

January 18, 2007

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 07-01

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 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
Equine Influenza Vaccine, Live Canarypox Vector	1501.R0	Merial, Inc., Est. 298	11/27/06
Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	1559.23	Wyeth, Est. 112	11/8/06
Feline Calicivirus Vaccine, Killed Virus	15C5.21	Wyeth, Est. 112	11/8/06
Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus	16D5.23	Wyeth, Est. 112	11/8/06
Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia	16E5.23	Wyeth, Est. 112	11/8/06
Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector	19K5.R0	Boehringer Ingelheim Vetmedica, Inc., Est. 124	10/11/06
Mycoplasma Hyopneumoniae Bacterin	2775.03	Merial, Inc., Est. 298	12/13/06
Leptospira Hardjo-Pomona Bacterin	26M1.00	Wyeth, Est. 112	11/8/06
Bovine Rhinotracheitis Vaccine, Modified Live Virus, Leptospira Hardjo-Pomona Bacterin	4069.20	Wyeth, Est. 112	11/24/06
Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Leptospira Hardjo-Pomona Bacterin	4399.20	Wyeth, Est. 112	11/24/06

True Name	Product Code	Establishment/ Permittee	Date
Encephalomyelitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid	4835.46	Intervet Inc., Est. 286	11/7/06
Canine Heartworm Antigen Test Kit	5018.04	Synbiotics Corp., Est. 312	11/30/06
Canine Parvovirus Antigen Test Kit	5024.01	AGEN, Inc., Permittee 338A	11/27/06
Classical Swine Fever Virus RNA Test Kit	5441.80	Tetracore, Inc. Est. 644	11/28/06
Canine Heartworm Antigen Test Kit	E018.00	Synbiotics Corp., Permittee 312B	11/30/06
Lymphocyte T-Cell Immunomodulator	9410.00	T-Cyte Therapeutics, Inc., Est. 598	12/15/06

U.S. Veterinary Biologics Establishment License No. 598 was issued on December 15, 2006, to the following:

T-Cyte Therapeutics, Inc.
41718 Eastman Drive
Murrieta, California 92562
MAIL: T-Cyte Therapeutics, Inc.
41718 Eastman Drive
Murrieta, California 92562

The following product licenses for Wyeth, Est. 112, were terminated without prejudice on October 16, 2006:

Canine Distemper Vaccine, Modified Live Virus, Code 1301.00

Canine Distemper-Adenovirus Type 2 Vaccine, Modified Live Virus,
Code 13A1.30

Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live
Virus, Code 13C1.30

Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live
Virus, Code 13C1.31

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine,
Modified Live Virus, Code 13D1.23

Canine Distemper-Parvovirus Vaccine, Modified Live Virus, Code 13P1.20

Canine Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Code 1441.20

Canine Coronavirus Vaccine, Killed Virus, Code 14P5.21

Equine Influenza Vaccine, Killed Virus, Code 1505.23

Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus, Code 1515.25

Feline Leukemia Vaccine, Killed Virus, Code 1555.20

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus and Chlamydia, Code 1559.22

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live Virus & Chlamydia & Killed Virus, Code 1559.2B

Feline Panleukopenia Vaccine, Modified Live Virus, Code 1561.20

Chlamydia Psittaci Vaccine, Modified Live Chlamydia, Code 1581.20

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus, Code 1599.23

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus, Code 15B9.20

Porcine Reproductive and Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus, Code 19S1.20

Borrelia Burgdorferi Bacterin, Code 2126.01

Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4637.21

Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Bacterin, Code 46J7.21

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid, Code 4845.30

Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern, Western & Venezuelan, Killed Virus, Tetanus Toxoid, Code 4847.30

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid, Code 4865.20

Encephalomyelitis-Influenza Vaccine, Eastern, Western & Venezuelan, Killed Virus, Tetanus Toxoid, Code 4875.A0

