



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

1920 Dayton Ave PO Box 844 Ames, IA 50010

(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 18-12

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

FROM: Byron Rippke
Director [Signature]

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, 2018 and September 30, 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: HIPRA USA, LLC Lincoln, NE, 449A, Permittee

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 their codes.

True Name	Code	Est. Name/No.
Moraxella Bovoculi Bacterin	2A77.01	Addison Biological Laboratory, Inc./Est No. 355
Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector	19K5.R4	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Staphylococcus Aureus Bacterin	2852.00	HIPRA USA, LLC/Est No. 449A
West Nile Virus Vaccine, Killed Virus	1995.21	Boehringer Ingelheim Vetmedica, Inc./Est No. 124

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.
Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Haemophilus Parasuis-Pasteurella Multocida Bacterin-Toxoid	7045.00	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin-Toxoid	7054.00	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	45H5.20	Texas Vet Lab, Inc./Est No. 290
Bovine Rhinotracheitis Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	45H5.21	Texas Vet Lab, Inc./Est No. 290
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA	5430.22	Bio-Rad Laboratories/Est No. 624
Bovine Virus Diarrhea Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	4C95.20	Texas Vet Lab, Inc./Est No. 290
Campylobacter Fetus-jejuni Bacterin	2860.00	Hygieia Biological Laboratories/Est No. 407
Canine Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus	14R7.22	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus	1599.20	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46J9.28	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	4637.28	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterial Extract	4639.28	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.20	Elanco US Inc./Est No. 196
Chronic Wasting Disease Antigen Test Kit, ELISA	5420.22	Bio-Rad Laboratories/Est No. 624
Clostridium Perfringens Type C Toxoid	H101.00	Colorado Serum Company/Est No. 188
Encephalomyelitis-Influenza-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	46W5.21	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4847.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Feline Calicivirus Vaccine, Killed Virus	15C5.21	Elanco US Inc./Est No. 196
Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus	15D5.R0	Elanco US Inc./Est No. 196
Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	15B5.20	Elanco US Inc./Est No. 196
Feline Rhinotracheitis-Calicivirus Vaccine, Modified Live Virus	16C1.22	Elanco US Inc./Est No. 196
Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	7895.00	Texas Vet Lab, Inc./Est No. 290
Leptospira Canicola-Icterohaemorrhagiae Bacterial Extract	2671.05	Elanco US Inc./Est No. 196
Mannheimia Haemolytica Bacterin-Toxoid	7905.00	Texas Vet Lab, Inc./Est No. 290
Parvovirus Vaccine, Modified Live Virus	18M1.24	Elanco US Inc./Est No. 196
Porcine Epidemic Diarrhea Vaccine, RNA	19U5.D0	Intervet Inc./Est No. 165A

True Name	Code	Est. Name/No.
Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus	19S1.21	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Salmonella Choleraesuis Vaccine, Avirulent Live Culture	19A1.01	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Salmonella Enteritidis Antibody Test Kit	5SE5.00	IDEXX Laboratories, Inc./Est No. 313
Scrapie Antigen Test Kit, ELISA	5410.21	Bio-Rad Laboratories/Est No. 624

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

