

July 7, 2006

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-17**

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 2006. 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
Coccidiosis Vaccine, Live Oocysts, Chicken Isolates	1431.55	Embrex Poultry Health, LLC, Est. 412	4/17/06
Equine Influenza Vaccine, Modified Live Virus	1501.20	Intervet Inc., Est. 286	6/27/06
Escherichia Coli Vaccine, Live Culture	1551.R0	Wyeth, Est. 112	4/7/06
Feline Panleukopenia Vaccine, Modified Live Virus	1561.20	Intervet Inc., Est. 286	5/30/06
Chlamydia Psittaci Vaccine, Modified Live Chlamydia	1581.20	Intervet Inc., Est. 286	5/30/06
Feline Rhinotracheitis-Calicivirus Vaccine, Modified Live Virus	16C1.20	Intervet Inc., Est. 286	5/31/06
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus	16D1.22	Intervet Inc., Est. 286	5/31/06
Feline Rhinotracheitis-Calici-Panleukopenia-Rabies Vaccine, Modified Live & Killed Virus	16T9.20	Intervet Inc., Est. 286	6/12/06
Porcine Circovirus Vaccine, Type 1 - Type 2 Chimera, Killed Virus	19K5.R1	Wyeth, Est. 112	4/24/06
Autogenous Bacterin	2051.00	Schering-Plough Animal Health Corp., Est. 165A	5/11/06
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	43S5.20	Texas Vet Lab, Inc., Est. 290	5/25/06

True Name	Product Code	Establishment/ Permittee	Date
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4465.22	Wyeth, Est. 112	5/16/06
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44B1.20	Intervet Inc., Est. 286	4/3/06
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4847.32	Intervet Inc., Est. 286	6/12/06
Canine Heartworm Antigen Test Kit	5018.01	AGEN, Inc., Permittee 338A	6/13/06
Mycobacterium Paratuberculosis Antibody Test Kit	5064.03	IDEXX Laboratories, Inc., Est. 313	6/16/06

U.S. Veterinary Biological Product Permit No. 338A was issued on June 13, 2006, to the following:

AGEN, Inc.  
MAIL: AGEN, Inc.  
9075 Guilford Road, Suite A  
Columbia, Maryland 21046

U.S. Veterinary Biologics Establishment License No. 412 was issued on April 17, 2006, to the following:

Embrex Poultry Health, LLC  
22300 Skyway Church Road  
Maxton, North Carolina 28364  
MAIL: Embrex Poultry Health, LLC  
c/o Embrex, Inc.  
P.O. Box 13989  
Durham, North Carolina 27709-3989

The following product license for International Duck Research Cooperative, Inc., Est. 268, was terminated without prejudice on April 19, 2006:

Duck Virus Hepatitis Antibody, Chicken Origin, Code 3508.00

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on April 21, 2006:

- Anthrax Spore Vaccine, Nonencapsulated Live Culture, Code 1011.00
- Bovine Rhinotracheitis Vaccine, Modified Live Virus, Code 1101.21
- Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture, Code 11A8.20
- Encephalomyocarditis Vaccine, Killed Virus, Code 1495.20
- Equine Influenza Vaccine, Killed Virus, Code 1505.20
- Equine Influenza Vaccine, Killed Virus, Code 1505.21
- Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.20
- Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.21
- Erysipelothrix Rhusiopathiae Vaccine, Avirulent Live Culture, Code 1541.01
- Hemorrhagic Enteritis Vaccine, Live Virus, Code 17E1.22
- Marble Spleen Disease Vaccine, Live Virus, Code 17M1.21
- Ovine Ecthyma Vaccine, Live Virus, Code 1821.50
- Pseudorabies Vaccine, Modified Live Virus, Code 1891.R2
- Pseudorabies Vaccine, Killed Virus, Code 1895.20
- Wart Vaccine, Killed Virus, Code 1985.50
- Swine Influenza Vaccine, Killed Virus, Code 19A5.10
- Porcine Rotavirus Vaccine, Modified Live Virus, Code 19E1.21
- Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin, Code 2101.01
- Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin, Code 2106.00

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin, Code 2109.00

Actinobacillus Pleuropneumoniae-Erysipelothrix Rhusiopathiae Bacterin,  
Code 2640.00

Escherichia Coli Bacterin, Code 2648.00

Actinobacillus Pleuropneumoniae-Erysipelothrix Rhusiopathiae-Streptococcus  
Suis Bacterin, Code 264B.00

Haemophilus Parasuis Bacterin, Code 2652.00

Actinobacillus Pleuropneumoniae Bacterin, Code 2657.00

Actinobacillus Pleuropneumoniae-Streptococcus Suis Bacterin, Code 2672.00

Leptospira Pomona Bacterin, Code 2691.01

Serpulina Hyodysenteriae Bacterin, Code 2857.00

Serpulina Hyodysenteriae Bacterin, Code 2857.01

Bovine Rhinotracheitis-Parainfluenza 3 Vaccine, Modified Live Virus,  
Leptospira Pomona Bacterin, Code 4209.31

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus,  
Leptospira Pomona Bacterin, Code 4389.00

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live  
Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-  
Pomona Bacterin, Code 4439.30

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live  
Virus, Leptospira Pomona Bacterin, Code 4509.30

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

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus,  
Tetanus Toxoid, Code 4835.44

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern and Western,  
Killed Virus, Tetanus Toxoid, Code 4845.30

