January 8, 2002

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-03

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 2001. These do not include those licenses reissued to update pertinent information. A product license has been issued for each of the following:

<table>
<thead>
<tr>
<th>True Name</th>
<th>Product Code</th>
<th>Establishment/Permittee</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine Rhinotracheitis-Parainfluenza, Respiratory Syncytial Virus Vaccine, Modified Live Virus</td>
<td>1071.22</td>
<td>Pfizer Inc., Est. 189</td>
<td>12/20/01</td>
</tr>
<tr>
<td>Chicken Anemia Virus Vaccine, Live Virus</td>
<td>10A1.01</td>
<td>Biomune Co., Est. 368</td>
<td>11/01/01</td>
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<tr>
<td>Bovine Rhinotracheitis Vaccine, Modified Live Virus</td>
<td>1101.20</td>
<td>Grand Laboratories, Inc., Est. 303</td>
<td>12/18/01</td>
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<tr>
<td>Bovine Rhinotracheitis Vaccine, Modified Live Virus</td>
<td>1101.22</td>
<td>Pfizer Inc., Est. 189</td>
<td>12/20/01</td>
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<tr>
<td>Bovine Rhinotracheitis-Parainfluenza, Vaccine, Modified Live Virus</td>
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<td>Grand Laboratories, Inc., Est. 303</td>
<td>11/06/01</td>
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<tr>
<td>Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live and Killed Virus</td>
<td>1157.22</td>
<td>Pfizer Inc., Est. 189</td>
<td>12/20/01</td>
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<td>Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza, Respiratory Syncytial Virus Vaccine, Modified Live and Killed Virus</td>
<td>1187.22</td>
<td>Pfizer Inc., Est. 189</td>
<td>12/20/01</td>
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<tr>
<td>Establishments/permittees</td>
<td>True Name</td>
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<td>Pfizer Inc., Est. 189</td>
<td>Bovine Virus Diarrhoea Vaccine, Killed Virus</td>
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<td>12/20/01</td>
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<tr>
<td>American Home Products Corp., Est. 112</td>
<td>Equine Influenza Vaccine, Killed Virus</td>
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<td>12/04/01</td>
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<tr>
<td>American Home Products Corp., Est. 112</td>
<td>Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus</td>
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<td>11/20/01</td>
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<tr>
<td>Biomune Co., Est. 368</td>
<td>Newcastle Disease Vaccine, $B_1$ Type, LaSota Strain, Live Virus</td>
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<td>11/13/01</td>
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<tr>
<td>American Home Products Corp., Est. 112</td>
<td>Newcastle-Bronchitis Vaccine, $B_1$ Type, Mass. Type, Live Virus</td>
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<td>Merial Select, Inc., Est. 279</td>
<td>Newcastle-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus</td>
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<tr>
<td>Grand Laboratories, Inc., Est. 303</td>
<td>Bovine Coronavirus Vaccine, Killed Virus</td>
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<td>12/18/01</td>
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<tr>
<td>Jerry Zinn, Permit 335</td>
<td>Infectious Salmon Anemia Virus Vaccine, Killed Virus</td>
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<td>10/05/01</td>
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<tr>
<td>Jerry Zinn, Permit 335</td>
<td>Aeromonas Salmonicida-Vibrio Anguillarum-Oralii-Salmonicida Bacterin</td>
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<td>ImmTech Biologics, LLC, Est. 480</td>
<td>Mycoplasma Hyopneumoniae Bacterin</td>
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<tr>
<td>Intervet Inc., Est. 286</td>
<td>Mycoplasma Hyopneumoniae Bacterin</td>
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<td>12/18/01</td>
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<tr>
<td>Grand Laboratories, Inc., Est. 303</td>
<td>Bovine Rhinotracheitis Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin</td>
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<td>12/18/01</td>
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<tr>
<td>Grand Laboratories, Inc., Est. 303</td>
<td>Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin</td>
<td></td>
<td>11/06/01</td>
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</table>
The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on October 18, 2001:

