

October 7, 2003

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-16

Subject: Issuance of Licenses

To: Biologics Licenses, 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 2003. 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
Lawsonia Intracellularis Vaccine, Avirulent Live Culture	10L1.01	Boehringer Ingelheim Vetmedica, Inc., Est. 124	07/28/2003
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.20	Schering-Plough Animal Health Corp., Est. 165A	09/05/2003
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.25	Pfizer Inc., Est. 189	08/01/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ Vaccine, Modified Live Virus	1171.22	Schering-Plough Animal Health Corp., Est. 165A	09/05/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ Vaccine, Modified Live Virus	1171.22	Wyeth Est. 112	08/08/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ Vaccine, Modified Live Virus	1171.25	Pfizer Inc., Est. 189	08/01/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.20	Novartis Corp. Est. 303	07/10/2003

True Name	Product Code	Establishment/ Permittee	Date
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.22	Wyeth Est. 112	08/08/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.25	Pfizer Inc., Est. 189	08/01/2003
Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Modified Live Virus	11A1.25	Pfizer Inc., Est. 189	08/01/2003
Canine Adenovirus Type 2-Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus and Avirulent Live Culture	12X1.20	Schering-Plough Animal Health Corp., Est. 165A	09/05/2003
Mink Enteritis Vaccine, Killed Virus	1685.22	United Vaccines, Inc., Est. 245	08/01/2003
Feline Rhinotracheitis-Calici-Chlamydia Psittaci Vaccine, Modified Live Virus and Chlamydia	16F1.21	Merial Inc., Est. 298	07/10/2003
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus	19A5.22	Wyeth Est. 112	08/08/2003
Fowl Pox-Mycoplasma Gallisepticum Vaccine, Live Fowl Pox Vector	1D51.R0	Biomune Co. Est. 368	07/03/2003
Pseudomonas Aeruginosa Bacterin	2735.02	United Vaccines, Inc., Est. 245	08/01/2003
Mycoplasma Bovis Bacterin	2760.00	American Animal Health, Inc. Est. 315	08/26/2003
West Nile Virus Antibody, Equine Origin	3995.00	Novartis Corp., Est. 303	08/07/2003
Bovine Rhinotracheitis-Virus Diarrhea-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Pomona Bacterin	4367.25	Pfizer Inc., Est. 189	08/01/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo Icterohaemorrhagiae-Pomona Bacterin	4461.25	Pfizer Inc., Est. 189	08/01/2003

True Name	Product Code	Establishment/ Permittee	Date
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44B1.25	Pfizer Inc. Est. 189	08/01/2003
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ₃ Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4560.25	Pfizer Inc., Est. 189	08/01/2003
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Mycoplasma Hypopneumoniae Bacterin	4995.22	Wyeth Est. 112	09/02/2003
Aleutian Disease Virus, Counterelectrophoresis Antigen	5001.02	United Vaccines, Inc., Est. 245	08/01/2003
Brucella Abortus Antibody Test Kit	5013.30	Meridian Diagnostics, Inc., Est. 320	07/11/2003
Bordetella Avium Antibody Test Kit	5015.00	Synbiotics Corp., Est. 312	07/11/2003
Mycobacterium Bovis Gamma Interferon Test Kit For Cervids	5A64.10	Biocor Animal Health, Est. 462	08/01/2003
Bovine Rhinotracheitis Virus, Modified Live Virus	A101.23	Pfizer Inc., Est. 189	09/02/2003
Bovine Virus Diarrhea Virus, Killed Virus	A205.22	Pfizer Inc., Est. 189	07/21/2003
Bovine Virus Diarrhea Virus, Killed Virus	A205.23	Pfizer Inc., Est. 189	09/02/2003
Bovine Virus Diarrhea Virus, Killed Virus	A205.24	Pfizer Inc., Est. 189	09/02/2003
Mink Enteritis Virus, Killed Virus	A685.20	Heska Corp., Est. 213	08/01/2003
Mink Enteritis Virus, Killed Virus	A685.21	Heska Corp., Est. 213	08/01/2003
Pseudomonas Aeruginosa, Killed Culture	B735.00	Heska Corp., Est. 213	08/01/2003
Pseudomonas Aeruginosa, Killed Culture	B735.01	Heska Corp., Est. 213	08/01/2003
Pseudomonas Aeruginosa, Killed Culture	B735.02	Heska Corp., Est. 213	08/01/2003

True Name	Product Code	Establishment/ Permittee	Date
Pseudomonas Aeruginosa, Killed Culture	B735.03	Heska Corp., Est. 213	08/01/2003
Pseudomonas Aeruginosa, Killed Culture	B735.04	Heska Corp., Est. 213	08/01/2003
Pseudomonas Aeruginosa, Killed Culture	B735.05	Heska Corp., Est. 213	08/01/2003
Pseudomonas Aeruginosa, Killed Culture	B735.06	Heska Corp., Est. 213	08/01/2003
Aleutian Disease Virus Counterelectrophoresis Antigen	E001.20	Heska Corp. Est. 213	08/01/2003

The following product license for Texas Vet Lab, Inc., Est. 290, was terminated without prejudice on August 13, 2003:

Mycoplasma Bovis Bacterin, Code 2760.00

The following product licenses for Heska Corporation, Est. 213, were terminated without prejudice on September 17, 2003:

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Campylobacter Fetus-Leptospira-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4145.30

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 44B9.20

The following product licenses for Schering-Plough Animal Health Corp., Est. 165A, were terminated without prejudice on August 12, 2003:

Bordetella Avium Vaccine, Avirulent Live Culture, Code 1021.00

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1185.20

Mink Distemper Vaccine, Modified Live Virus, Code 1451.00

Escherichia Coli Vaccine, Avirulent Live Culture, Avian Isolate, Code 1551.00

Fowl Laryngotracheitis Vaccine, Live Virus, Code 1601.10

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

Transmissible Gastroenteritis Vaccine, Modified Live Virus, Code 1961.00

Moraxella Bovis Bacterin, Code 2772.00

Moraxella Bovis Bacterin, Code 2772.01

Mycoplasma Hyopneumoniae Bacterin, Code 2775.00

Campylobacter Fetus Bacterin, Code 2862.00

Escherichia Coli Monoclonal Antibody, Murine Origin, Code 3525.00

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4465.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 44D7.20

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine, Killed Virus, Haemophilus Somnus Bacterin, Code 44E7.20

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Clostridium Botulinum Type C Bacterin-Toxoid, Code 4929.30

Mink Distemper-Enteritis Vaccine, Modified Live and Killed Virus, Clostridium Botulinum Type C Pseudomonas Aeruginosa Bacterin-Toxoid, Code 4949.30

Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Modified Live and Killed Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid, Code 49B9.20

Bordetella Bronchiseptica-Pasteurella Multocida Bacterin-Toxoid, Code 7080.01

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C&D-Moraxella Bovis Bacterin-Toxoid, Code 7425.00

Moraxella Bovis Bacterin, Code B772.00

Moraxella Bovis, Killed Culture, Code B772.01

/s/Richard E. Hill

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

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