

July 13, 2007

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 07-10

Subject: Issuance of Licenses

To: Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
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 2007. 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 Vaccine, Modified Live Virus	1151.22	Boehringer Ingelheim Vetmedica, Inc., Est. 124	4/4/07
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.23	Boehringer Ingelheim Vetmedica, Inc., Est. 124	6/22/07
Bronchitis Vaccine, Mass & Ark Types, Live Virus	1231.13	Intervet Inc., Est. 286	4/19/07
Bronchitis Vaccine, Mass & Conn Types, Live Virus	1231.1G	Intervet Inc., Est. 286	4/19/07
Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus	16L1.05	Lohmann Animal Health Int'l., Est. 196	4/24/07
Fowl Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector	16J1.R1	Intervet Inc., Est. 286	6/22/07
Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector	16N1.R0	Biomune Co., Est. 368	6/5/07
Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector	1A88.R0	Biomune Co., Est. 368	6/5/07
Haemophilus Somnus-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2664.01	Boehringer Ingelheim Vetmedica, Inc., Est. 124	4/4/07

True Name	Product Code	Establishment/ Permittee	Date
Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.01	Boehringer Ingelheim Vetmedica, Inc., Est. 124	4/4/07
Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.07	Novartis Animal Health US, Inc., Est. 303	6/6/07
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4141.20	Boehringer Ingelheim Vetmedica, Inc., Est. 124	4/4/07
Feline Leukemia Virus Antigen Test Kit	5028.00	AGEN, Inc., Permittee 338A	4/3/07
Scrapie Antigen Test Kit, ELISA	5410.21	Bio-Rad Laboratories, Est. 624	4/17/07
Mycobacterium Bovis-Mycobacterium Tuberculosis Antibody Test Kit	5470.00	Chembio Diagnostic Systems, Inc., Est. 645	6/6/07
Allergenic Extract, Mixed Grasses	9522.03	Allergy Laboratories, Inc., Est. 629	6/6/07
Allergenic Extract, Cat Hair	95C1.00	Allergy Laboratories, Inc., Est. 629	6/6/07

Due to the acquisition of Embrex, Inc., Est. 412, by Pfizer Inc., Est. 189, the following product previously issued to Est. 412 was reissued to Est. 189 on April 17, 2007:

Coccidiosis Vaccine, Live Oocysts, Chicken Isolates, Code 1431.55

U. S. Veterinary Biologics Establishment License No. 645 was issued on June 6, 2007, to the following:

Chembio Diagnostic Systems, Inc.
 3661 Horseblock Road
 Medford, New York 11763
 MAIL: Chembio Diagnostic Systems, Inc.
 3661 Horseblock Road
 Medford, New York 11763

U. S. Veterinary Biologics Establishment License No. 629 was issued on June 6, 2007, to the following:

Allergy Laboratories Inc.,
1005 SW 2nd Street
Oklahoma City, Oklahoma 73109
MAIL: Allergy Laboratories, Inc.
1005 SW 2nd Street
Oklahoma City, Oklahoma 73109

The following product licenses for Wyeth, Est. 112, were terminated without prejudice on June 27, 2007:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Code 1171.22

Bovine Rhinotracheitis-Virus Diarrhea- Parainfluenza₃ Vaccine, Killed Virus, Code 1175.22

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Code 13D1.22

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Code 1475.22

Canine Coronavirus-Parvovirus Vaccine, Modified Live and Killed Virus, Code 14R7.27

Canine Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Code 14R9.27

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Code 1599.22

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Code 1599.27

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4431.22

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4435.21

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4469.22

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus, Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4565.20

Bovine Virus Diarrhea Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4595.21

Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4657.21

Canine Coronavirus Vaccine, Killed Virus, Leptospira Bacterin, Code 46E5.22

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Bacterin, Code 46J7.20

The following product licenses for Boehringer Ingelheim Vetmedica, Inc., Est. 124 were terminated without prejudice on April 20, 2007:

Autogenous Vaccine, Killed Virus, Code 1015.20

Parvovirus Vaccine, Killed Virus, Code 18P5.20

Autogenous Bacterin, Code 2051.00

Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2642.00

Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2642.01

Escherichia Coli Bacterin, Code 2648.00

Erysipelothrix Rhusiopathiae-Escherichia Coli Bacterin, Code 26A6.00

Erysipelothrix Rhusiopathiae-Haemophilus Parasuis-Mycoplasma Hyopneumoniae Bacterin, Code 2A46.00

Porcine Reproductive and Respiratory Syndrome Vaccine, Reproductive Form, Modified Live Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 41S1.20

Porcine Reproductive and Respiratory Syndrome Vaccine, Reproductive Form, Modified Live Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 41S1.21

Porcine Reproductive and Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus, Erysipelothrix Rhusiopathiae Bacterin, Code 41V9.20

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 48C5.20

Porcine Reproductive and Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus, Erysipelothrix Rhusiopathiae-Haemophilus Parasuis-Mycoplasma Hyopneumoniae Bacterin, Code 49R9.20

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

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid, Code 7060.01

Clostridium Perfringens Type C-Erysipelothrix Rhusiopathiae-Escherichia Coli Bacterin-Toxoid, Code 7874.00

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

Salmonella Choleraesuis, Avirulent Live Culture, Code A9A1.00

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin-Toxoid, Code G054.00

The following product licenses for Boehringer Ingelheim Vetmedica, Inc., Est. 124, were terminated without prejudice on June 20, 2007:

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Code 1151.21

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Killed Virus, Code 1175.20

Erysipelothrix Rhusiopathiae Bacterin, Code 2641.00

Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona-Staphylococcus Aureus Bacterin, Code 2666.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D-Moraxella Bovis Bacterin-Toxoid, Code 7425.02

