# Inspection and Compliance Unit

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The Center for Veterinary Biologics (CVB) Inspection and Compliance (IC) unit is responsible for developing and implementing programs to ensure veterinary biologics are prepared and distributed in compliance with the Virus-Serum-Toxin Act and the regulations promulgated from it. The Act requires that both products and facilities be licensed, and products distributed in the United States must not be worthless, dangerous, contaminated, or harmful.

## Mission

Our mission is to ensure that veterinary biological products are produced and maintained in compliance with the Virus-Serum-Toxin Act.

Inherent within this mission are several fundamental concepts integrally associated with effectively achieving this charge. These include:

- Serving agriculture, the public, agricultural organizations, the biologics industry, APHIS, and other Federal agencies by facilitating communications and regulating the production and distribution of veterinary biological products.
- Educating biologics manufacturers and users and monitoring product performance, thus assuring the availability and proper use of veterinary biologics.

- Creating an environment where all people are valued and everyone works together as a high-performing team.
- Developing, maintaining, and using a diverse and high level of scientific knowledge.

# How We Assure Compliance

Facilities Inspections

Periodic unannounced in-depth inspections of all licensed facilities are conducted by specialists trained in quality assurance inspections. Products imported from foreign countries must meet all U.S. standards, and foreign facilities are inspected at the same rate as domestic firms. Additionally, facilities are inspected prior to the issuance of an establishment license.

### Administrative Inspection Review

The Administrative Inspection Review (AIR) is an annual review of all active licensees, all active permittees, and their records in comparison to the records kept at the CVB in order for our personnel to more effectively and efficiently enforce the Virus-Serum-Toxin Act and the pursuant rules and regulations. The review validates active licensees, active permittees, and their records concerning licensed premises, all responsible personnel, and production. The components of this review are specific to each licensee and permittee. It may include reports from CVB's databases, certified documents, and a generated AIR Worksheet of requested information about the licensee and permittee. These documents are authenticated by the licensee/permittee's official liaison.

The Director of CVB-Inspection and Compliance (CVB-IC) has been delegated the authority to direct the inspections of licensed establishments, prospective licensees, foreign manufacturers, and recipients of imported biological products under the Virus-Serum-Toxin Act. The CVB-IC team leaders, senior biologics specialists, and biologics specialists (hereafter called the Specialist) plan, schedule, and conduct the inspections with the support of the biologics compliance assistants.

### About Facilities Inspections

Each inspection is one of three types (reference VS Memo 800.91):

- An **in-depth** inspection is an unannounced, detailed inspection in which overall compliance with regulations and other requirements is systematically examined. The size of the plant, the number of inspectors on the inspection team, and problems encountered determine the length of time expended at the establishment. As many inspection categories as possible are examined.
- **Followup** inspections are conducted to determine if corrections required as a result of a previous in-depth (or followup) inspection have been made. Need for a "followup" and length of time for the inspection are determined by the Specialist, based upon the nature of the corrections required.
- A **special** inspection is any inspection not of the previous two types. This type of inspection is requested in writing by CVB-PEL personnel or other Government officials or is directed by the CVB-IC Director. Examples of special inspections include:
    - Prelicensing facility inspections
    - Select agent inspections
    - Onsite product inspections (for example, field trials, efficacy studies, duration of immunity studies, and bench record review)

## Product Inspections

Test results of every batch of veterinary biologic are submitted by the manufacturer for review. Results are compared with check testing conducted by the CVB's Policy, Evaluation, and Licensing (CVB-PEL) unit, and each batch is approved or rejected by CVB-IC for marketing.

Release of satisfactory veterinary biologics for marketing by licensees, the handling of various requests from the licensees concerning biologics, and other related necessary administrative tasks are handled by the CVB-IC in Ames, IA.

All licensees and permittees are required to submit an APHIS Form 2008 for each serial or subserial which reaches any stage of identification and testing. CVB-IC receives these forms and enters key information into a biologics database. This information is used to ask the CVB-PEL for test information, to prepare the semiannual publication on numbers of doses prepared and destroyed, and to provide information for biologics specialists to use during inspections.

Serials found satisfactory, or those to be released without testing by the CVB-PEL, are processed without delay by the biologics compliance assistants (BCAs). Serial release is the top priority for the BCAs.

## Adverse Event Reporting

The use and performance of veterinary biologics in the field are monitored through analysis of adverse event reports received by CVB.

Learn more about adverse event reporting

## Investigations

Investigation of alleged violations of the Virus-Serum-Toxin Act (VSTA) involving veterinary biologics can be divided into three categories:

1. **Violation of the VSTA by unlicensed manufacturer**—This is the preparation, sale, barter, exchange or shipment of products by a manufacturer not licensed; the importation into the United States of an unlicensed product intended for the treatment, prevention, or diagnosis of disease in domestic animals; or the adulteration of licensed product by an unlicensed person.
2. **Violation of the VSTA by licensed manufacturer**—This includes illegal movement of a known defective, licensed product or of an unlicensed product produced by a licensed manufacturer; importation into the United States by a licensed manufacturer of an unlicensed product intended for the treatment, prevention, or diagnosis of disease in domestic animals; or a licensed manufacturer making false or misleading claims about a licensed product.
3. **Violation of regulations under the VSTA by licensed manufacturer**—This occurs when conditions found upon inspection of a licensed manufacturer are not in accordance with 9 CFR Parts 101–118. Action may also be taken under 9 CFR Part 123.

Based on authority granted in the VSTA and regulations, CVB-IC takes appropriate action based on findings from product monitoring, inspection, or investigations. Recommendations for other actions are submitted to the CVB Director.

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