UNITED STATES ANIMAL HEALTH ASSOCIATION
2014 RESOLUTION
118TH ANNUAL MEETING
OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

**RESOLUTION NUMBER:** **26** **APPROVED**

**SOURCE:** **COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY**

**SUBJECT MATTER:** **Manufacturing of Veterinary Biologicals without Licensure**

**BACKGROUND INFORMATION:**

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), Center for Veterinary Biologics (CVB), has the licensing and enforcement responsibilities for the Virus-Serum-Toxin Act (VST Act) to assure that veterinary biological products distributed in the United States are pure, safe, potent, and effective.

The VST Act requires USDA to provide by regulation an exemption from licensure requirements for biological products made by a veterinarian for use within that veterinarian's practice. USDA-APHIS has promulgated such a regulation at 9 Code of Federal Regulations (CFR) § 107.1(a). Veterinary biologics that fall under this provision are not manufactured in a USDA-APHIS-VS-CVB licensed establishment and have not been reviewed by USDA-APHIS-VS-CVB for safety or efficacy. Some commercial enterprises have undertaken to contract with veterinarians to manufacture and supply unlicensed vaccine products as their "agents." Millions of doses of unlicensed and unregulated vaccines have been administered to food animals under this arrangement, thus exponentially increasing the risk and potential impact from a manufacturing error by the unlicensed manufacturer.

In order to correct this practice, USDA-APHIS published a proposed rule to amend the 9CFR 107.1 regulation in July 2012 [77 Federal Register 42195, July 18, 2012]. The effect of the proposed rule would be to guide such outsourced biologicals into the USDA-APHIS-VS-CVB approval process where safety and efficacy are evaluated and manufacturing is overseen, while preserving the intent of the exemption. The proposed rule has not been finalized. With this action, USDA-APHIS has signaled to those who wish to responsibly interact with the agency that this market activity is inappropriate and being eliminated. In individual interactions, USDA-APHIS-VS-CVB has advised biologics manufacturers not to approach the market in this manner, as it is being eliminated. However, there are companies that continue to operate in this manner.

**RESOLUTION:**

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service to finalize proposed rule 77 Federal Register 42195, July 18, 2012 regarding the exemption to licensure of veterinary biologics.

**INTERIM RESPONSE:**

The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association and appreciates the opportunity to respond.

In late fiscal year 2014, VS' Center for Veterinary Biologics (CVB) posted a revision to VS Memo 800.211 on the website for public comment. This memo addresses many of the concerns that were raised by various individuals and groups when the proposed rule to revise 9 CFR 107.1 was originally published in late 2012. The revised memo expands the ability of biologics manufacturers to utilize platform technologies/biotechnology to bring innovative products to the market more quickly, reducing the need to produce unlicensed product under a veterinary exemption using a 3rd party manufacturer. The comment period closed January 16, 2015. CVB is currently assessing the comments received. Once the outstanding concerns are addressed, VS Memo 800.211 can be finalized. CVB will also proceed with the publication of the final rule to revise 9 CFR 107.1.