The following product licenses for Pfizer Inc., Est.189, were terminated without prejudice on June 28, 2007:

Bovine Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1095.20

Bovine Rhinotracheitis-Parainfluenza₃ Vaccine, Modified Live Virus, Code 1121.25

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Code 1171.23

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus, Code 1175.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1185.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Code 1187.23

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-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-Hepatitis-Parainfluenza Vaccine, Modified Live Virus, Code 1381.21

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 Panleukopenia Vaccine, Modified Live Virus, Code 1561.22

Feline Panleukopenia Vaccine, Killed Virus, Code 1565.22

Feline Rhinotracheitis-Calici Vaccine, Modified Live Virus, Code 16C1.22

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus, Code 16D8.21

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

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

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

Parvovirus Vaccine, Modified Live Virus, Code 18M1.24

Parvovirus Vaccine, Modified Live Virus, Code 18M1.25

Parvovirus Vaccine, Killed Virus, Code 18M5.22

Haemophilus Somnus Bacterin, Code 2659.01

Leptospira Canicola-Icterohaemorrhagiae Bacterin, Code 2671.03

Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 2863.05

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4435.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4439.21

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4465.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 44D7.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus Bacterin, Code 44E7.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin, Code 44H9.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4560.23

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-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin, Code 4639.41

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

Canine Distemper-Hepatitis-Parainfluenza Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4809.21

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

The following product licenses for Lohmann Animal Health International, Est.196, were terminated without prejudice on April 20, 2007:

Avian Reovirus, Killed Virus, Code A045.02

Bronchitis Virus, Mass. and Ark. Types, Killed Virus, Code A235.15

The following product licenses for Heska Corporation, Est. 213, were terminated without prejudice on June 21, 2007:

Transmissible Gastroenteritis Vaccine, Modified Live Virus, Code 1961.00

Escherichia Coli Bacterin, Code 2648.01

Clostridium Perfringens Type C Bacterin-Toxoid, Code 7800.00

Clostridium Perfringens Type D Bacterin-Toxoid, Code 7840.00

Clostridium Perfringens Types C & D Bacterin-Toxoid, Code 7870.00

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

Mink Distemper Virus, Modified Live Virus, Code A451.02

Mink Enteritis Virus, Killed Virus, Code A685.20

Mink Enteritis Virus, Killed Virus, Code A685.21

Pseudomonas Aeruginosa, Killed Culture, Code B735.00

Pseudomonas Aeruginosa, Killed Culture, Code B735.01

Pseudomonas Aeruginosa, Killed Culture, Code B735.02

Pseudomonas Aeruginosa, Killed Culture, Code B735.03

Pseudomonas Aeruginosa, Killed Culture, Code B735.04

Pseudomonas Aeruginosa, Killed Culture, Code B735.05

Pseudomonas Aeruginosa, Killed Culture, Code B735.06

Aleutian Disease Virus Counter-electrophoresis Antigen, Code E001.20

Clostridium Botulinum Type C, Killed Culture, Code G010.00

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on April 12, 2007:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture, Code 11A8.21

Equine Influenza Vaccine, Killed Virus, Code 1505.22

Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.22

Equine Rhinopneumonitis Vaccine, Killed Virus, Code 1525.20

Transmissible Gastroenteritis Vaccine, Killed Virus, Code 1965.20

Porcine Rotavirus Vaccine, Killed Virus, Code 19E5.20

Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Killed Virus, Code 19H5.20

Ehrlichia Risticii Bacterin, Code 2639.00

Erysipelothrix Rhusiopathiae Bacterin, Code 2641.03

Campylobacter Fetus Bacterin, Code 2862.00

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid, Code 4845.31

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid, Code 4847.30

Encephalomyelitis-Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid, Code 4875.A0

Rabies Vaccine, Killed Virus, Ehrlichia Risticii Bacterin, Code 4905.20

Campylobacter Fetus, Killed Culture, Code B862.00

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus,
Tetanus Toxoid, Code D835.44

The following product licenses for Texas Vet Lab, Inc., Est. 290, were terminated without prejudice on May 10, 2007:

Escherichia Coli-Mannheimia Haemolytica-Pasteurella Multocida-Salmonella
Typhimurium Bacterin, Code 2651.00

Mannheimia Haemolytica-Pasteurella Multocida-Salmonella Typhimurium
Bacterin-Toxoid, Code 7926.00

The following product license for Immuno-Dynamics, Inc., Est. 379, was terminated without prejudice on June 26, 2007:

Bovine IgG, Code 3606.01

The following product license for Kestrel, Inc., Est. 415 was terminated without prejudice on April 5, 2007:

Bursal Disease Virus, Live Variant, Code A2B9.40

The Permit for Distribution and Sale of the following products for AGEN, Inc., Permittee No. 338, was terminated without prejudice on June 22, 2007:

Canine Heartworm Antigen Test Kit, Code 5018.01

Canine Parvovirus Antigen Test Kit, Code 5024.01

Feline Leukemia Virus Antigen Test Kit, Code 5028.00

The Permit for Distribution and Sale of the following products for AGEN, Inc., Permittee No. 338A was terminated without prejudice on June 22, 2007:

Canine Heartworm Antigen Test Kit, Code 5018.01

Canine Parvovirus Antigen Test Kit, Code 5024.01

Feline Leukemia Virus Antigen Test Kit, Code 5028.00

The Establishment License and following product for Natur's Way Company, Est. 404, were terminated on June 28, 2007:

Bovine IgG, Code 3606.00

The Establishment License and following product for Natur's Way Company, Est. No. 404A, were terminated on June 28, 2007:

Bovine IgG, Code C606.00

/s/Richard E. Hill, Jr.

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

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