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

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

Equine Influenza Vaccine, Killed Virus, Streptococcus Equi Bacterial Extract, Code 48D6.20

Porcine Rotavirus Vaccine, Modified Live Virus, Bordetella Bronchiseptica-Clostridium Perfringens Type C-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin-Toxoid, Code 49Z9.20

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4BC5.20

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin-Toxoid, Code 7054.02

Bordetella Bronchiseptica-Clostridium Perfringens Type C-Erysipelothrix Rhusiopathiae-Escherichia Coli-Pasteurella Multocida Bacterin-Toxoid, Code 7150.01

Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid, Code 7160.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii Bacterin-Toxoid, Code 7390.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii Bacterin-Toxoid, Code 7390.02

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid, Code 7410.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid, Code 7410.02

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid, Code 7448.00

Clostridium Perfringens Types C & D Bacterin-Toxoid, Code 7870.01

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid, Code D835.43

The following product license for Boehringer Ingelheim Vetmedica, Inc., Est. 124, was terminated without prejudice on May 10, 2006:

Mycoplasma Hyopneumoniae Bacterin, Code 2775.00

The following product license for Intervet Inc., Est. 286, was terminated without prejudice on May 22, 2006:

Erysipelothrix Rhusiopathiae Bacterin, Code 2641.01

The following product licenses for Immucell Corporation, Est. 327, were terminated without prejudice on May 31, 2006:

Mycobacterium Paratuberculosis Antibody Test Kit, Code 5064.01

Bovine Leukemia Virus Antibody Test Kit, Code 5505.20

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on June 15, 2006:

Autogenous Vaccine, Killed Virus, Code 1015.00

Autogenous Vaccine, Killed Virus, Code 1015.11

Avian Encephalomyelitis Vaccine, Live Virus, Code 1051.12

Avian Encephalomyelitis-Fowl Pox Vaccine, Live Virus, Code 10M1.12

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

Bursal Disease Vaccine, Live Virus, Code 1271.00

Bursal Disease Vaccine, Live Virus, Code 1271.01

Bursal Disease Vaccine, Live Virus, Code 1271.02

Bursal Disease Vaccine, Killed Virus, Code 1275.02

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.43

Feline Leukemia Vaccine, Killed Virus, Code 1555.20

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live Virus and Chlamydia and Killed Virus, Code 1559.2B

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live and Killed Virus, Code 15B9.20

Fowl Pox Vaccine, Live Virus, Code 1621.01

Fowl Pox Vaccine, Live Virus, Code 1621.12

Marek's Disease Vaccine, Serotype 1, Live Virus, Code 1631.01

Marek's Disease Vaccine, Serotype 2, Live Virus, Code 1631.02

Marek's Disease Vaccine, Serotype 2, Live Virus, Code 1631.04

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.01

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.02

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.05

Marek's Disease Vaccine, Serotypes 1 & 3, Live Marek's Disease Virus Vector, Code 1641.R0

Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 1651.03

Marek's Disease Vaccine, Serotypes 1, 2, & 3, Live Virus, Code 1652.00

Marek's Disease Vaccine, Serotypes 1, 2 & 3, Live Virus, Code 1652.01

Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Code 1652.02

Marek's Disease Vaccine, Serotypes 1, 2, & 3, Live Virus, Code 1656.00

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus, Code 16D1.21

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

Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 16G1.00

Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 16G8.00

Marek's Disease Vaccine, Serotypes 1, 2, & 3, Live Virus, Code 16L1.03

Marek's Disease Vaccine, Serotype 1, Live Virus, Code 16L1.04

Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Code 16L1.05

Marek's Disease Vaccine, Serotype 1, Live Virus, Code 16M1.00

Marek's Disease Vaccine, Serotypes 1, 2, & 3, Live Virus, Code 16M2.00

Marek's Disease Vaccine, Serotypes 1, 2, & 3, Live Virus, Code 16M3.00

Newcastle Disease Vaccine, Killed Virus, Code 1705.11

Newcastle Disease Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Live Virus, Code 1711.11

Newcastle Disease Vaccine, B<sub>1</sub> Type, LaSota Strain, Live Virus, Code 1721.13

Newcastle-Bronchitis Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Mass. Type, Live Virus, Code 1761.11

Marek's Disease-Newcastle Disease Vaccine, Serotypes 1 & 3, Live Marek's Disease Virus Vector, Code 17H1.R0

Marble Spleen Disease Vaccine, Live Virus, Code 17M1.20

Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Code 1C82.00

Bordetella Avium Bacterin, Code 2039.00

Autogenous Bacterin, Code 2051.04

Autogenous Vaccine, Killed Virus, Autogenous Bacterin, Code 4500.10

Feline Leukemia Virus, Killed Virus, Code A555.20

Feline Leukemia Vaccine, Killed Virus, Code A555.21

The following product license for Novartis Animal Health US, Inc., Est. 303, was terminated without prejudice on June 20, 2006:

West Nile Virus Antibody, Equine Origin, Code 3995.00

The establishment license and the following product licenses for Stolle Milk Biologics, Inc., Est. 633, were terminated without prejudice on June 1, 2006:

Renibacterium Salmoninarum Antigen Test Kit, ELISA, Code 5800.20

Renibacterium Salmoninarum Antigen Test Kit, ELISA, Code 5800.21

/s/Byron E. Rippke for

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