Licensing Veterinary Biologics in the United States

Center for Veterinary Biologics
Veterinary Services
Animal and Plant Health Inspection Service
United States Department of Agriculture
Ames, Iowa USA
Organizational Structure

- USDA
  - United States Department of Agriculture
- APHIS
  - Animal and Plant Health Inspection Service
- VS
  - Veterinary Services
- CVB
  - Center for Veterinary Biologics
Mission: The Veterinary Biologics Program implements the provisions of the Virus-Serum-Toxin Act to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective.
Regulated Industry

- 120 Licensees/Permittees
- 238 Manufacturing sites
- ~2500 Active products
- 207 different animal diseases
- ~18,000 Serials (batches) released
- ~80 Billion doses
- ~220 Reagents
**Number/Location of Inspection Sites**

**US Sites:** 201  
**Foreign Sites:** 37

*Map showing the distribution of inspection sites across the US and several foreign locations.*

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Safeguarding Animal Health
Ensuring Quality of Veterinary Biologics in the U. S.

- Licensing
- Quality Manufacturing
- Inspection
- Testing
- Serial (batch) Release
- Compliance Actions
- Pharmacovigilance
Licensed Influenza Biologics (Avian)

- Avian Influenza Vaccines (Full or Conditionally licensed; all have restrictions on use)
  - Killed Virus (Chickens)
  - Killed Virus (Turkeys)
  - Autogenous (Turkeys)
  - Avian Influenza-Fowl Pox Vaccine, Live Fowl Pox Vector (Chickens, export only)

- Avian Influenza Diagnostic Products
  - Antibody Test Kit
  - Antigen Test Kit (Conditionally licensed)
Licensed Influenza Biologics (Canine, Equine, and Swine)

- Canine Influenza Vaccines
  - License applications being accepted

- Equine Influenza Vaccines (monovalent and in combination with other antigens)
  - Killed Virus Modified
  - Live Virus

- Swine Influenza Vaccines (monovalent and in combination with other antigens)
  - Killed Virus
  - Autogenous
### Licensed Influenza Biologics

<table>
<thead>
<tr>
<th>Species</th>
<th># of Manufacturers</th>
<th>2005 Doses Produced</th>
<th># of Product Licenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avian*</td>
<td>4</td>
<td>&gt;500,000,000</td>
<td>16</td>
</tr>
<tr>
<td>Equine**</td>
<td>8</td>
<td>&gt;5,000,000</td>
<td>50</td>
</tr>
<tr>
<td>Swine**</td>
<td>8</td>
<td>~50,000,000</td>
<td>24</td>
</tr>
</tbody>
</table>

*APHIS-owned Vaccine H5, H7 Bank ~40 Million + (30 Million) doses not listed
**Not all manufacturers in production in 2005
§ 103.1 Preparation of experimental biological products.

...Upon application therefore, the Administrator may authorize the preparation of experimental products on the premises of a licensed establishment if he determines that such preparation will not result in contamination of the licensed products.
§ 114.2 Products not prepared under license.

(b) Except as provided in 9 CFR part 103, a biological product shall not be prepared in a licensed establishment unless the person to whom the establishment license is issued holds an unexpired, unsuspended, and unrevoked product license issued by the Administrator to prepare such biological product, or unless the products prepared are subject to the provisions of §107.2 of this subchapter.
§114.3 Separation of establishments.

(c) When a partially prepared biological product cannot be completed at a licensed establishment due to failure of essential equipment, the Administrator may authorize the use of similar equipment at another licensed establishment: Provided, That, such authorization shall be limited to the duration of the emergency and to the phase of production affected by the equipment failure.