



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-03

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, 2020 and March 31, 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:

Table with 3 columns: True Name, Code, Est. Name/No. containing details for various vaccines and products like Bovine Rhinotracheitis-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Fowl Laryngotracheitis-Marek's Disease Vaccine, etc.

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

Table with 3 columns: Est. Name and Address, Est. No., Type. Contains one entry for Abaxis, Inc. in Union City, CA.

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. Contains one entry for Anaplasmosis Vaccine, Avirulent Live Culture.

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True Name	Code	Est. Name/No.
Bluetongue Vaccine, Serotype 10, Modified Live Virus	1061.C1	Poultry Health Laboratories/Est No. 357
Bluetongue Vaccine, Serotype 11, Modified Live Virus	1061.C2	Poultry Health Laboratories/Est No. 357
Bluetongue Vaccine, Serotype 17, Modified Live Virus	1061.C0	Poultry Health Laboratories/Est No. 357
Bordetella Bronchiseptica Vaccine, Avirulent Live Culture	1081.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bordetella Bronchiseptica Vaccine, Avirulent Live Culture	1081.00	Elanco US Inc./Est No. 196
Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid	7060.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Borrelia Burgdorferi Bacterin	2126.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	2146.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bovine Rhinotracheitis Vaccine, Modified Live Virus	1101.21	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1071.21	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.26	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona-Mannheimia Haemolytica Bacterin	4475.20	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Mannheimia Haemolytica Bacterin	44A5.20	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.25	Elanco US Inc./Est No. 196
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.26	Elanco US Inc./Est No. 196
Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.10	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.10	Elanco US Inc./Est No. 196
Canine Anaplasma Antibody Test Kit	5751.20	Abaxis, Inc./Est No. 424
Canine Borrelia Burgdorferi Antibody Test Kit	5017.50	Abaxis, Inc./Est No. 424
Canine Coronavirus Vaccine, Killed Virus	14P5.22	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Coronavirus Vaccine, Killed Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	47E5.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46E5.27	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Borrelia Burgdorferi Bacterin	47C5.29	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46B9.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Icterohaemorrhagiae Bacterial Extract	46L9.27	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus	1599.27	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	45J9.20	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	46P9.27	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live Virus	13C1.20	Elanco US Inc./Est No. 196
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46D9.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Canine Ehrlichia Antibody Test Kit	5039.20	Abaxis, Inc./Est No. 424
Canine Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus, Avirulent Live Culture	14M1.20	Elanco US Inc./Est No. 196
Canine Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola Icterohaemorrhagiae Bacterin	47B1.20	Elanco US Inc./Est No. 196
Chlamydia Psittaci Vaccine, Killed Chlamydia	1585.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Encephalomyelitis Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4867.22	Zoetis Inc./Est No. 190

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True Name	Code	Est. Name/No.
Encephalomyelitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4875.26	Zoetis Inc./Est No. 190
Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Killed Flavivirus Chimera	14W5.R1	Intervet Inc./Est No. 165A
Equine Rhinopneumonitis Vaccine, Modified Live Virus	1521.21	Elanco US Inc./Est No. 196
Feline Leukemia Vaccine, Killed Virus	1555.R1	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Leukemia Vaccine, Killed Virus	1555.R5	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	15B5.22	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus	15B9.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	1559.23	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.22	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.23	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus	16D8.20	Elanco US Inc./Est No. 196
Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	16E5.23	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live Virus, Killed Chlamydia	16E6.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Heartworm Antigen Test Kit	5018.00	Abaxis, Inc./Est No. 424
Mannheimia Haemolytica Toxoid	8699.01	Elanco US Inc./Est No. 196
Mycobacterium Avium subspecies Paratuberculosis Bacterin	2773.00	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Mycobacterium Avium subspecies Paratuberculosis Bacterin	2773.00	Elanco US Inc./Est No. 196
Newcastle Disease Vaccine, Killed Virus	1705.11	Elanco US Inc./Est No. 196
Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Ark Types, Live Virus	17A1.1M	Zoetis Inc./Est No. 190
Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass & Conn Types, Live Virus	1771.17	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Parvovirus Vaccine, Killed Virus	18P5.22	Zoetis Inc./Est No. 190
Parvovirus Vaccine, Killed Virus	A8P5.23	Zoetis Inc./Est No. 190
Parvovirus Vaccine, Modified Live Virus	18M1.29	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Parvovirus Vaccine, Modified Live Virus	18M1.21	Elanco US Inc./Est No. 196
Rabies Vaccine, Killed Virus	1905.24	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Rabies Vaccine, Live Raccoon Poxvirus Vector	1901.R5	Elanco US Inc./Est No. 196
Trichomonas Foetus Vaccine, Killed Protozoa	1859.00	Elanco US Inc./Est No. 196
Trichomonas Foetus Vaccine, Killed Protozoa-Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4990.00	Elanco US Inc./Est No. 196

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

Previous Est. No./Prod Code	True Name	Code	Purchasing Est. Name/No.
From Firm 424 - Code 575120	Canine Anaplasma Antibody Test Kit	5751.20	Zoetis Inc./Est No. 190
From Firm 424 - Code 501750	Canine Borrelia Burgdorferi Antibody Test Kit	5017.50	Zoetis Inc./Est No. 190
From Firm 424 - Code 503920	Canine Ehrlichia Antibody Test Kit	5039.20	Zoetis Inc./Est No. 190
From Firm 424 - Code 501800	Heartworm Antigen Test Kit	5018.01	Zoetis Inc./Est No. 190