

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. 20-09

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 July 01, 2020 and September 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-Parainfluenza 3-Respiratory Syncytial Virus-Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Modified Live Virus, Avirulent Live Culture	11C8.20	Intervet Inc./Est No. 165A	
Bursal Disease-Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector	1J81.R0	Boehringer Ingelheim Animal Health USA Inc./Est No. 124	
Epizootic Bovine Abortion Agent Vaccine, Live Culture	1544.00	Hygieia Biological Laboratories/Est No. 407	
Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive & Respiratory Forms, Modified Live Virus	19T1.20	Elanco US Inc./Est No. 196	

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.	
Bronchitis Vaccine, Mass Type, Killed Virus	1235.10	Elanco US Inc./Est No. 196	
Bursal Disease Virus, Live Variant	A2B9.42	Kestrel, Inc./Est No. 415	
Bursal Disease Virus, Live Virus	A3B1.00	Kestrel, Inc./Est No. 415	
Bursal Disease Virus, Variant Strain, Live Virus	A2B9.40	A2B9.40 Kestrel, Inc./Est No. 415	
Equine Infectious Anemia Virus Antibody Test Kit	5515.21	Zoetis Inc./Est No. 190	

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True Name	Code	Est. Name/No.	
Heartworm Antigen Test Kit	5018.03	Diamond Animal Health, Inc./Est No. 213	
Heartworm Antigen Test Kit	5018.01	Zoetis Inc./Est No. 190	
Pullorum Antigen, Stained Antigen Polyvalent	5207.00	Elanco US Inc./Est No. 196	
Trichinella Spiralis Antibody Test Kit	5350.00	Safepath Laboratories/Est No. 430	

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.
Identical to Code 4637.29 (licensed) except that production moved from Fort Dodge site to Athens as part of FTC divestiture. Fallout of Code 46J9.23.	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract	4637.24	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Formerly Code 2668.05.	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae- Pomona Bacterial Extract	2668.06	Boehringer Ingelheim Animal Health USA Inc./Est No. 124