., Est. 298	8/13/04
Arcanobacterium Pyogenes-Fusobacterium Necrophorum Toxoid	8625.00	Schering-Plough Animal Health Corp., Est. 165A	7/14/04
Autogenous Vaccine, Killed Virus	A015.20	Hennessy Research Assoc., LLC, Est. 597	9/13/04
Bursal Disease Virus, Live Variant	A2B9.43	Kestrel, Inc., Est. 415	8/2/04
Bursal Disease Virus, Live Virus	A3B1.02	Kestrel, Inc., Est. 415	7/20/04
Feline Leukemia Virus Antigen Test Kit	E028.05	Synbiotics Corporation, Permittee 312C	8/23/04
Feline Leukemia Virus Antigen Test Kit	E028.05	SafePath Laboratories LLC, Est. 430	8/23/04

U.S. Veterinary Biologics Establishment License No. 597 was issued on September 13, 2004, to the following:

Hennessy Research Associates, LLC  
 12700 Johnson Drive  
 Shawnee, Kansas 66216-1643  
 MAIL: Hennessy Research Associates, LLC  
 12700 Johnson Drive  
 Shawnee, Kansas 66216-1643

U.S. Veterinary Biologics Permit No.189A was issued on July 19, 2004, to the following:

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

The following product licenses for American Animal Health, Inc., Est. 315, were terminated without prejudice on September 22, 2004:

Actinobacillus Pleuropneumoniae-Erysipelothrix Rhusiopathiae Bacterin,  
Code 2640.00

Actinobacillus Pleuropneumoniae Bacterin, Code 2657.00

Salmonella Choleraesuis-Typhimurium Bacterin, Code 2791.00

The following product license for Heska Corporation, Est. 213, was terminated without prejudice on September 22, 2004:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial  
Virus Vaccine, Modified Live Virus, Code A181.30

The following product license for International Duck Research Cooperative, Inc., Est. 268, was terminated without prejudice on September 30, 2004:

Duck Virus Hepatitis Vaccine, Killed Virus, Code 14B5.10

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on August 11, 2004:

Bursal Disease Vaccine, Live Virus, Code 1271.13

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine,  
Modified Live Virus, Code 13D1.21

Tenosynovitis Vaccine, Modified Live Virus, Code 1951.02

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine,  
Modified Live Virus, Leptospira Bacterin, Code 4637.21

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus  
Vaccine, Modified Live & Killed Virus, Leptospira Bacterin, Code 46J9.21

Bursal Disease Vaccine, Live Virus, Code A271.14

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine,  
Modified Live Virus, Code A3D1.21

Tenosynovitis Vaccine, Modified Live Virus, Code A951.01

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on September 15, 2004:

Bovine Rhinotracheitis Vaccine, Modified Live Virus, Code 1101.20

Bovine Rhinotracheitis-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus,  
Code 1121.31

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus,  
Code 1151.00

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

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live  
Virus, Code 1171.30

Bovine Virus Diarrhea Vaccine, Killed Virus, Code 1205.20

Pseudorabies Vaccine, Modified Live Virus, Code 1891.R0

Pseudorabies Vaccine, Killed Virus, Code 1895.21

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

Clostridium Chauvoei-Septicum-Mannheimia Haemolytica-Pasteurella Multocida  
Bacterin, Code 2460.00

Actinomyces Pyogenes-Mannheimia Haemolytica-Pasteurella Multocida  
Bacterin, Code 2633.00

Escherichia Coli Bacterin, Code 2648.56

Leptospira Pomona Bacterin, Code 2691.00

Pasteurella Multocida Bacterin, Porcine Isolates, Code 2701.01

Moraxella Bovis Bacterin, Code 2772.00

Mycoplasma Hyopneumoniae Bacterin, Code 2775.01

Salmonella Choleraesuis-Typhimurium Bacterin, Code 2791.00

Salmonella Dublin-Typhimurium Bacterin, Bovine Isolates, Code 2821.00

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona-Clostridium Haemolyticum Bacterin, Code 2864.00

Campylobacter Fetus-Leptospira Pomona Bacterin, Code 2865.00

Bovine Rhinotracheitis Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4089.01

