



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 22-09

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

FROM: David M. White
Acting Director

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, 2022 and September 30, 2022. 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. Rows include Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus; Canine Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus, Avirulent Live Culture; Lawsonia Intracellularis Bacterin.

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:

Table with 3 columns: True Name, Code, Est. Name/No. Rows include Autogenous Bacterin; Autogenous Vaccine, Killed Virus; Autogenous Vaccine, Killed Virus, Autogenous Bacterin; Autogenous Virus, Killed Virus; Avian Influenza Virus Antibody Test Kit, cELISA.

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| True Name | Code | Est. Name/No. |
|--|-------------|---|
| Avian Influenza Virus Type A Antigen Test Kit | E180.50 | Zoetis Inc./Est No. 190D |
| Avian Influenza Virus Type A Antigen Test Kit | 5180.50 | Zoetis Inc./Est No. 190 |
| Avian Leukosis Virus Antigen Test Kit | 5007.00 | Zoetis Inc./Est No. 190 |
| Avibacterium Paragallinarum Bacterin | 2658.00 | Elanco US Inc./Est No. 196 |
| Brucella Abortus Antibody Test Kit | 5013.30 | VMRD, Inc./Est No. 332 |
| Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector | 1A88.R1 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Canine Brucellosis Antibody Test Kit | 5021.00 | Zoetis Inc./Est No. 190 |
| Canine Coronavirus Vaccine, Modified Live Virus | 14P1.20 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Canine Coronavirus-Parvovirus Vaccine, Modified Live Virus | 14R1.20 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Canine Distemper Vaccine, Live Canarypox Vector | 1301.R0 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Encephalomyelitis-Influenza-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid | D6W5.22 | Hennessy Research Associates, LLC/Est No. 597 |
| Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid | D847.21 | Hennessy Research Associates, LLC/Est No. 597 |
| Feline Interleukin-2 Immunomodulator, Live Canarypox Vector | 9401.R0 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Feline Leukemia Virus Antigen-Feline Immunodeficiency Virus Antibody Test Kit | 502A.00 | Zoetis Inc./Est No. 190 |
| Feline Rhinotracheitis-Calici-Chlamydia Psittaci Vaccine, Modified Live Virus, Modified Live Chlamydia | 16F1.21 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci-Rabies Vaccine, Modified Live & Killed Virus, Modified Live Chlamydia | 1619.20 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Feline Rhinotracheitis-Calici-Panleukopenia-Rabies Vaccine, Modified Live & Killed Virus | 16T9.20 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Feline Rhinotracheitis-Calivirus Vaccine, Modified Live Virus | 16C1.21 | Boehringer Ingelheim Animal Health USA Inc./Est No. 124 |
| Mycoplasma Bovis Bacterin | 2760.00 | American Animal Health, Inc./Est No. 315 |
| Staphylococcus Aureus Phage Lysate | 9355.00 | Delmont Laboratories, Inc./Est No. 339 |
| Swine Influenza Virus Type A Antigen Test Kit | 5181.50 | Zoetis Inc./Est No. 190 |

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