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# **Assessing Compliance with the Requirement of State Veterinarian Approval**

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**Notes:**

## Assessing Compliance with the Requirement for State Veterinarian Approval

### Background:

Certain requirements of the regulations require State Veterinarian or State Official approval. Examples of such requirements can be found in title 9, *Code of Federal Regulations* (9 CFR), part 113.113(a)(2)(x), 113.113(a)(3)(iii) and 102.5(b)(5).

On occasion, the request for approval is neither approved nor denied by the State Veterinarian. In many cases, State Veterinarians respond in a letter and indicate they do not have the authority to approve or deny the request for the firm. The process below provides guidance for the Biologics Specialist when inspecting for State authorization approval letters or when guidance concerning the applicable regulation is requested by the firm.

### Procedure:

1. The specialist reviews approval letters during inspections under the applicable requirement.
2. If a firm has requested State Veterinarian (or official) approval and the documentation returned to the firm indicates that they do not have the authority to approve or deny the request for the firm, the Specialist can accept the letter as being compliant with the applicable regulation.
3. If the letter from the State indicates that future requests will not be responded to:
  - a. The Specialist then determines if the firm has a system in place to periodically request authorizations since State policies may change.
  - b. If the firm does not have a periodic system in place for requests, the action should be for the firm to initiate periodic requests.
4. If there is no indication in the State letter regarding future requests, the firm is required to request State Veterinarian (or official) approval with each required instance.
5. If the firm requests information concerning compliance with State authorizations, the information above may be shared with the firm as guidance for compliance.