



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-05

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, 2017 and March 31, 2017. 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 various biological products and their associated codes and manufacturers.

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. Lists terminated entities like Allergy Laboratories, Inc. and Professional Veterinary Services, Inc.

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

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True Name	Code	Est. Name/No.
Allergenic Extract, Cat Hair	95C1.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, House Dust	9521.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Epidermals	9527.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Grasses	9522.03	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Inhalants	9524.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Insects	9528.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Mites	95A1.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Molds	9523.00	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Ragweed	9522.01	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Trees	9522.02	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Mixed Weeds	9522.04	Allergy Laboratories, Inc./Est No. 629
Allergenic Extract, Prescription Product	9531.00	Allergy Laboratories, Inc./Est No. 629
Antivenin, Crotalidae Polyvalent, Equine Origin	6101.01	Lake Immunogenics, Inc./Est No. 318
Coccidiosis Vaccine, Live Oocysts	1431.56	Biomune Company/Est No. 368A
Erysipelothrix Rhusiopathiae Vaccine, Avirulent Live Culture	1541.02	Arko Laboratories Ltd./Est No. 337
Pasteurella Multocida Vaccine, Avirulent Live Culture, Avian Isolate	1871.02	Arko Laboratories Ltd./Est No. 337
Pasteurella Multocida Vaccine, Avirulent Live Culture, Avian Isolate	1871.03	Arko Laboratories Ltd./Est No. 337
Tuberculin, PPD Bovis, Intradermic	5302.00	Professional Veterinary Services, Inc./Est No. 422A

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 Est. 112 / Prod. 6101.00	Antivenin, Crotalidae Polyvalent	6101.00	Elanco US Inc./Est No. 196
Firm 124 - Code 108100	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture	1081.00	Elanco US Inc./Est No. 196
Firm 124 - Code 108102	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture	1081.02	Elanco US Inc./Est No. 196
Firm 124 - Code 212601	Borrelia Burgdorferi Bacterin	2126.01	Elanco US Inc./Est No. 196
Firm 124 - Code 212600	Borrelia Burgdorferi Bacterin	2126.00	Elanco US Inc./Est No. 196
Firm 124 - Code 214600	Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	2146.00	Elanco US Inc./Est No. 196
Firm 124 - Code 110121	Bovine Rhinotracheitis Vaccine, Modified Live Virus	1101.21	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1071.20	Bovine Rhinotracheitis-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1071.21	Elanco US Inc./Est No. 196
Firm 124 - Code 115126	Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.26	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1185.22	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus	1185.23	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 4465.21	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4465.24	Elanco US Inc./Est No. 196
Firm 124 - Code 447520	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona-Mannheimia Haemolytica Bacterin	4475.20	Elanco US Inc./Est No. 196
Firm 124 - Code 44A520	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Mannheimia Haemolytica Bacterin	44A5.20	Elanco US Inc./Est No. 196
Firm 124 - Code 118125	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.25	Elanco US Inc./Est No. 196
112 Code 1181.22	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.26	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1205.22	Bovine Virus Diarrhea Vaccine, Killed Virus	1205.22	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 2863.10	Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.10	Elanco US Inc./Est No. 196

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Previous Est. No./Prod Code	True Name	Code	Purchasing Est. Name/No.
From Est. 112 / Prod. 12X1.20	Canine Adenovirus Type 2-Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus & Avirulent Live Culture	12X1.20	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 14P5.20	Canine Coronavirus Vaccine, Killed Virus	14P5.20	Elanco US Inc./Est No. 196
Firm 124 - Code 14P522	Canine Coronavirus Vaccine, Killed Virus	14P5.22	Elanco US Inc./Est No. 196
Firm 124 - Code 47A520	Canine Coronavirus Vaccine, Killed Virus, Borrelia Burgdorferi Bacterin	47A5.20	Elanco US Inc./Est No. 196
Firm 124 - Code 47E521	Canine Coronavirus Vaccine, Killed Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	47E5.21	Elanco US Inc./Est No. 196
Firm 124 - Code 46E527	Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46E5.27	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 46E5.21	Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46E5.21	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 46D5.27	Canine Coronavirus Vaccine, Killed Virus, Leptospira Icterohaemorrhagiae Bacterial Extract	46D5.27	Elanco US Inc./Est No. 196
Firm 124 - Code 14R722	Canine Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus	14R7.22	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 14R7.29	Canine Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus	14R7.29	Elanco US Inc./Est No. 196
Firm 124 - Code 159920	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus	1599.20	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1599.29	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus	1599.29	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 47C5.29	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Borrelia Burgdorferi Bacterin	47C5.29	Elanco US Inc./Est No. 196
Firm 124 - Code 46B921	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	Elanco US Inc./Est No. 196
Firm 124 - Code 46J928	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
Firm 124 - Code 46J929	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46J9.29	Elanco US Inc./Est No. 196
Firm 124 - Code 46L927	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
Firm 124 - Code 159927	Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus	1599.27	Elanco US Inc./Est No. 196
Firm 124 - Code 45J920	Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	45J9.20	Elanco US Inc./Est No. 196
Firm 124 - Code 46P927	Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Icterohaemorrhagiae Bacterial Extract	46P9.27	Elanco US Inc./Est No. 196
Firm 124 - Code 13C120	Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live Virus	13C1.20	Elanco US Inc./Est No. 196
Firm 124 - Code 13D127	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.27	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 13D1.29	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.29	Elanco US Inc./Est No. 196
Firm 124 - Code 46D920	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	46D9.20	Elanco US Inc./Est No. 196
Firm 124 - Code 463728	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
From Est. 112 / Prod. 4637.29	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	4637.29	Elanco US Inc./Est No. 196
Firm 124 - Code 463928	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterial Extract	4639.28	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1331.27	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.27	Elanco US Inc./Est No. 196

