

CPG Sec. 645.100 Biological Drugs for Animal Use

BACKGROUND:

Animal biologicals are subject to both the Food, Drug, and Cosmetic Act and the Virus, Serum, Toxin Act (Public Law 430 of 1913, 73 Stat 832-833, 21 U.S.C. 151-158). However, section 902(c) of the FD&C Act states: "Nothing contained in this Act shall be construed as in any way effecting, modifying, repealing, or superseding the provisions of ... the virus, serum, toxin, and analogous products provisions of ... 37 Stat 832-833." Animal biologicals are not subject to the biologics provisions of the Public Health Service Act (42 U.S.C. 262). The Animal and Plant Health Inspection Service (APHIS), USDA enforces the VST Act.

The VST Act forbids the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous or harmful animal biologicals in interstate commerce. It provides for licensure of products and establishments and requires permits for the importation of animal biologicals. Regulations require preparation of biologicals in accordance with an approved "Outline of Production" so as to meet prescribed test requirements for purity, safety, potency, and efficacy. Regulations also require submission of all labeling and claims to be made in advertising for approval. Regulations pertaining to the VST Act are found at 9 CFR 101-117.

Animal biologicals produced and distributed in full conformance with the VST are exempt from section 512 (see 21 CFR 510.4). Licensing under the VST Act is tantamount to registration and drug listing under section 510, and registration and listing are not required for manufacturers of animal biologicals which hold unsuspended and unrevoked licenses. (See 21 CFR 207.65(g).) However, all animal biological manufacturers unlicensed by the USDA are required to register and list under Section 510 of the FD&C Act. Animal biologicals produced in accordance with the license and outline of production are considered to be in compliance with good manufacturing practice and would not be considered to be in violation of section 501(a)(2)(B).

Animal biologicals are subject to sections 501 and 502 of the FD&C Act, with the exceptions of section 501(a)(2)(B), 501(a)(5) and 502(o). Animal biologicals in violation of the VST Act are subject to all provisions of the FD&C Act. Intrastate animal biologicals may be subject to the FD&C Act if any of their components have moved in interstate commerce.

The term biological is defined to mean "all viruses, serums, toxins and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals." (9 CFR 101.2(w)).

POLICY:

ORA should not inspect firms manufacturing only animal biologicals unless such firms are unlicensed by the USDA because they do not market finished products in interstate commerce. Where a firm manufactures both biologicals and non-biological animal drugs, inspection may include intrastate biologicals not licensed by USDA. If a manufacturer sells only in intrastate commerce, but utilizes

interstate components, the firm and its products are subject to the FD&C Act and may be inspected. ORA may inspect distributors of animal biologicals. Animal biologicals imported without a permit should be referred to local USDA officials for their action.

When found in interstate commerce, animal biologicals which violate the FD&C Act are subject to regulatory action. *CVM* Case Guidance Branch (HFV-236) will consult as necessary with APHIS and otherwise keep them informed of our actions.

Violations of the VST Act should be referred to local USDA officials. Although biologicals in violation of the VST Act become subject to certain provisions of the FD&C Act from which they were previously exempt (e.g., sections 510 and 512), any action under the FD&C Act, in such cases, should be initiated only in consultation with *CVM.*

Material between asterisks is new or revised

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