Veterinary Biologics: History and Summary of Activities

Last Modified:

Federal regulation of veterinary biologics began in 1913 with passage of the Virus-Serum-Toxin Act. This law was enacted largely because of public concern over the importation of contaminated veterinary vaccines from Europe and in reaction to complaints about worthless and contaminated hog cholera products being sold throughout the country. The new law required the Department of Agriculture (USDA) to ensure that veterinary biologics (vaccines, bacterins, antiserums and similar products) sold in interstate commerce are pure, safe, potent, and efficacious. In 1985, the Virus-Serum-Toxin Act was amended to include biologics sold in intrastate.

For nearly 50 years, the biologics program was carried out by USDA veterinary field inspectors located in the commercial biologics manufacturing establishments and by licensing staff in Washington, DC. In 1961, the biologics program was allocated ten percent of the space at the National Animal Disease Laboratory (now Center) that had just been established in Ames, Iowa. The regulatory emphasis shifted from plant inspection to product testing by the USDA at a central location. For several years in the 1960s, this was the sole method of product monitoring. The current monitoring program combines both testing by the USDA as well as plant inspection, although due to the size and complexity of today's biologics industry, inspection is coordinated from a centralized office.

The biologics laboratory functions were moved to the facility at 1800 Dayton Avenue in 1978. The biologics field office (now known as the Inspection and Compliance

unit) was located in various office spaces within Ames, Iowa. Until 1997, the licensing staff was located in Washington D.C. and various suburbs (Hyattsville and Riverdale, Maryland).

The veterinary biologics program was originally part of the USDA's Bureau of Animal Industry. In 1953, it became part of the Animal Health Division of the Agricultural Research Service. When the USDA formed the Animal and Plant Inspection Service (APHIS) in 1972, the biologics program was moved to the Veterinary Services (VS) unit of APHIS. From 1988-1996, the licensing staff and the field office were organizationally part of the Biologics, Biotechnology, and Environmental Protection staff of APHIS. The biologics laboratory remained within VS.

In 1996, the units of the veterinary biologics program were reunited under VS and formed the Center for Veterinary Biologics. Organizationally, the Center was comprised of three units: Licensing and Policy Development, Inspection and Compliance, and the Laboratory. In 1997, the licensing staff moved to Ames locating at 510 South 17th Street, along with the Inspection and Compliance unit. An Operational Support section remains in Riverdale, Maryland.

In 2003, the Center underwent an organizational realignment to its current two-unit structure. Review and testing functions were consolidated into the Policy, Evaluation and Licensing unit. The Inspection and Compliance unit was expanded to include information management and quality assurance functions for the Center.

Construction was completed in April 2009 on a major modernization effort of the Ames facilities. In July 2009, the Center colocated with the National Veterinary Services Laboratories and the National Animal Disease Center as part of the newly formed National Centers for Animal Health.

Print