

### 3.3. EXEMPTIONS TO VIRUS-SERUM-TOXIN ACT

#### Overview

One of the provisions of the Virus-Serum-Toxin Act (VSTA) is that all biologicals in the U.S. must be prepared, bartered, sold, or shipped pursuant to an unsuspended and unrevoked license or permit. The Act does, however, authorize exemptions to the requirement for a license under certain conditions:

- Official USDA Program use
- USDA experimental use
- Emergency disease situation
- For use within valid veterinarian-patient-client relationship
- For use in manufacturer's own animals
- Preparation under state license

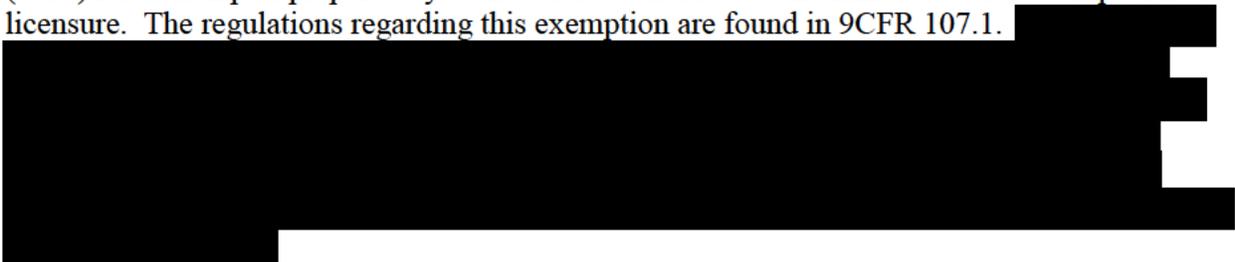
Certain products prepared solely for export are also exempted from licensure under the Food and Drug Administration Export Reform and Enhancement Act (see FDA-EREA chapter for more information.)

#### USDA Use

Per 9CFR 106.1, the USDA may utilize unlicensed products for official animal disease eradication or control programs. Likewise, they may use any product on an experimental basis or in an emergency disease situation. Under most circumstances, however, the USDA uses products that we have licensed or for which we have issued a permit for distribution and sale. We work closely with other parts of APHIS and the USDA to ensure that products used in such programs meet our standards for purity, safety, potency, and efficacy. As our visibility within the USDA has evolved, we have been increasingly involved in discussions regarding the products that will be used in program diseases. In recent cases, data obtained from experimental use by APHIS have been used to support licensure of products for program diseases.

#### Veterinary Practitioners and Animal Owners

Products prepared by veterinary practitioners for use under a valid veterinary-client-patient (VCP) relationship or prepared by owners for use in one's own animals are also exempted from licensure. The regulations regarding this exemption are found in 9CFR 107.1.



The CVB does retain the authority to take action if the exempted products are found to be worthless, contaminated, dangerous, or harmful. When live products are shipped, we also may request information regarding the safety of the product and its effect on the environment.

[REDACTED]

[REDACTED]

[REDACTED]

### State Licensure

States may issue their own biological product licenses, although at this time, there are no states that do so. If state licensing programs are deemed to be consistent with the intent of the VSTA, then products prepared under a state license may be sold *in that state* without a federally issued license. A state must apply for an exemption, and the request must include the information described in 9CFR 107.2 (b)(1-5). The CVB may conduct an on-site evaluation of the state program at any time.

If an exemption is granted, the state notifies the CVB whenever it issues or terminates a state license.