

April 14, 2004

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-10**

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 January, February, and March 2004. 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:

<b>True Name</b>	<b>Product Code</b>	<b>Establishment/ Permittee</b>	<b>Date</b>
Bordetella Avium Vaccine, Avirulent Live Culture	1021.01	ARKO Laboratories, Ltd., Est. 337	3/18/04
Bovine Rhinotracheitis Vaccine, Modified Live Virus	1101.B0	SolidTech Animal Health, Inc., Est. 604	1/07/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.21	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus	1181.24	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus	12D5.T0	Wyeth, Est. 112	1/07/04
Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus, Canarypox Vector	1331.R1	Merial, Inc., Est. 298	2/26/04
Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus	13D1.T0	Wyeth, Est. 112	3/15/04
Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.02	Biocor Animal Health, Inc., Est. 462	3/15/04

True Name	Product Code	Establishment/ Permittee	Date
Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2863.02	Biocor Animal Health, Inc., Est. 462	3/15/04
Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	2A41.00	Pfizer Inc., Est. 189	2/03/04
Equine IgG-Rhodococcus Equi Antibody, Equine Origin	3900.00	Veterinary Dynamics, Inc., Est. 360	1/22/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4461.20	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4469.24	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin	44C9.21	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin	44C9.24	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44D9.21	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	44D9.24	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	45B9.21	Boehringer Ingelheim Vetmedica, Inc., Est. 124	3/12/04

True Name	Product Code	Establishment/ Permittee	Date
Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C Bacterin-Toxoid	4955.22	United Vaccines, Inc., Est. 245	3/15/04
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	4994.20	Pfizer Inc., Est. 189	2/3/04
Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C-Pseudomonas Aeruginosa Bacterin-Toxoid	49A5.22	United Vaccines, Inc., Est. 245	3/15/04
Canine Heartworm Antigen Test Kit	5018.05	Synbiotics Corp., Est. 312	1/12/04
Caprine Arthritis-Encephalitis Virus Antibody Test Kit, cELISA	5139.20	VMRD, Inc., Est. 332	3/12/04
Chronic Wasting Disease Antigen Test Kit	5420.51	Prion Developmental Laboratories, Est. 632	2/27/04
Bovine Spongiform Encephalopathy Antigen Test Kit, ELISA	5430.20	Bio-Rad Laboratories, Est. 624	3/17/04
Bovine Spongiform Encephalopathy Antigen Test Kit, EIA	5430.21	IDEXX Laboratories, Inc., Est. 313	3/17/04
Foot and Mouth Disease Virus Antibody Test Kit	5FM0.01	United Biomedical, Inc., Est. 620	2/19/04
Clostridium Botulinum Type C Bacterin-Toxoid	7010.02	United Vaccines, Inc., Est. 245	3/10/04
Canine Gonadotropin Releasing Factor Immunotherapeutic	9220.00	Biocor Animal Health, Inc., Est. 462	2/25/04
Bordetella Avium, Avirulent Live Culture	A021.01	Schering-Plough Animal Health Corp., Est. 165A	2/18/04
Bovine Rhinotracheitis Virus, Modified Live Virus	A101.20	Heska Corp., Est. 213	1/7/04
Mycoplasma Hyopneumoniae Bacterin, Killed Culture	B775.06	ProtaTek International, Inc., Est. 329	1/7/04
Canine Heartworm Antigen Test Kit	E018.05	Synbiotics Corp., Permittee 312C	1/12/04

True Name	Product Code	Establishment/ Permittee	Date
Canine Heartworm Antigen Test Kit	E018.05	SafePath Laboratories, LLC, Est. 430	1/12/04
Canine Gonadotropin Releasing Factor, Immunotherapeutic	I220.00	Biocor Animal Health, Inc., Est. 462A	2/25/04

U.S. Veterinary Biological Product Permit No. 312C was issued on January 12, 2004, to the following:

Synbiotics Corporation  
16420 Via Esprillo  
San Diego, California 92127

U.S. Veterinary Biologics Establishment License No. 620 was issued on February 19, 2004, to the following:

United Biomedical, Inc.  
25 Davids Drive  
Hauppauge, New York 11788  
MAIL: United Biomedical, Inc.  
25 Davids Drive  
Hauppauge, New York 11788

U.S. Veterinary Biological Establishment License No. 632 was issued on February 27, 2004, to the following:

Prion Developmental Laboratories  
900 Asbury Drive  
Buffalo Grove, Illinois 60089  
MAIL: Prion Developmental Laboratories  
900 Asbury Drive  
Buffalo Grove, Illinois 60089

The following product licenses for Heska Corporation, Est. 213, were terminated without prejudice on January 22, 2004:

Moraxella Bovis Bacterin, Code 2772.B0

Moraxella Bovis Bacterin, Code 2772.I0

The following product licenses for Heska Corporation, Est. 213, were terminated without prejudice on March 15, 2004:

Clostridium Chauvoei-Septicum-Mannheimia Haemolytica-Pasteurella Multocida  
Bacterin, Code 2460.00

Bovine Rhinotracheitis-Parainfluenza<sub>3</sub> Vaccine, Modified Live Virus,  
Mannheimia Haemolytica-Pasteurella Multocida Bacterin, Code 4269.00

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Modified Live  
Virus, Mannheimia Haemolytica-Pasteurella Multocida Bacterin, Code 4539.00

The following product for Mr. Jerry Zinn, Permittee No. 335, was terminated without prejudice on February 6, 2004:

Infectious Salmon Anemia Virus Vaccine, Killed Virus, Code 1A45.20

/s/Richard E. Hill, Jr.

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

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