

January 12, 2004

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-03**

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 October, November and December 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:

<b>True Name</b>	<b>Product Code</b>	<b>Establishment/ Permittee</b>	<b>Date</b>
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.20	Wyeth, Est. 112	12/23/03
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus	1151.20	Novartis Corp. Est. 303	12/19/03
Encephalomyelitis-West Nile Virus Vaccine, Eastern and Western, Killed Virus	14W5.22	Wyeth, Est. 112	11/07/03
Encephalomyelitis-West Nile Virus Vaccine, Eastern, Western, and Venezuelan, Killed Virus	14W5.23	Wyeth, Est. 112	11/07/03
Equine Influenza Vaccine, Killed Virus	1505.10	Protatek International, Inc., Est. 329	12/05/03
Equine Influenza Vaccine, Killed Virus	1505.25	Wyeth, Est. 112	12/23/03
Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus	1515.27	Wyeth, Est. 112	12/23/03

True Name	Product Code	Establishment/ Permittee	Date
Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus and Chlamydia	1559.22	Wyeth, Est. 112	10/21/03
Feline Immunodeficiency Virus Vaccine, Killed Virus	15A5.23	Wyeth, Est. 112	10/09/03
Escherichia Coli Vaccine, Avirulent Live Culture	15R1.00	ARKO Lab., Ltd. Est. 337	12/23/03
Newcastle Disease Vaccine, B <sub>1</sub> Type, B <sub>1</sub> Strain, Live Virus	1711.18	Wyeth, Est. 112	11/20/03
Rabies Vaccine, Killed Virus	1905.23	Wyeth, Est. 112	10/07/03
Rabies Vaccine, Killed Virus	1905.24	Merial, Inc., Est. 298	12/19/03
West Nile Virus Vaccine, Live Canarypox Vector	1991.R0	Merial, Inc., Est. 298	12/22/03
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus	19A5.22	Novartis Corp., Est. 303	12/05/03
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus	19A5.24	Schering-Plough Animal Health Corp., Est. 165A	11/03/03
Salmonella Typhimurium Vaccine, Live Culture	19C1.02	Lohmann Animal Health Intl., Est. 196	11/04/03
Erysipelothrix Rhusiopathiae Bacterin	2641.01	Novartis Corp., Est. 303	09/26/03
Moraxella Bovis Bacterin	2772.B0	SolidTech Animal Health, Inc., Est. 604	12/19/03
Moraxella Bovis Bacterin	2772.I0	SolidTech Animal Health, Inc., Est. 604	12/19/03
West Nile Virus Antibody, Equine Origin	3995.00	Lake Immunogenics Inc., Est. 318	10/22/03
Bovine Rotavirus-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C & D-Escherichia Coli Bacterin-Toxoid	4575.20	Schering-Plough Animal Health Corp., Est. 165A	11/17/03

True Name	Product Code	Establishment/ Permittee	Date
Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Leptospira Bacterin	46J9.26	Wyeth, Est. 112	10/09/03
Canine Distemper-Adeno virus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Borrelia Burgdorferi Bacterin	47C5.29	Wyeth, Est. 112	10/09/03
Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	4835.22	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	4835.23	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	4845.22	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	4845.23	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western and Venezuelan, Killed Virus, Tetanus Toxoid	4847.22	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western and Venezuelan, Killed Virus, Tetanus Toxoid	4847.23	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Influenza Vaccine, Eastern, Western and Venezuelan, Killed Virus, Tetanus Toxoid	4875.22	Wyeth, Est. 112	10/27/03
Encephalomyelitis-Influenza Vaccine, Eastern, Western and Venezuelan, Killed Virus, Tetanus Toxoid	4875.23	Wyeth, Est. 112	10/27/03
Encephalomyelitis-West Nile Virus Vaccine, Eastern, Western and Venezuelan, Killed Virus, Tetanus Toxoid	48W5.20	Wyeth, Est. 112	10/27/03
Encephalomyelitis-West Nile Virus Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	48W5.21	Wyeth, Est. 112	11/26/03
Encephalomyelitis-West Nile Virus Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	48W5.22	Wyeth, Est. 112	11/07/03

True Name	Product Code	Establishment/ Permittee	Date
Encephalomyelitis-West Nile Virus Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid	48W5.23	Wyeth, Est. 112	11/07/03
Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	4BC5.21	Intervet Inc., Est. 286	12/22/03
Canine Heartworm Antigen Test Kit	5018.01	AGEN Inc. Permit No. 338	10/10/03
Feline Leukemia Virus Antigen Test Kit	5028.00	AGEN Inc., Permit No. 338	10/10/03
Chronic Wasting Disease Antigen Test Kit, EIA	5420.21	IDEXX Corp., Est. 313	11/04/03
Canine Heartworm Antigen-Borrelia Burgdorferi-Ehrlichia Canis Antibody Test Kit	5E20.01	IDEXX Corp., Est. 313	11/14/03
Giardia Antigen Test Kit	5G05.50	IDEXX Corp., Est. 313	12/09/03
Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid	7410.01	Novartis Corp., Est. 303	10/08/03
Giardia Antigen Test Kit	EG05.50	IDEXX Corp., Est. 313	12/09/03
Giardia Antigen Test Kit	EG05.50	Medical Packaging Corp., Est. 607	12/09/03

U.S. Veterinary Biological Establishment License No. 604 was issued on December 19, 2003, to the following:

SolidTech Animal Health, Inc.,  
812 Northeast 24<sup>th</sup> Street  
Newcastle, Oklahoma 73065-6359  
MAIL: SolidTech Animal Health, Inc.,  
812 Northeast 24<sup>th</sup> Street  
Newcastle, Oklahoma 73065-6359

The following product licenses for IDEXX Laboratories, Inc., Est. 313, were terminated without prejudice on September 11, 2003:

Pseudorabies Virus gpX Antibody Test Kit, Code 5111.00

Equine Infectious Anemia Virus Antibody Test Kit, Code 5515.21

Canine Heartworm Antigen-Ehrlichia Canis Antibody Test Kit, Code 5E18.00

*/s/Richard E. Hill, Jr.*

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