

NOTES ON FEDERAL PREEMPTION ON VETERINARY BIOLOGIC PRODUCTS

- The Virus-Serum-Toxin Act (21 USC 151 *et seq*), administered by the USDA Center for Veterinary Biologics, preempts state law regulating the manufacturing or use of veterinary biological products.
 - 57 Fed. Reg. 38758, 38759

“The legislative history relating to the 1985 amendments to the Act, which extends USDA’s authority over veterinary biologics, clearly expresses Congressional intent that Federal regulation of veterinary biologics is needed to prevent and eliminate burdens on commerce and that there is a need for uniform national standards regarding these products. Therefore, States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA’s authority to determine which biologics are pure, safe, potent, and efficacious.”
 - When addressing comments to the federal register on this topic, USDA stated:

“Seven commenters indicated that States should have the authority to add to Federal restrictions, as appropriate, based on a need to protect animal or human health and safety so long as such restrictions do not lessen the effect of Federal regulations. APHIS agrees with the comment that States should not be allowed to lessen the effect of Federal restrictions on the distribution and use of veterinary biological products. APHIS, however, does not agree that States should be allowed to add various restrictions, as appropriate, based upon a need to protect domestic animals or the public health, interest, or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.”
- States may only add restrictions on the distribution and use of veterinary biologics when addressing local disease conditions
 - 57 Fed. Reg. 38758, 38759

“However, it has been APHIS’ consistent position that individual States may impose certain restrictions on the distribution and use of biological products licensed by USDA based on local disease conditions when such restrictions are made on a product-by-product basis. For example, a State is permitted to restrict distribution of a biological product where a particular disease does not exist in the State and where use of the biological product would make it difficult to distinguish between exposed and vaccinated animals.

Likewise, a State is permitted to restrict use of a product to licensed veterinarians when a disease exists in the State and the State has an active eradication program. In this case, such a restriction may be necessary to ensure the effectiveness of the eradication program.”

...

“For example, a State is permitted to restrict distribution of a biological product where a particular disease does not exist in the State and where use of the biological product would make it difficult to distinguish between exposed and vaccinated animals.

Likewise, a State is permitted to restrict use of a product to licensed veterinarians when a disease exists in the State and the State has an active eradication program. In this case, such a restriction may be necessary to ensure the effectiveness of the eradication program.”

- USDA has a mechanism for states to request restrictions on veterinary biological products.
 - The process is specified at 9 CFR 102.5(e)

States may request that the distribution and use of a veterinary biological product be restricted if the restriction pertains to the protection of domestic animals or the public health, interest, or safety, or both. Requests must go to the USDA Center for Veterinary Biologics and must specify the restriction requested, explain why the restrictions are needed, and supporting documents, such as scientific literature, published or unpublished articles, or data from tests.