



October 14, 2008

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-17**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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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 July, August, and September 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    |
|---|--------------|--|---------|
| Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live Virus                                  | 1171.24      | Pfizer Inc., Est. 189                          | 8/12/08 |
| Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus      | 1181.23      | Pfizer Inc., Est. 189                          | 8/12/08 |
| Marek's Disease Vaccine, Serotypes 1 & 3, Live Herpesvirus Chimera  | 1631.R0      | Schering-Plough Animal Health Corp., Est. 165A | 9/29/08 |
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus  | 19A5.23      | Pfizer Inc., Est. 189                          | 8/1/08  |
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus  | 19A5.29      | Pfizer Inc., Est. 189                          | 8/1/08  |
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae Bacterin                           | 4993.21      | Pfizer Inc., Est. 189                          | 8/1/08  |
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hypopneumoniae Bacterin | 4994.23      | Pfizer Inc., Est. 189                          | 8/1/08  |
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hypopneumoniae Bacterin | 4994.24      | Pfizer Inc., Est. 189                          | 8/1/08  |



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|---|---------|---|---------|
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Mycoplasma Hypopneumoniae Bacterin  | 4995.25 | Pfizer Inc.,<br>Est. 189                                | 8/1/08  |
| Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Mycoplasma Hypopneumoniae Bacterin  | 4995.26 | Pfizer Inc.,<br>Est. 189                                | 8/1/08  |
| Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin | 49F6.23 | Pfizer Inc.,<br>Est. 189                                | 7/24/08 |
| Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin | 49F6.24 | Pfizer Inc.,<br>Est. 189                                | 8/1/08  |
| Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin             | 49G6.23 | Pfizer Inc.,<br>Est. 189                                | 7/24/08 |
| Parvovirus-Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin            | 49G6.24 | Pfizer Inc.,<br>Est. 189                                | 8/1/08  |
| Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector, Mycoplasma Hypopneumoniae Bacterin   | 49K5.R1 | Boehringer<br>Ingelheim<br>Vetmedica, Inc.,<br>Est. 124 | 7/22/08 |
| Canine Heartworm Antigen Test Kit   | 5018.00 | SafePath<br>Laboratories<br>LLC, Est. 430               | 7/25/08 |
| Avian Influenza Virus Type A Antigen Test Kit   | 5180.50 | Inverness<br>Medical<br>Innovations,<br>Est. 330        | 7/23/08 |
| Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA  | 5430.22 | Bio-Rad<br>Laboratories,<br>Est. 624                    | 8/22/08 |
| Canine Parvovirus, Modified Live Virus  | A8M1.23 | Intervet Inc.,<br>Est. 286                              | 8/21/08 |

The Establishment License and following product for Merck Sharp & Dohme, Est. No. 3, were terminated on July 29, 2008:

Rubeola Virus, Live Virus, Code A661.00

The Establishment License and following product for Immune Modulators, LLC, Est. No. 606, were terminated on August 13, 2008:

Bacterial Immunomodulator, Killed Bacteria, Code 9200.00

The Permit for Distribution and Sale of the following products for Abbott Laboratories, Permittee No. 460A, was terminated without prejudice on August 21, 2008:

Feline Leukemia Virus Antigen Test Kit, Code 5028.00

Canine Parvovirus Antigen Test Kit, Code 5024.00

The Permit for Distribution and Sale of the following product for Abbott Laboratories, Permittee No. 460B, was terminated on August 21, 2008:

Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA, Code 5430.20

The following product license for Wyeth, Est. 112, was terminated without prejudice on September 29, 2008:

Sarcocystis Neurona Vaccine, Code 1SN5.20

The following product licenses for Pfizer Inc., Est. 189, were terminated without prejudice on July 24, 2008:

Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus, Code 1091.21

Bovine Rhinotracheitis Vaccine, Modified Live Virus, Code 1101.22

Bovine Rhinotracheitis-Parainfluenza3 Vaccine, Modified Live Virus,  
Code 1121.22