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Firm 124 - Code 133120	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.20	Elanco US Inc./Est No. 196
Firm 124 - Code 133123	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.23	Elanco US Inc./Est No. 196
Firm 124 - Code 47N920	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	47N9.20	Elanco US Inc./Est No. 196
Firm 124 - Code 15K521	Canine Influenza Vaccine, H3N8, Killed Virus	15K5.21	Elanco US Inc./Est No. 196
Firm 124 - Code 14M120	Canine Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus, Avirulent Live Culture	14M1.20	Elanco US Inc./Est No. 196
Firm 124 - Code 47B120	Canine Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola Icterohaemorrhagiae Bacterin	47B1.20	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1585.20	Chlamydia Psittaci Vaccine, Killed Chlamydia	1585.20	Elanco US Inc./Est No. 196
Firm 124 - Code 152121	Equine Rhinopneumonitis Vaccine, Modified Live Virus	1521.21	Elanco US Inc./Est No. 196
Firm 124 - Code 15C522	Feline Calicivirus Vaccine, Killed Virus	15C5.22	Elanco US Inc./Est No. 196
Firm 124 - Code 15C521	Feline Calicivirus Vaccine, Killed Virus	15C5.21	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 15A5.23	Feline Immunodeficiency Virus Vaccine, Killed Virus	15A5.23	Elanco US Inc./Est No. 196
Firm 124 - Code 15A521	Feline Immunodeficiency Virus Vaccine, Killed Virus	15A5.21	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 15D5.R0	Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus	15D5.R0	Elanco US Inc./Est No. 196
Firm 124 - Code 1555R1	Feline Leukemia Vaccine, Killed Virus	1555.R1	Elanco US Inc./Est No. 196
Firm 124 - Code 1555R5	Feline Leukemia Vaccine, Killed Virus	1555.R5	Elanco US Inc./Est No. 196
Firm 124 - Code 1A6920	Feline Leukemia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	1A69.20	Elanco US Inc./Est No. 196
Firm 124 - Code 15B520	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	15B5.20	Elanco US Inc./Est No. 196
Firm 124 - Code 15B521	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	15B5.21	Elanco US Inc./Est No. 196
Firm 124 - Code 15B522	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	15B5.22	Elanco US Inc./Est No. 196
Firm 124 - Code 15B921	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus	15B9.21	Elanco US Inc./Est No. 196
Firm 124 - Code 155920	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	1559.20	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1559.23	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	1559.23	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1559.2C	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live & Killed Virus, Killed Chlamydia	1559.2C	Elanco US Inc./Est No. 196
Firm 124 - Code 156121	Feline Panleukopenia Vaccine, Modified Live Virus	1561.21	Elanco US Inc./Est No. 196
Firm 124 - Code 16D522	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.22	Elanco US Inc./Est No. 196
Firm 124 - Code 16D523	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.23	Elanco US Inc./Est No. 196
Firm 124 - Code 16D520	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.20	Elanco US Inc./Est No. 196
Firm 124 - Code 16D720	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus	16D7.20	Elanco US Inc./Est No. 196
Firm 124 - Code 16D820	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus	16D8.20	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 16D1.22	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus	16D1.22	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 16E5.20	Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	16E5.20	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 16E5.23	Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	16E5.23	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 16E6.20	Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live Virus, Killed Chlamydia	16E6.20	Elanco US Inc./Est No. 196
Firm 124 - Code 16C120	Feline Rhinotracheitis-Calicivirus Vaccine, Modified Live Virus	16C1.20	Elanco US Inc./Est No. 196

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Previous Est. No./Prod Code	True Name	Code	Purchasing Est. Name/No.
Firm 124 - Code 16C122	Feline Rhinotracheitis-Calicivirus Vaccine, Modified Live Virus	16C1.22	Elanco US Inc./Est No. 196
Firm 124 - Code 266802	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	2668.02	Elanco US Inc./Est No. 196
Firm 124 - Code 266805	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	2668.05	Elanco US Inc./Est No. 196
Firm 124 - Code 267105	Leptospira Canicola-Icterohaemorrhagiae Bacterial Extract	2671.05	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 8699.01	Mannheimia Haemolytica Toxoid	8699.01	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 2773.00	Mycobacterium Paratuberculosis Bacterin	2773.00	Elanco US Inc./Est No. 196
Firm 124 - Code 18M124	Parvovirus Vaccine, Modified Live Virus	18M1.24	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 18M1.29	Parvovirus Vaccine, Modified Live Virus	18M1.29	Elanco US Inc./Est No. 196
Firm 124 - Code 18M121	Parvovirus Vaccine, Modified Live Virus	18M1.21	Elanco US Inc./Est No. 196
Firm 124 - Code 190524	Rabies Vaccine, Killed Virus	1905.24	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1905.21	Rabies Vaccine, Killed Virus	1905.21	Elanco US Inc./Est No. 196
Firm 124 - Code 1901R5	Rabies Vaccine, Live Raccoon Poxvirus Vector	1901.R5	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 1859.00	Trichomonas Foetus Vaccine, Killed Protozoa	1859.00	Elanco US Inc./Est No. 196
From Est. 112 / Prod. 4990.00	Trichomonas Foetus Vaccine, Killed Protozoa-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4990.00	Elanco US Inc./Est No. 196