Bovine Rhinotracheitis Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4089.20

Bovine Rhinotracheitis-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4209.20

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4335.20

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Leptospira Pomona Bacterin, Code 4385.20

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4389.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Leptospira Pomona Bacterin, Code 4509.20

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4975.20

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

Porcine Rotavirus Vaccine, Modified Live Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid, Code 49C1.20

Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Modified Live Virus, Bordetella Bronchiseptica-Clostridium Perfringens Type C-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin-Toxoid, Code 49T9.20

Tetanus Antitoxin, Equine Origin, Code 6302.00

Bordetella Bronchiseptica-Clostridium Perfringens Type C-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin-Toxoid, Code 7052.00

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid, Code 7060.00

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid, Code 7060.01

Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii Bacterin-Toxoid, Code 7070.00

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin-Toxoid, Code 7159.00

Clostridium Chauvoei-Septicum-Novyi Bacterin-Toxoid, Code 7330.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Haemophilus Somnus Bacterin-Toxoid, Code 7400.00

Clostridium Perfringens Type C Bacterin-Toxoid, Code 7800.00

Clostridium Perfringens Type D Bacterin-Toxoid, Code 7840.00

Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid, Code 7890.00

Flea Antigen (Desensitizing), Code 9511.00

Anthrax Spore, Live Culture, Code A01C.00

Pseudorabies Vaccine, Killed Virus, Code A895.R0

Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Modified Live Virus, Code A9H1.20

Ovine Ecthyma Virus, Live Virus, Code AA11.00

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin, Code B101.00

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin, Code B109.00

Mycoplasma Hyopneumoniae Bacterin, Code B775.00

Mycoplasma Hyopneumoniae, Killed Culture, Code B775.02

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin-Toxoid, Code G054.01

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid, Code G060.01

Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid, Code G160.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid, Code G410.00

The following product licenses for Merial, Inc., Est. 298, were terminated without prejudice on September 15, 2004:

Avian Reovirus Vaccine, Killed Virus, Code 1045.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live and Killed Virus, Code 1177.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Code 1187.20

Bovine Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Killed Virus, Code 12A5.20

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus-Rabies Vaccine, Modified Live and Killed Virus, Canarypox Vector, Code 13F9.R0

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus-Rabies Vaccine, Modified Live and Killed Virus, Canarypox Vector, Code 14K9.R1

Rabies Vaccine, Killed Virus, Code 1905.22

Leptospira Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 26A8.00

Mycoplasma Hyopneumoniae Bacterin, Code 2775.00

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus-Rabies Vaccine, Modified Live and Killed Virus, Canarypox Vector, Leptospira Bacterin, Code 4699.R0

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus-Rabies Vaccine, Modified Live and Killed Virus, Canarypox Vector, Leptospira Bacterin, Code 469A.R1

Encephalomyelitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid, Code 4835.43

Rabies Vaccine, Killed Virus, Leptospira Bacterin, Code 4985.20

Leptospira Canicola, Killed Culture, Code B661.00

Leptospira Icterohaemorrhagiae, Killed Culture, Code B66A.00

Leptospira Grippotyphosa, Killed Culture, Code B675.00

Leptospira Pomona, Killed Culture, Code B691.00

Leptospira Hardjo, Killed Culture, Code B6M7.00

Mycoplasma Hyopneumoniae, Killed Culture, Code B775.01

The following product licenses for Newport Laboratories, Est. 455, were terminated without prejudice on September 7, 2004:

Autogenous Vaccine, Killed Virus, Code 1015.01

Autogenous Bacterin, Code 2051.01

Autogenous Vaccine, Killed Virus, Autogenous Bacterin, Code 4500.00

Due to the acquisition of Biocor Animal Health Inc., Est. 462, by Pfizer Inc., Est. 189, the following products previously issued to Est. 462 have been reissued to Est. 189:



Bovine Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1095.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Killed Virus, Code 1175.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1185.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Code 1189.20

Bovine Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Killed Virus, Code 12A5.20

Canine Adenovirus Type 2-Parvovirus Vaccine, Modified Live and Killed Virus, Code 12T7.20

