



April 11, 2008

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-06

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

510 S. 17th Street
Suite 104
Ames, IA 50010

(515) 232-5785
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Subject: Issuance of Licenses
To: VS Management Team (VSMT)
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS

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 2008. 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 |
|--|---------------------|--|-------------|
| Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live Virus | 13C1.20 | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus | 13D1.21 | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Equine Influenza Vaccine, Killed Virus | 1505.28 | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus | 1515.2A | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Parvovirus Vaccine, Modified Live Virus | 18M1.21 | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Rabies Vaccine, Killed Virus | 1905.23 | Intervet Inc., Est. 286 | 3/28/08 |
| Autogenous Bacterin | 2051.00 | PerOs USA Inc., Est. 419 | 3/31/08 |



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
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Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

| True Name | Product Code | Establishment/ Permittee | Date |
|---|---------------------|---|-------------|
| Aeromonas Salmonicida-Moritella Viscosa-Vibrio Anguillarum-Salmonicida Bacterin | 2139.00 | Maine BioTek, Inc., Est. 630A | 1/15/08 |
| Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo- Icterohaemorrhagiae-Pomona Bacterin | 2642.02 | Pfizer Inc., Est. 189 | 3/10/08 |
| Mycoplasma Bovis Bacterin | 2760.01 | Biomune Co. Est. 368 | 1/17/08 |
| Canine Distemper-Adenovirus Type 2- Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola- Icterohaemorrhagiae Bacterin | 46J8.20 | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Canine Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola- Icterohaemorrhagiae Bacterin | 47B1.20 | Boehringer Ingelheim Vetmedica, Inc., Est. 124 | 1/22/08 |
| Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo- Icterohaemorrhagiae-Pomona Bacterin | 48C5.22 | Pfizer, Inc., Est. 189 | 3/10/08 |
| Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa- Hardjo-Icterohaemorrhagiae-Pomona Bacterin | 4BC5.22 | Pfizer, Inc., Est. 189 | 3/10/08 |
| Avian Influenza Virus Antibody Test Kit, ELISA | 5004.20 | IDEXX Laboratories, Inc., Est. 313 | 3/18/08 |
| Canine Heartworm Antigen Test Kit | 5018.00 | Quadraspec, Inc., Est. 583 | 1/22/08 |
| Feline Infectious Peritonitis Virus Antibody Test Kit | 5029.00 | Modern Veterinary Therapeutics, LLC, Permittee 544A | 3/12/08 |
| Mycobacterium Bovis Gamma Interferon Test Kit, For Cattle | 5A64.00 | Prionics USA, Inc., Permittee 582A | 3/11/08 |

| True Name | Product Code | Establishment/ Permittee | Date |
|--|---------------------|---|-------------|
| Equine Influenza Vaccine, Killed Virus | A505.20 | Hennessy Research Associates, LLC, Est. 597 | 1/22/08 |
| Salmonella Enteritidis, Killed Culture | B785.00 | Biomune Co., Est. 368 | 3/28/08 |

U.S. Veterinary Biologics Establishment License No. 419 was issued on March 31, 2008, to the following:

PerOs USA Inc.
540 West Industrial Lake Drive
Suite 4
Lincoln, Nebraska 68528
MAIL: PerOs USA Inc.
540 West Industrial Lake Drive
Suite 4
Lincoln, Nebraska 68528

U.S. Veterinary Biological Product Permit No. 544A was issued on March 12, 2008, to the following:

Modern Veterinary Therapeutics, LLC
MAIL: Modern Veterinary Therapeutics, LLC
Kendar Executive Center
1550 Madruga Avenue, Suite 329
Coral Gables, Florida 33146

U.S. Veterinary Biologics Establishment License No. 583 was issued on January 22, 2008, to the following:

Quadraspec, Inc.
3000 Kent Avenue
West Lafayette, Indiana 47906
MAIL: Quadraspec, Inc.
3000 Kent Avenue
West Lafayette, Indiana 47906

U.S. Veterinary Biological Product Permit No. 630A was issued on January 15, 2008, to the following:

Maine Biotek, Inc.
MAIL: Maine Biotek, Inc.
P.O. Box 408
259 Maine Street
Winterport, Maine 04496

The Permit for Distribution and Sale and the following products for Synbiotics Corporation, Permittee No. 312A, were terminated without prejudice on March 14, 2008:

Canine Heartworm Antigen Test Kit, Code 5018.00

Canine Heartworm Antigen Test Kit, Code 5018.01

Canine Parvovirus Antigen Test Kit, Code 5024.01

Feline Leukemia Virus Antigen Test Kit, Code 5028.00

Feline Heartworm Antibody Test Kit, Code 5F18.01

The Permit for Distribution and Sale and the following product for Fonterra, Inc., Permittee No. 341, were terminated without prejudice on March 27, 2008:

Escherichia Coli Antibody, Bovine Origin, Code 3524.00

The following product license for IDEXX Laboratories, Inc., Est. 313, was terminated without prejudice on January 10, 2008:

Bovine Rhinotracheitis Virus Antibody Test Kit, Code 5A09.00

The following product licenses for Merial, Inc., Est. 298, were terminated without prejudice on February 14, 2008:

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Code 1155.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃ Vaccine, Modified Live and Killed Virus, Code 1179.20

Bovine Virus Diarrhea, Killed Virus, Code 1205.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial
Virus Vaccine, Killed Virus, Escherichia Coli-Leptospira Canicola-
Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin-Toxoid,
Code 4A65.20

Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine,
Modified Live Virus and Chlamydia, Code A6E8.20

Rabies Vaccine, Killed Virus, Ehrlichia Risticii Bacterin, Code D905.20

The following product licenses for Synbiotics Corporation, Est. 312, were terminated
without prejudice on March 14, 2008:

Canine Lymphoma Monoclonal Antibody, Code 3405.00

Canine Heartworm Antigen Test Kit, Code 5018.02

Feline Heartworm Antigen Test Kit, Code 5F18.00

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics