

October 11, 2006

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-22

Subject: Issuance of Licenses

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
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 2006. 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
Avian Influenza Vaccine, H5N3 Subtype, Killed Virus	1057.R3	Wyeth, Est. 112	8/1/06
Bovine Rhinotracheitis-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	1071.20	Texas Vet Lab, Inc., Est. 290	9/5/06
Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus	1331.20	Wyeth, Est. 112	7/13/06
Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus	1515.24	Intervet Inc., Est. 286	9/13/06
West Nile Virus Vaccine, Live Flavivirus Chimera	1991.R1	Intervet Inc., Est. 286	8/31/06
Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector	1A88.R2	Merial Select, Inc., Est. 279	8/7/06
Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.07	Novartis Animal Health US, Inc., Est. 303	9/21/06
Leptospira Hardjo Bacterin	26M7.02	Pfizer Inc., Est. 189	8/25/06
Mycoplasma Hyopneumoniae Bacterin	2775.02	ProtaTek International, Inc., Est. 329	8/25/06
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4431.22	Wyeth, Est. 112	8/7/06

True Name	Product Code	Establishment/ Permittee	Date
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44B5.20	Novartis Animal Health US, Inc., Est. 303	8/7/06
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Campylobacter Fetus-Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44M5.22	Novartis Animal Health US, Inc., Est. 303	8/7/06
Encephalomyelitis-Rhinopneumonitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4844.30	Intervet Inc., Est. 286	9/13/06
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4845.33	Intervet Inc., Est. 286	8/7/06
Encephalomyelitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid	4875.A1	Intervet Inc., Est. 286	8/7/06
Bovine Virus Diarrhea Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	4C95.20	Texas Vet Lab, Inc., Est. 290	8/25/06
Mycobacterium Paratuberculosis DNA Test Kit, Polymerase Chain Reaction	5066.80	Tetracore, Inc., Est. 644	8/25/06
Clostridium Perfringens Type A Toxoid	8081.01	Novartis Animal Health US, Inc., Est. 303	7/17/06
Bovine Virus Diarrhea Virus, Killed Virus	A205.25	Pfizer Inc., Est. 189	8/7/06

U.S. Veterinary Biologics Establishment License No. 644 was issued on August 25, 2006, to the following:

Tetracore, Inc.
 9901 Belward Campus Drive, Suite 300
 Rockville, Maryland 20850
 MAIL: Tetracore, Inc.
 9901 Belward Campus Drive, Suite 300
 Rockville, Maryland 20850

The following product licenses for Wyeth, Est. 112, were terminated without prejudice on July 20, 2006:

Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1A82.01

Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus,
Code 1B82.30

/s/Richard E. Hill, Jr.

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

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