



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 18-06

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 January 01, 2018 and March 31, 2018. These do not include those licenses reissued to update pertinent information.

New U.S. Veterinary Biological Establishment Licenses and Permits (new permittees) were issued as follows:

Table with 3 columns: Est. Name and Address, Est. No., Type. Row 1: Medgene Labs Brookings, SD, 474, Licensee

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. Multiple rows listing various vaccines and products with their respective codes and establishment names.

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:

True Name	Code	Est. Name/No.
Avian Encephalomyelitis Vaccine, Live Virus	1051.11	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Parainfluenza 3 Vaccine, Killed Virus, Mannheimia Haemolytica-Pasteurella Multocida Bacterin	4265.00	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Parainfluenza 3 Vaccine, Modified Live Virus	1121.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.23	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin	44C9.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin	44C9.23	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44D9.23	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4469.23	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Virus Diarrhea Vaccine, Modified Live Virus	1201.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Brucella Abortus, Killed Culture	E013.02	Colorado Serum Company/Est No. 188
Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Virus	1A82.50	Zoetis Inc./Est No. 190
Canine Distemper-Hepatitis-Parainfluenza Vaccine, Modified Live Virus	1381.21	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Canine Distemper-Hepatitis-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterin	47P9.22	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Encephalomyelitis Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4865.27	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Encephalomyelitis Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4867.21	Zoetis Inc./Est No. 190
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus	1485.20	Colorado Serum Company/Est No. 188
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4865.20	Colorado Serum Company/Est No. 188
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4865.26	Zoetis Inc./Est No. 190
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4865.21	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Encephalomyelitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4875.23	Zoetis Inc./Est No. 190
Encephalomyelitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4835.23	Zoetis Inc./Est No. 190
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4847.23	Zoetis Inc./Est No. 190
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4845.23	Zoetis Inc./Est No. 190
Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	48W5.23	Zoetis Inc./Est No. 190
Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	48W5.22	Zoetis Inc./Est No. 190
Haemophilus Parasuis Vaccine, Avirulent Live Culture	A9J1.00	Newport Laboratories, Inc./Est No. 455
Haemophilus Parasuis Vaccine, Avirulent Live Culture	19J1.01	Newport Laboratories, Inc./Est No. 455
Haemophilus Parasuis Vaccine, Avirulent Live Culture, Mycoplasma Hyopneumoniae Bacterin	4A79.00	Newport Laboratories, Inc./Est No. 455
Mycoplasma Hyopneumoniae Bacterin	2775.00	Newport Laboratories, Inc./Est No. 455
Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterin	4960.00	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Tetanus Toxoid	8601.01	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Tetanus Toxoid	8601.03	Zoetis Inc./Est No. 190

There were no Product Licenses or Permits (codes) issued due to an acquisition this quarter.