



UNITED STATES ANIMAL HEALTH ASSOCIATION

2016 Resolution

120th Annual Meeting

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RESOLUTION NUMBER: 25

APPROVED

SOURCE:

COMMITTEE ON BIOLOGICS & BIOTECHNOLOGY

SUBJECT MATTER:

International Promotion of the United States Regulatory System for the Regulation of Veterinary Biological Products

BACKGROUND INFORMATION:

The United States Department of Agriculture (USDA) has regulated the veterinary biologics industry for over 100 years, and under the Virus-Serum-Toxin Act of 1913 (amended in 1985), has developed regulatory methods to ensure that the veterinary biologics manufactured in the United States (US) are pure, safe, potent, and effective. This regulatory system is described in the Code of Federal Regulations (CFR) beginning at 9 CFR part 101 (Subchapter E). In 2015, the US domestic veterinary biologics industry manufactured over 100 billion doses of high quality products for both domestic and global markets. More recently, certain countries (often with local industry support interests) have intimated in the international arena that the US regulatory system is not equivalent, and by implication inferior, to their regulatory systems. Consequently, some countries are no longer accepting inspection certification from the USDA. Some insist on conducting their own inspections, while others will accept certificates of inspection from a regulatory body that is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). PIC/S is a non-binding cooperative arrangement between regulatory authorities to promote quality inspections and to facilitate cooperation and networking among these authorities to promote mutual confidence. Approximately fifty regulatory authorities are currently members of the PIC/S.

The USDA, Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics has worked to promote an understanding of their regulatory system through participation in the Veterinary International Conference on Harmonization (VICH), outreach to Latin America through a World Organization of Animal Health (OIE) program called CAMEVET, and participation in the Institute of International Cooperation in Animal Biologics, which is an OIE collaborating center located at Iowa State University that conducts programs that are often attended by foreign governments. These outreach efforts are appreciated, however more is needed to help promote and protect export markets for US veterinary biologics. Countries with recent specific issues include Russia, Thailand, and Turkey. The USDA-APHIS-CVB should evaluate leveraging other ongoing USDA-APHIS trade outreach programs to further promote their regulatory system and evaluate joining the PIC/S.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service programs, including International Services, Veterinary Services' National Import Export Services, and Center for Veterinary Biologics to develop a plan to increase USDA efforts to promote the United States regulatory system for veterinary biologics as a high quality regulatory system designed to ensure the production of pure, safe, potent, and efficacious veterinary biological products. The plan should specifically evaluate outreach to problematic areas and joining the Pharmaceutical Inspection Cooperation Scheme.