Canine Distemper-Adenovirus Type 2-Hepatitis-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Code 1377.20

Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live and Killed Virus, Code 13C1.40

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Code 13D9.20

Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live Virus and Chlamydia, Code 16E8.20

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

Salmonella Choleraesuis Vaccine, Avirulent Live Culture, Code 19A1.00

Haemophilus Somnus Bacterin, Code 2659.01

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4435.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4465.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 44D7.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus Bacterin, Code 44E7.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin, Code 44H9.20

Canine Adenovirus Type 2-Parvovirus Vaccine, Killed Virus, Leptospira Bacterin, Code 4605.20

Canine Adenovirus Type 2-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 4608.20

Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 4657.30

Canine Distemper-Adenovirus Type 2-Hepatitis-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 46A9.20

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4975.21

Canine Distemper-Adenovirus Type 2-Hepatitis-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 49A9.20

Mycobacterium Bovis Gamma Interferon Test Kit for Cervids, Code 5A64.10

Mycobacterium Tuberculosis Gamma Interferon Test Kit for Non-Human Primates, Code 5A64.20

Canine Gonadotropin Releasing Factor Immunotherapeutic, Code 9220.00

Leptospira Hardjo Bacterin, Code B6M7.01

The following Est. 462 licenses were reissued to Est. 189 with different code numbers to avoid duplication of numbers:

Bovine Rhinotracheitis-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Code 1121.25 (formerly 1121.20)

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Code 1171.23 (formerly 1171.20)

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub>-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Code 1187.23 (formerly 1187.20)

Canine Distemper-Hepatitis-Parainfluenza Vaccine, Modified Live Virus, Code 1381.21 (formerly 1381.20)

Feline Leukemia Vaccine, Killed Virus, Code 1555.22 (formerly 1555.20)

Feline Panleukopenia Vaccine, Modified Live Virus, Code 1561.22 (formerly 1561.21)

Feline Panleukopenia Vaccine, Killed Virus, Code 1565.22 (formerly 1565.20)

Feline Rhinotracheitis-Calici Vaccine, Modified Live Virus, Code 16C1.22 (formerly 16C1.20)

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus, Code 16D5.21 (formerly 16D5.20)

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus, Code 16D8.21 (formerly 16D8.20)

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live and Killed Virus, Code 16D9.21 (formerly 16D9.20)

Feline Rhinotracheitis-Calici-Chlamydia Psittaci Vaccine, Modified Live Virus and Chlamydia, Code 16F1.21 (formerly 16F1.20)

Parvovirus Vaccine, Modified Live Virus, Code 18M1.24 (formerly 18M1.21)

Parvovirus Vaccine, Modified Live Virus, Code 18M1.25 (formerly 18M1.20)

Parvovirus Vaccine, Killed Virus, Code 18M5.22 (formerly 18M5.20)

Bordetella Bronchiseptica Bacterin, Code 2100.02 (formerly 2100.00)

Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2665.03 (formerly 2665.01)

Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2665.04 (formerly 2665.02)

Leptospira Canicola-Icterohaemorrhagiae Bacterin, Code 2671.03 (formerly 2671.00)

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2863.05 (formerly 2863.01)

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2863.04 (formerly 2863.02)

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4439.21 (formerly 4439.20)

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4560.23 (formerly 4560.20)

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 4639.41 (formerly 4639.40)

Canine Distemper-Hepatitis-Parainfluenza Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4809.21 (formerly 4809.20)

Due to the acquisition of Biocor Animal Health Inc., Permittee No. 462A by Pfizer Inc., Permittee No. 189A, the following products listed on Permit 462A have been reissued on Permit 189A:

Leptospira Hardjo Bacterin, Code 26M7.01

Mycobacterium Paratuberculosis Antibody Test Kit, Code 5064.00

Mycobacterium Bovis Gamma Interferon Test Kit for Cattle, Code 5A64.00

Leptospira Hardjo Bacterin, Code B6M7.01

Mycobacterium Bovis Gamma Interferon Test Kit for Cervids, Code EA64.10

Canine Gonadotropin Releasing Factor Immunotherapeutic, Code I220.00

*/s/ Richard E. Hill, Jr.*

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