



Animal and Plant Health Inspection Services

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 21-01

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, 2020 and December 31, 2020. 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:

Table with 3 columns: Est. Name and Address, Est. No., Type. Rows include Boehringer Ingelheim Animal Health USA Inc. and Zoetis Inc.

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. Lists various vaccines and biologics with their respective codes and manufacturers.

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<b>True Name</b>	<b>Code</b>	<b>Est. Name/No.</b>
Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector	16N1.R3	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Newcastle Disease Vaccine, VG/GA Strain, Live Virus	17A2.V3	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive Form, Modified Live Virus	19Q1.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus	19S1.23	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Porcine Reproductive & Respiratory Syndrome-Circovirus Vaccine, Respiratory Form, Type 2, Modified Live Virus, Killed Baculovirus Vector	19P9.R1	Boehringer Ingelheim Animal Health USA Inc./Est No. 124

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

<b>Est. Name and Address</b>	<b>Est. No.</b>	<b>Type</b>
T-Cyte Therapeutics, Inc. Murrieta, CA	598	Licensee

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

<b>True Name</b>	<b>Code</b>	<b>Est. Name/No.</b>
Autogenous Vaccine, Killed Virus	1015.20	Kennebec River Biosciences, Inc./Est No. 476
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.20	Kennebec River Biosciences, Inc./Est No. 476
Bluetongue Virus Antibody Test Kit	5010.00	Veterinary Diagnostic Technology, Inc./Est No. 336
Bluetongue Virus Antibody Test Kit, cELISA	5010.20	Veterinary Diagnostic Technology, Inc./Est No. 336
Bovine Leukemia Virus Antibody Test Kit	5505.20	Veterinary Diagnostic Technology, Inc./Est No. 336
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona-Mannheimia Haemolytica Bacterin	4475.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector	1A89.R1	Biomune Company/Est No. 368
Canine Osteosarcoma Vaccine, Live Listeria Vector	9243.R0	Huvepharma, Inc./Est No. 605
Caprine Arthritis-Encephalitis-Ovine Progressive Pneumonia Virus Antibody Test Kit	5140.00	Veterinary Diagnostic Technology, Inc./Est No. 336
Epizootic Hemorrhagic Disease Virus Antibody Test Kit	5A27.00	Veterinary Diagnostic Technology, Inc./Est No. 336
Glaesserella Parasuis Vaccine, Avirulent Live Culture	19J1.00	Newport Laboratories, Inc./Est No. 455
Lymphocyte T-Cell Immunomodulator	9410.00	T-Cyte Therapeutics, Inc./Est No. 598
Mycoplasma Hyopneumoniae Bacterin	B775.07	Pharmgate Biologics, Inc./Est No. 329
Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	48C5.21	Boehringer Ingelheim Animal Health USA Inc./Est No. 124
Porcine Reproductive & Respiratory Syndrome-Parvovirus Vaccine, Reproductive Form, Modified Live & Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4P19.20	Boehringer Ingelheim Animal Health USA Inc./Est No. 124

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