- **Bordetella Bronchiseptica-Mycoplasma Hyopneumoniae-Pasteurella Multocida Bacterin-Toxoid**, Code 7085.01
- **Pasteurella Multocida, Killed Culture**, Code H551.00

The following product licenses for Biocor Animal Health Inc., Est. 462, were terminated without prejudice on November 28, 2001:

- **Canine Distemper-Hepatitis Vaccine, Modified Live Virus**, Code 1311.20
- **Pseudorabies Vaccine, Modified Live Virus**, Code 1891.R1
- **Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza, Vaccine, Killed Virus, Haemophilus Somnus Bacterin**, Code 44H5.20
Canine Distemper-Hepatitis Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4689.20

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Pseudorabies Virus GPIII Antibody Test Kit, Code 5112.00

Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Killed Culture, Code B680.00

Clostridium Perfringens Type C, Killed Culture, Code G800.00

The following product licenses for IDEXX Corporation, Est. 313, were terminated without prejudice on December 11, 2001:

Canine Borrelia Burgdorferi Antibody Test Kit, Code 5017.00

Bovine Leukemia Virus Antibody Test Kit, Code 5505.21

Mycoplasma Gallisepticum DNA Test Kit, Accessory F Strain, Code 5A75.00

Due to the acquisition of Maine Biological Laboratories, Inc., Est. No. 240, by Lohmann Animal Health International (formerly Immunogenetics, Inc.), Est. No. 196, the following products previously issued to Est. No. 240 have been reissued to Est. No. 196:

Autogenous Vaccine, Killed Virus, Code 1015.10

Avian Encephalomyelitis Vaccine, Killed Virus, Code 1055.10

Avian Influenza Vaccine, H10 Subtype, Killed Virus, Code 1057.H0

Avian Influenza Vaccine, H1 Subtype, Killed Virus, Code 1057.H1

Avian Influenza Vaccine, H2 Subtype, Killed Virus, Code 1057.H2

Avian Influenza Vaccine, H3 Subtype, Killed Virus, Code 1057.H3

Avian Influenza Vaccine, H4 Subtype, Killed Virus, Code 1057.H4

Avian Influenza Vaccine, H5 Subtype, Killed Virus, Code 1057.H5

Avian Influenza Vaccine, H6 Subtype, Killed Virus, Code 1057.H6
Avian Influenza Vaccine, H9 Subtype, Killed Virus, Code 1057.H9

Avian Paramyxovirus Vaccine, Type 3, Killed Virus, Code 10C5.10

Avian Paramyxovirus Vaccine, Type 1, Killed Virus, Code 10C5.11

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Bronchitis Vaccine, Mass. and Conn. Types, Live Virus, Code 1231.14
Bronchitis Vaccine, Conn. Type, Live Virus, Code 1231.15
Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.16
Bronchitis Vaccine, Ark. Type, Live Virus, Code 1231.20
Bronchitis Vaccine, Mass. Type, Killed Virus, Code 1235.10
Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code 1235.15

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Killed Virus, Code 1245.40

Bursal Disease Vaccine, Killed Virus, Code 1275.01
Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code 12B5.4A
Bursal Disease-Reovirus Vaccine, Killed Virus, Code 12D5.02
Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12D5.45
Bursal Disease-Bursal Disease-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12E5.4A
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, Standard and Variant, Mass. Type, Killed Virus, Code 12M5.01
Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12M5.41
Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12M5.42

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12P5.41

Newcastle Disease Vaccine, Killed Virus, Code 1705.11

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

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

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

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

Mycoplasma Gallisepticum Vaccine, Live Culture, Code 1751.00

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 Conn. Types, Live Virus, Code 1761.1H

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 1771.1A

Newcastle-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code 1785.10

Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 1785.11

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Ark. Types, Live Virus, Code 17A3.1M

Newcastle-Paramyxovirus Vaccine, Type 3, Killed Virus, Code 17P5.10
Salmonella Typhimurium Vaccine, Live Culture, Code 19C1.01

