

United States Department of Agriculture

Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-04

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 April 01, 2020 and June 30, 2020. 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:

True Name	Code	Est. Name/No.
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Mannheimia Haemolytica Bacterial Extract-Toxoid	4X29.R0	Elanco US Inc./Est No. 196
Bovine Virus Diarrhea Vaccine, Modified Live Virus, Mannheimia Haemolytica Bacterial Extract-Toxoid	4X39.R0	Elanco US Inc./Est No. 196
Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector	1A89.R1	Biomune Company/Est No. 368
Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector	1A91.R2	Biomune Company/Est No. 368
Canine Coronavirus Vaccine, Killed Virus	14P5.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46E5.28	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus	1599.24	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46J9.23	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Icterohaemorrhagiae Bacterial Extract	46P9.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.24	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.22	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Clostridium Chauvoei, Killed Culture	B250.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Lawsonia Intracellularis Bacterin	2799.21	Intervet Inc./Est No. 165A

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U.S. Veterinary Biologics Establishment Licenses and Permits (Permittees) were terminated without prejudice as follows:

Est. Name and Address	Est. No.	Туре
Thermo Fisher Scientific Austin, TX	582A	Permittee

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

True Name	Code	Est. Name/No.
Allergenic Extract, Prescription Product	9531.00	ALK-Abello, Inc./Est No. 259
Bordetella Bronchiseptica Bacterin	2100.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44D7.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4465.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass Type, Killed Virus	12M5.91	Zoetis Inc./Est No. 190
Canine Coronavirus Vaccine, Killed Virus, Borrelia Burgdorferi Bacterin	47A5.20	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Icterohaemorrhagiae Bacterial Extract	46L9.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Icterohaemorrhagiae Bacterial Extract	46P9.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Parainfluenza Vaccine, Modified Live Virus	1421.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Parainfluenza Vaccine, Modified Live Virus, Bordetella Bronchiseptica Bacterin	47A1.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124

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