Bovine Rhinotracheitis-Parainfluenza3 Vaccine, Modified Live Virus,  
Code 1121.23

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus,  
Code 1151.25

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live and Killed Virus,  
Code 1157.22

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3 Vaccine, Modified Live  
Virus, Code 1171.21

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial  
Virus Vaccine, Modified Live and Killed Virus, Code 1187.22

Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine,  
Modified Live Virus, Code 11A1.25

Bovine Virus Diarrhea Vaccine, Killed Virus, Code 1205.22

Bordetella Bronchiseptica Bacterin, Code 2100.01

Erysipelothrix Rhusiopathiae Bacterin, Code 2641.00

Actinobacillus Pleuropneumoniae Bacterin, Code 2657.02

Leptospira Hardjo Bacterin, Code 26M7.00

Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus  
Somnus Bacterin, Code 40A6.20

Bovine Rhinotracheitis-Parainfluenza3 Vaccine, Modified Live Virus,  
Haemophilus Somnus Bacterin, Code 4139.20

Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine,  
Modified Live Virus, Leptospira Pomona Bacterin, Code 4367.25

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3 Vaccine, Modified Live  
Virus, Haemophilus Somnus Bacterin, Code 44H9.30

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine,  
Modified Live Virus, Bordetella Bronchiseptica Bacterin, Code 46E9.21

Canine Parainfluenza Vaccine, Modified Live Virus, Bordetella Bronchiseptica  
Bacterin, Code 47A1.20

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-  
Icterohaemorrhagiae-Pomona Bacterin, Code 4975.20

Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida  
Bacterin-Toxoid, Code 7054.00

The following product license for Lohmann Animal Health International, Est. 196, was terminated without prejudice on July 16, 2008:

Marek's Disease Vaccine, Serotype 2, Live Virus, Code 1631.00

The following product licenses for Lohmann Animal Health International, Est. 196, were terminated without prejudice on September 22, 2008:

Avian Reovirus Vaccine, Killed Virus, Code 1045.00

Bursal Disease Vaccine, Standard & Variant, Killed Virus, Code 12B5.40

The following product licenses for Merial Select, Inc., Est. 279, were terminated without prejudice on August 14, 2008:

Bursal Disease-Marek's Disease Vaccine, Standard & Variant, Serotypes 2 & 3, Live Virus, Code 12C8.41

Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus, Code 1711.11

Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus, Code 1721.10

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Conn Types, Live Virus, Code 1761.1X

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

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on August 7, 2008:

Bursal Disease Virus, Killed Virus, Code A275.00

Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture, Code A861.00

Bursal Disease Vaccine, Killed Virus, Code 1275.00

Bursal Disease Vaccine, Killed Virus, Code 1275.10

Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code 12B5.40

Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus,  
Code 12D5.00

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.10

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.40

Bursal Disease-Newcastle Disease Vaccine, Standard and Variant, Killed Virus,  
Code 12G5.41

Bursal Disease-Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus,  
Code 12J5.40

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard and Variant,  
Mass. Type, Killed Virus, Code 12J5.60

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and  
Variant, Mass. Type, Killed Virus, Code 12M5.00

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass. Type,  
Killed Virus, Code 12M5.10

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant,  
Killed Virus, Code 12P5.40

Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture,  
Code 1861.00

The following product licenses for Intervet Inc., Est. 286, were terminated without  
prejudice on September 17, 2008:

Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.23

Fusobacterium Necrophorum Bacterin, Code 2556.00

Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona  
Bacterin, Code 2665.00

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-  
Icterohaemorrhagiae-Pomona Bacterin, Code 2863.00

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western, and  
Venezuelan, Killed Virus, Tetanus Toxoid, Code 4847.31

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The following product license for IDEXX Laboratories, Inc., Est. 313, was terminated without prejudice on September 26, 2008:

Bovine Leukemia Virus Antibody Test Kit, Code 5505.20

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

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