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 and 3X4, Code 2704.00

Salmonella Enteritidis Bacterin, Code 2785.00

Autogenous Vaccine, Killed Virus, Autogenous Bacterin, Code 4500.00

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, and 4, Code 4635.40

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Newcastle Disease-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Salmonella Enteritidis Bacterin, Code 48D7.10

Newcastle Disease-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Salmonella Enteritidis Bacterin, Code 48D7.11

Avian Reovirus, Killed Virus, Code A045.02

Avian Encephalomyelitis Virus, Live Virus, Code A051.10

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

Bronchitis Virus, Mass. Type, Live Virus, Code A231.12

Bronchitis Virus, Mass. and Ark. Types, Killed Virus, Code A235.15

Bronchitis Virus, Mass. Type, Killed Virus, Code A235.16

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

Newcastle Disease Virus, B 1 Type, LaSota Strain, Killed Virus, Code A705.11

Newcastle Disease Virus, B 1 Type, B 1 Strain, Live Virus, Code A711.11

Newcastle Disease Virus, B 1 Type, LaSota Strain, Live Virus, Code A721.10

Newcastle-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus,
Code A785.10

Swine Influenza Virus, H1N1, Live Virus, Code A9A6.10

Pasteurella Multocida, Killed Culture, Avian Isolates, Types 1, 3, and 4, Code B702.13

Salmonella Enteritidis, Killed Culture, Code B785.00

Salmonella Enteritidis Bacterin, Code B785.01

Avian Influenza Virus, H7 Subtype, Live Virus, Code E004.00

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Avian Reovirus, Live Virus, Code E041.00

Mycoplasma Meleagris, Live Culture, Code E172.00

Bronchitis Virus, Mass. Type, Live Virus, Code E231.11

Bronchitis Virus, Killed Virus, Code E235.11

Bursal Disease Virus, Live Virus, Code E271.10

Bursal Disease Virus, Killed Virus, Code E275.10

Newcastle Disease Virus, B1 Type, B1 Strain, Live Virus, Code E711.10

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

Newcastle Disease Virus, B1 Type, LaSota Strain, Killed Virus, E725.10

The following Est. No. 240 licenses are reissued to Est.196 with different code numbers to avoid duplication of numbers:

Avian Reovirus Vaccine, Killed Virus, Code 1045.02 (formerly 1045.00)

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.1F (formerly 1231.12)

Bronchitis Vaccine, Mass. and Ark. Types, Live Virus, Code 1231.1G (formerly 1231.13)

Bursal Disease Vaccine, Killed Virus, Code 1275.02 (formerly 1275.00)
Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code 12B5.01 (formerly 12B5.40)

Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12D5.03 (formerly 12D5.00)

Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12D5.04 (formerly 12D5.01)

Bursal Disease-Newcastle Disease Vaccine, Standard and Variant, Killed Virus, Code 12G5.42 (formerly 12G5.41)

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Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.43 (formerly 12G5.40)

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 12J5.41 (formerly 12J5.40)

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass. Type, Killed Virus, Code 12M5.91 (formerly 12M5.90)

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12P5.43 (formerly 12P5.40)

Fowl Pox Vaccine, Live Virus, Code 1621.01 (formerly 1621.00)

Newcastle Disease Vaccine, Killed Virus, Code 1705.15 (formerly 1705.12)

Newcastle Disease Vaccine, B1 Type, B1 Strain, Live Virus, Code 1711.12 (formerly 1711.10)

Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus, Code 1721.13 (formerly 1721.10)

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass. Type, Live Virus, Code 1761.A1 (formerly 1761.12)

Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass. Type, Live Virus, Code 1771.12 (formerly 1771.11)
Pigeon Pox Vaccine, Live Virus, Code 1881.12 (formerly 1881.10)

Autogenous Bacterin, Code 2051.04 (formerly 2051.00)

Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, and 4, Code 2702.15 (formerly 2702.13)

Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, 4, and 3X4, Code 2703.18 (formerly 2703.15)

/s/Richard E. Hill, Jr.

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