



April 6, 2012

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-08

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for
Veterinary Biologics

1920 Dayton
Avenue PO Box 844
Ames, IA 50010
(515) 337- 6100

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team
Area Veterinarians in Charge
State Veterinarians

FROM: Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Issuance of Licenses

The purpose of this notice is to bring to the attention of interested parties licenses issued and terminated during the months of January, February, and March 2012. These do not include those licenses reissued to update pertinent information. A product license or permit for distribution and sale has been issued for each of the following:

True Name	Product Code	Establishment/ Permittee	Date
Autogenous Vaccine, Killed Virus	1015.21	Novartis Animal Health US, Inc., Est. 303	2/13/12
Bordetella Bronchiseptica Vaccine, Avirulent Live Culture	1081.02	Boehringer Ingelheim Vetmedica, Inc., Est. 124	2/13/12
Coccidiosis Vaccine, Live Oocysts	1431.5E	Intervet, Inc., Est. 165A	1/9/12
Cyprinid Herpesvirus Type 3 Vaccine, Modified Live Virus	1443.20	Novartis Animal Health US, Inc., Est. 303B	2/3/12
Marek's Disease Vaccine, Serotype 1, Live Virus	16L1.09	Pfizer Inc., Est. 189	2/13/12
Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus	19S1.21	Pfizer Inc., Est. 189	2/22/12

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-08

Page 2

Canine Borrelia Burgdorferi Antibody Test Kit	5017.50	Abaxis, Inc., Est. 424	2/7/12
Swine Influenza Virus Type A Antigen Test Kit	5181.50	Synbiotics Corporation, Est. 312	1/31/12
Canine Distemper-Adenovirus Type 2-Parvovirus Antibody Test Kit, Dot Blot	53P2.50	Biogal USA, Inc., Est. 454A	3/26/12
Salmonella Enteritidis-Typhimurium Antibody Test Kit	57E5.00	BioChek USA, Est. 588A	1/6/12
Canine Heartworm Antigen-Anaplasma Phagocytophilum-Platys-Borrelia Burgdorferi-Ehrlichia Canis-Ewingii Antibody Test Kit	5P21.00	IDEXX Laboratories, Inc., Est. 313	3/26/12
Autogenous Virus, Killed Virus	A015.20	MVP Laboratories, Inc., Est. 301	2/13/12

U.S. Veterinary Biological Product Permit No. 303B was issued on February 3, 2012, to the following:

Novartis Animal Health US, Inc.
1447 140th Street
Larchwood, Iowa 51241

U.S. Veterinary Biological Product Permit No. 454A was issued on March 26, 2012, to the following:

Biogal USA, Inc.
28300 DuPont Boulevard
Millsboro, DE 19966

The establishment license and following product licenses for Strategic Diagnostics, Inc., Est. 398, were terminated without prejudice on March 20, 2012:

Canine Parvovirus Antiserum, Rabbit Origin, Code A8M0.00

Canine Heartworm Antiserum, Rabbit Origin, Code E019.00

Feline Leukemia Virus Antiserum, Rabbit Origin, Code E026.00

The following product license for Fort Dodge Laboratories, Est. 112, was terminated without prejudice on February 13, 2012:

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-08

Page 3

Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterial Extract, Code 46E5.25

The following product licenses for Intervet Inc., Est. 165A, were terminated without prejudice on January 23, 2012:

Bronchitis Vaccine, Ark Type, Live Virus, Code 1231.22

Bursal Disease Vaccine, Live Virus, Code 1271.11

Bursal Disease Vaccine, Live Virus, Code 1271.18

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass Type, Killed Virus, Code 12M5.11

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard & Variant, Killed Virus, Code 12P5.41

Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus, Code 1711.14

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass Type, Live Virus, Code 1761.12

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Conn Types, Live Virus, Code 1761.14

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass Type, Live Virus, Code 1771.18

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Ark Types, Live Virus, Code 17A1.1N

The following product licenses for Lohmann Animal Health International, Est. 196, were terminated without prejudice on February 6, 2012:

Bronchitis Vaccine, Conn Type, Live Virus, Code 1231.15

Bursal Disease Vaccine, Live Virus, Code 1271.00

Tenosynovitis Vaccine, Modified Live Virus, Code 1951.01

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 & 3 & 4 & 3X4, Code 2703.17

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-08

Page 4

Bronchitis Virus, Mass Type, Killed Virus, Code A235.16

Newcastle Disease Virus, B1 Type, LaSota Strain, Killed Virus, Code A705.11

Swine Influenza Virus, H1N1, Live Virus, Code A9A6.10

Mycoplasma Meleagridis, Live Culture, Code E172.00

The following product licenses for Merial Select, Inc., Est. 279, were terminated without prejudice on March 14, 2012:

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Ark Types, Live Virus, Code 12H1.4M

Fowl Pox Vaccine, Live Virus, Code 1621.10

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass Type, Live Virus, Code 1761.12

The following product license for IDEXX Laboratories, Inc., Est. 313, was terminated without prejudice on February 6, 2012:

Brucella Abortus Antibody Test Kit, Code 5013.02

The following product licenses for Meridian Life Science, Inc., Est. 320, were terminated without prejudice on January 26, 2012:

Brucella Abortus Antibody Test Kit, Code 5013.30

Pseudorabies Virus Antibody Test Kit, Code 5110.00

Pseudorabies Virus Antibody Test Kit, Code 5110.01

Equine Infectious Anemia Virus Antibody Test Kit, Code 5515.01

The following product licenses for Poultry Health Laboratories, Est. 357, were terminated without prejudice on February 15, 2012:

Haemophilus Paragallinarum Bacterin, Code 2658.C0

Haemophilus Paragallinarum-Pasteurella Multocida Bacterin, Code 265J.C0

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 & 3 & 4 & 3 X 4, Code 2703.C0

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-08

Page 5

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 & 3 & 4 & 3 X 4,
Code 2703.C1

Due to the acquisition of Fort Dodge Animal Health (Division of Wyeth), Est. 112, by Boehringer Ingelheim Vetmedica, Inc., Est. 124, the following products have been issued to Est. 124:

January 5, 2012:

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid,
Code 4X49.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid,
Code 4X49.21

Pasteurella Multocida Bacterial Extract-Mannheimia Haemolytica Toxoid,
Code 7945.00

Mannheimia Haemolytica Toxoid, Code 8699.01

February 22, 2012:

Salmonella Dublin Vaccine, Live Culture, Code 19D1.R0

Due to the acquisition of Fort Dodge Animal Health (Division of Wyeth), Est. 112, by Pfizer Inc., Est. 189, the following products have been issued to Est. 189:

January 5, 2012:

Equine Influenza Vaccine, Killed Virus, Code 1505.25

Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.27

Tetanus Antitoxin, Code 6302.00

February 13, 2012:

Equine Rhinopneumonitis Vaccine, Killed Virus, Code 1525.24

Mycoplasma Hyopneumoniae Bacterin, Code 2775.02

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-08

Page 6

Mycoplasma Hyopneumoniae Bacterin, Code 2775.03

Mycoplasma Hyopneumoniae Bacterin, Code 2775.05

Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 48C5.01

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4975.01

February 27, 2012:

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid, Code 4845.23

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid, Code 4847.23

Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid, Code 4865.26

Encephalomyelitis Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid, Code 4867.21

Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid, Code 48W5.22

March 20, 2012:

Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus, Code 19S1.20

Encephalomyelitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid, Code 4875.23

March 23, 2012:

Mycoplasma Gallisepticum Vaccine, Live Culture, Code 1751.01