

#### **United States Department of Agriculture**

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. 18-01**

**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 October 01, 2017 and December 31, 2017. These do not include those licenses reissued to update pertinent information.

New U.S. Veterinary Biological Establishment Licenses and Permits (new permittees) were issued as follows:

Est. Name and Address	Est. No.	Туре
TechLab, Inc. Radford, VA	446	Licensee

New U.S. Veterinary Biologics Product Licenses and Biological Product Permits (new codes) were issued as follows:

True Name	Code	Est. Name/No.
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.20	Hennessy Research Associates, LLC/Est No. 597
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.90	Colorado Serum Company/Est No. 188
Avian Influenza Vaccine, H5 Subtype, DNA	1057.D0	Antelope Valley Bios, Inc./Est No. 419
Bordetella Bronchiseptica Bacterin	2100.00	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine IgG	3606.03	Alta Genetics USA, Inc./Est No. 448A
Bovine Rotavirus-Coronavirus-Escherichia Coli Antibody, Bovine Origin	3625.R2	ImmuCell Corporation/Est No. 327
Bovine Virus Diarrhea Antigen Test Kit	5A05.50	Zoetis Inc./Est No. 190
Canine Anaplasma Antibody Test Kit	5751.20	SA Scientific, Ltd./Est No. 373
Canine Osteosarcoma Vaccine, Live Listeria Vector	9243.R0	Antelope Valley Bios, Inc./Est No. 419
Canine Parainfluenza Vaccine, Modified Live Virus	1421.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Canine Parainfluenza Vaccine, Modified Live Virus, Bordetella Bronchiseptica Bacterin	47A1.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Equine Rhinopneumonitis Vaccine, Killed Virus	1525.22	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus	1515.22	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Giardia Antigen Test Kit	5G05.20	TechLab, Inc./Est No. 446
Hemorrhagic Enteritis Vaccine, Live Virus	17E1.20	Hygieia Biological Laboratories/Est No. 407
Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector	17H1.R1	Merial, Inc./Est No. 298
Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector	17H1.R2	Merial, Inc./Est No. 298
Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector	19K5.R2	Boehringer Ingelheim Vetmedica, Inc./Est No. 124

### **CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 18-01**

## Page 2

True Name	Code	Est. Name/No.
Swine Influenza Virus Type A Antigen Test Kit	5181.51	Zoetis Inc./Est No. 190
Transmissible Spongiform Encephalopathy Antigen Test Kit, ELISA	5431.20	Bio-Rad Laboratories/Est No. 624

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

Est. Name and Address	Est. No.	Туре
Alere Scarborough, Inc.	330	Licensee
Vetazyme Corporation	321	Licensee

## 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	Vetazyme Corporation/Est No. 321
Autogenous Killed Culture	B051.00	Newport Laboratories, Inc./Est No. 455
Autogenous Virus, Killed Virus	A015.20	Newport Laboratories, Inc./Est No. 455
Autogenous Virus, Killed Virus, Autogenous Killed Culture	D500.20	Newport Laboratories, Inc./Est No. 455
Avian Influenza Virus Type A Antigen Test Kit	5180.50	Alere Scarborough, Inc./Est No. 330
Avian Influenza Virus, H5 Subtype, Killed Baculovirus Vector	A057.R0	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.26	Zoetis Inc./Est No. 190
Coccidiosis Vaccine, Live Oocysts	1431.59	Intervet Inc./Est No. 165A
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus	1475.00	Colorado Serum Company/Est No. 188
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4865.00	Colorado Serum Company/Est No. 188
Encephalomyelitis Virus, Eastern, Killed Virus	A475.00	Colorado Serum Company/Est No. 188
Encephalomyelitis Virus, Western, Killed Virus	A495.00	Colorado Serum Company/Est No. 188
Mycobacterium Paratuberculosis Antibody Test Kit	5064.01	Thermo Fisher Scientific/Est No. 582A
Mycobacterium Tuberculosis Gamma Interferon Test Kit, For Non-Human Primates	5A64.20	Thermo Fisher Scientific/Est No. 582A

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