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

The following product licenses for Lohmann Animal Health, Est. 196, were terminated without prejudice on October 5, 2006:

Autogenous Vaccine, Killed Virus, Code 1015.00

Avian Reovirus Vaccine, Killed Virus, Code 1045.00

Avian Encephalomyelitis Vaccine, Killed Virus, Code 1055.10

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.1F

Bronchitis Vaccine, Mass. and Ark. Types, Live Virus, Code 1231.1G

Bursal Disease Vaccine, Live Virus, Code 1271.01

Bursal Disease Vaccine, Killed Virus, Code 1275.00

Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1282.00

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

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

Bursal Disease-Reovirus Vaccine, Killed Virus, Standard and Variant, Code 12D5.01

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

Bursal Disease-Newcastle Disease Vaccine, Standard and Variant, Killed Virus, Code 12G5.42

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

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 12J5.41

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

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12J5.63

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass. Type, Killed Virus, Code 12M5.91

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12P5.43

Fowl Pox Vaccine, Live Virus, Code 1621.01

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

Marek's Disease Vaccine, Serotypes 1, 2 & 3, Live Virus, Code 16L1.01

Newcastle Disease Vaccine, Killed Virus, Code 1705.10

Newcastle Disease Vaccine, Killed Virus, Code 1705.12

Newcastle Disease Vaccine, Killed Virus, Code 1705.13

Newcastle Disease Vaccine, Killed Virus, Code 1705.14

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

Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus, Code 1711.12

Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus, Code 1721.11

Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus, Code 1721.13

Newcastle Disease Vaccine, Roakin Type, Live Virus, Code 1731.10

Newcastle Disease-Avian Encephalomyelitis Vaccine, Killed Virus, Code 1745.10

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Conn. Types, Live Virus, Code 1761.15

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Florida Types, Live Virus, Code 1761.1B

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Conn. Types, Live Virus, Code 1761.1H

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. Type, Live Virus, Code 1761.A1

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. Type, Live Virus, Code 1768.12

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass. Type, Live Virus, Code 1771.12

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass. and Conn. Types, Live Virus, Code 1771.17

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass. Type, Live Virus, Code 1771.1A

Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 1775.10

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Ark. Types, Live Virus, Code 17A1.1M

Autogenous Bacterin, Code 2051.00

Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3 & 4, Code 2702.13

Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, 4, and 3X4, Code 2703.18

Avian Paramyxovirus, Type 3, Live Virus, Code A0C5.10

Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code A235.17

Bursal Disease Virus, Killed Virus, Code A275.10

Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code A2B5.40

Salmonella Enteritidis, Killed Culture, Code B785.00

Salmonella Enteritidis Bacterin, Code B785.01

Newcastle Disease Virus, B1 Type, LaSota Strain, Live Virus, Code E721.10

The following product licenses for ProtaTek International, Inc., Est. 329, were terminated without prejudice on October 20, 2006:

Anaplasmosis Vaccine, Killed Rickettsia, Code 1005.50

Trichomonas Foetus Vaccine, Killed Protozoa, Code 1859.01

Trichomonas Foetus Vaccine, Killed Protozoa, Code 1859.02

Trichomonas Foetus Vaccine, Killed Protozoa, Code 1859.03

Anaplasmosis Vaccine, Killed Culture Rickettsia, Code A005.50

The following product license for Boehringer Ingelheim Vetmedica, Inc., Est.124, was terminated without prejudice on November 14, 2006:

Bovine Respiratory Syncytial Virus Vaccine, Killed Virus, Code 1095.22

The following product license for ALK-Abello, Inc., Est. 259, was terminated without prejudice on December 18, 2006:

Allergenic Extract, Treatment Sets, Code 9533.00

The following product license for Merial, Inc., Est. 298, was terminated without prejudice on December 18, 2006:

Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus,
Tetanus Toxoid, Code 4835.44

/s/Richard E. Hill, Jr.

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