



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 21-08

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
Director

SUBJECT: Issuance of Licenses

The purpose of this notice is to bring to the attention of interested parties licenses issued and terminated between July 01, 2021 and September 30, 2021. These do not include those licenses reissued to update pertinent information.

There were no new U.S. Veterinary Biologics Establishment Licenses or Permits (new permittees) issued this quarter.

New U.S. Veterinary Biologics Product Licenses and Biological Product Permits (new codes) were issued as follows:

Table with 3 columns: True Name, Code, Est. Name/No. containing details of new licenses and permits issued.

There were no U.S. Veterinary Biologics Establishment Licenses or Permits (Permittees) terminated this quarter.

U.S. Veterinary Biological Product Licenses and Permits (codes) were terminated without prejudice as follows:

Table with 3 columns: True Name, Code, Est. Name/No. containing details of terminated licenses and permits.

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 21-07

True Name	Code	Est. Name/No.
Bovine Parainfluenza 3 Virus, Modified Live Virus	A841.22	Zoetis Inc./Est No. 190
Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus	1091.20	Zoetis Inc./Est No. 190
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.22	Intervet Inc./Est No. 165A
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4141.20	Intervet Inc./Est No. 165A
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus	1185.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus Bacterin	44D5.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Hardjo Bacterin	4L49.20	Zoetis Inc./Est No. 190
Bronchitis Vaccine, Georgia Type, Live Virus	1231.1J	Intervet Inc./Est No. 165A
Bursal Disease Vaccine, Live Virus	1271.40	Intervet Inc./Est No. 165A
Bursal Disease Virus, Live Virus	A271.21	Intervet Inc./Est No. 165A
Canine Distemper Vaccine, Modified Live Virus	1301.20	Intervet Inc./Est No. 165A
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus	1599.29	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.24	Intervet Inc./Est No. 165A
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	4637.29	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Parainfluenza Vaccine, Modified Live Virus	1421.20	Elanco US Inc./Est No. 196
Canine Parainfluenza Vaccine, Modified Live Virus, Bordetella Bronchiseptica Bacterin	47A1.20	Elanco US Inc./Est No. 196
Canine Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus, Avirulent Live Culture	14M1.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Clostridium Perfringens Type A Toxoid	8081.00	Elanco US Inc./Est No. 196
Clostridium Perfringens Type A Toxoid	8081.01	Elanco US Inc./Est No. 196
Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid	7890.00	Intervet Inc./Est No. 165A
Clostridium Perfringens Types C & D Antitoxin, Equine Origin	6221.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Coccidiosis Vaccine, Live Oocysts	1431.5C	Intervet Inc./Est No. 165A
Equine Rhinopneumonitis Vaccine, Modified Live Virus	1521.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Erysipelothrix Rhusiopathiae Bacterin	2641.02	Intervet Inc./Est No. 165A
Erysipelothrix Rhusiopathiae Bacterin	2641.01	Intervet Inc./Est No. 165A
Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	2A41.01	Intervet Inc./Est No. 165A
Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	2A41.00	Intervet Inc./Est No. 165A
Escherichia Coli Antibody, Equine Origin	3526.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Escherichia Coli Bacterin	2648.43	Intervet Inc./Est No. 165A
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus	16D9.20	Intervet Inc./Est No. 165A
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus	16D1.22	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Rhinotracheitis-Calicivirus Vaccine, Modified Live Virus	16C1.20	Intervet Inc./Est No. 165A
Fowl Laryngotracheitis Vaccine, Modified Live Virus	1601.02	Intervet Inc./Est No. 165A
Glaesserella Parasuis Bacterin	2652.00	Intervet Inc./Est No. 165A
Glaesserella Parasuis-Mycoplasma Hyopneumoniae Bacterin	2565.00	Intervet Inc./Est No. 165A
Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture	1861.R0	Intervet Inc./Est No. 165A
Marek's Disease Vaccine, Serotypes 1 & 3, Live Herpesvirus Chimera	1631.R0	Intervet Inc./Est No. 165A
Moraxella Bovis Bacterin	2772.04	Intervet Inc./Est No. 165A
Mycobacterium Cell Wall Fraction	1300.00	NovaVive USA Inc./Est No. 289
Mycoplasma Hyopneumoniae Bacterin	2775.05	Pharmgate Biologics, Inc./Est No. 329
Mycoplasma Hyopneumoniae Bacterin	2775.02	Pharmgate Biologics, Inc./Est No. 329
Parvovirus Vaccine, Modified Live Virus	18M1.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Parvovirus-Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49F6.2A	Zoetis Inc./Est No. 190
Parvovirus-Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	49G6.2A	Zoetis Inc./Est No. 190

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 21-07**

<b>True Name</b>	<b>Code</b>	<b>Est. Name/No.</b>
Pigeon Pox Vaccine, Live Virus	1881.14	Intervet Inc./Est No. 165A
Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus	19A5.2A	Zoetis Inc./Est No. 190
Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	4994.2B	Zoetis Inc./Est No. 190
Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Mycoplasma Hyopneumoniae Bacterin	4995.2A	Zoetis Inc./Est No. 190
Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Mycoplasma Hyopneumoniae Bacterin	4995.2B	Zoetis Inc./Est No. 190
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus	19A5.24	Intervet Inc./Est No. 165A
Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Mycoplasma Hyopneumoniae Bacterin	4995.23	Zoetis Inc./Est No. 190
Swine Influenza Vaccine, RNA	19A5.D0	Intervet Inc./Est No. 165A
Trueperella Pyogenes-Escherichia Coli-Pasteurella Multocida-Salmonella Typhimurium Antibody, Bovine Origin	3400.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124

Due to acquisitions, U.S. Veterinary Biological Product Licenses and Permits have been issued as follows:

<b>Previous Est. No./Prod Code</b>	<b>True Name</b>	<b>Code</b>	<b>Purchasing Est. Name/No.</b>
From Firm 124 - Code 155920, first licensed 04/04/2011	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	1559.22	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
From Firm 124 - Code 16D520, first licensed 04/04/2011	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124