APHIS and FDA update charter to clarify jurisdiction for animal biologicals

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Today, the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) and the U.S. Food and Drug Administration (FDA) making available a charter that details how the two agencies work together to determine the appropriate agency to regulate the small number of animal biologicals for which jurisdiction may be unclear.

Representatives from APHIS and FDA originally signed a Memorandum of Understanding in 2013 (FDA MOU 225-05-7000) that outlined which animal biologicals each would regulate. Since 2013, science has continued to advance, and the jurisdiction of some products is not clear under the MOU. As regulatory science and the nature of animal biologicals have evolved over time, APHIS’ Center for Veterinary Biologics and FDA’s Center for Veterinary Medicine have worked together to develop a common approach, consistent with the law, for both agencies to make jurisdictional determinations on the regulation of products as either drugs under the Federal Food, Drug, and Cosmetic Act or biological products under the Virus-Serum-Toxin Act.

The charter includes a flowchart to help clarify which agency will regulate a given product, as well as information on how to request a jurisdiction determination from APHIS and FDA for animal biologicals. The charter also discusses the agencies’

approach for products with multiple claims where oversight may fall to both agencies and describes a reconsideration process for jurisdiction decisions.

For more information:

- Charter for the jurisdiction determination process of the APHIS CVB/FDA CVM Jurisdiction Committee (406.05 KB)
- MOU 225-05-7000