

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. 19-01

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, 2018 and December 31, 2018. 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
IDT Biologika Corporation Rockville, MD	482A	Permittee

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

True Name	Code	Est. Name/No.
Bovine Coronavirus-Escherichia Coli Antibody, Bovine Origin	36B5.02	ImmuCell Corporation/Est No. 327
Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector	1A89.R1	Intervet Inc./Est No. 165A
Equine Rhinopneumonitis Vaccine, Modified Live Virus	A521.21	Merial, Inc./Est No. 298
Equine Rhinopneumonitis Vaccine, Modified Live Virus	1521.22	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Equine Rhinopneumonitis Virus, Modified Live Virus	A521.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Giardia Antigen Test Kit	5G05.52	Safepath Laboratories/Est No. 430
Mycobacterium Paratuberculosis Antibody Test Kit	5064.20	VMRD, Inc./Est No. 332

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

Est. Name and Address	Est. No.	Туре	
Antelope Valley Bios, Inc. Lincoln, NE	419	Licensee	
Transboundary Animal Biologics, Inc. Ames, IA	428B	Permittee	

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

True Name	Code	Est. Name/No.
Autogenous Bacterin	2051.01	Antelope Valley Bios, Inc./Est No. 419
Autogenous Vaccine, Killed Virus	1015.20	Antelope Valley Bios, Inc./Est No. 419
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.20	Antelope Valley Bios, Inc./Est No. 419
Avian Influenza Vaccine, H5 Subtype, DNA	1057.D0	Antelope Valley Bios, Inc./Est No. 419
Avian Polyomavirus Vaccine, Killed Virus	1A15.00	Antelope Valley Bios, Inc./Est No. 419
Bursal Disease Vaccine, Live Virus	1271.11	Elanco US Inc./Est No. 196
Canine Osteosarcoma Vaccine, Live Listeria Vector	9243.R0	Antelope Valley Bios, Inc./Est No. 419
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus	1475.00	Merial, Inc./Est No. 298
Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4865.00	Merial, Inc./Est No. 298
Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Live Canarypox Vector	14W7.R0	Merial, Inc./Est No. 298
Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Live Canarypox Vector, Tetanus Toxoid	48W9.R0	Merial, Inc./Est No. 298
Equine Influenza Vaccine, Live Canarypox Vector	1501.R0	Merial, Inc./Est No. 298
Escherichia Coli Bacterin-Toxoid	7900.R0	Zoetis Inc./Est No. 190
Feline Leukemia Vaccine, Live Canarypox Vector	1555.R3	Merial, Inc./Est No. 298
Marek's Disease Vaccine, Serotype 3, Live Virus	1641.01	Merial, Inc./Est No. 298
Mycoplasma Hyopneumoniae Bacterin	2775.02	Merial, Inc./Est No. 298
Mycoplasma Hyopneumoniae Bacterin	2775.03	Merial, Inc./Est No. 298
Mycoplasma Hyopneumoniae Bacterin	2775.04	Merial, Inc./Est No. 298
Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus	1711.10	Elanco US Inc./Est No. 196
Newcastle Disease Vaccine, VG/GA Strain, Live Virus	17A2.V1	Merial, Inc./Est No. 298
Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass & Conn Types, Live Virus	1771.14	Merial, Inc./Est No. 298
Newcastle-Bronchitis Vaccine, VG/GA Strain, Mass & Conn Types, Live Virus	17V1.11	Merial, Inc./Est No. 298
Porcine Circovirus Vaccine, Type 2, Killed Virus	19K5.20	Merial, Inc./Est No. 298
Porcine Circovirus Vaccine, Type 2, Killed Virus, Mycoplasma Hyopneumoniae Bacterin	48K5.20	Merial, Inc./Est No. 298
Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus	19S1.20	Boehringer Ingelheim Vetmedica, Inc./Est No. 124
Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus	19S1.R2	Merial, Inc./Est No. 298
Tetanus Toxoid	8601.00	Merial, Inc./Est No. 298
West Nile Virus Vaccine, Killed Virus	1995.22	Zoetis Inc./Est No. 190
West Nile Virus Vaccine, Live Canarypox Vector	1991.R0	Merial, Inc./Est No. 298

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 419 - Code 205101, first licensed 05/02/2008	Autogenous Bacterin	2051.01	Huvepharma, Inc./Est No. 605
From Firm 419 - Code 101520, first licensed 08/16/2016	Autogenous Vaccine, Killed Virus	1015.20	Huvepharma, Inc./Est No. 605
From Firm 419 - Code 450020, first licensed 11/01/2016	Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.20	Huvepharma, Inc./Est No. 605
From Firm 419 - Code 1057D0, first licensed 11/07/2017	Avian Influenza Vaccine, H5 Subtype, DNA	1057.D0	Huvepharma, Inc./Est No. 605

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Previous Est. No./Prod Code	True Name	Code	Purchasing Est. Name/No.
From Firm 419 - Code 1A1500, first licensed 04/28/2014	Avian Polyomavirus Vaccine, Killed Virus	1A15.00	Huvepharma, Inc./Est No. 605
From Firm 419 - Code 9243R0, first licensed 12/19/2017	Canine Osteosarcoma Vaccine, Live Listeria Vector	9243.R0	Huvepharma, Inc./Est No. 605