CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 01-16

Subject: Autogenous Products for Avian Influenza

To: Biologics Licensees, Permittees, and Applicants
    Directors, Center for Veterinary Biologics
    Veterinary Services Management Team
    Area Veterinarians in Charge, VS
    State Veterinarians

The purpose of this notice is to remind interested parties that domestic distribution and use of avian influenza (AI) vaccines for any species may only be done under the supervision and control of USDA, APHIS, Veterinary Services (VS).

Requirements for the licensure of AI vaccines and a summary of the restrictions on their use are provided in Veterinary Services Memorandum No. 800.85, dated July 23, 1999. Avian influenza is considered a program disease by APHIS, VS, and any importation or interstate movement of AI viruses is strictly regulated and is only authorized by permit in accordance with 9 CFR 122.2.

The practice of producing AI vaccines as autogenous products under a firm's existing autogenous product license without specific authorization from APHIS, VS, does not meet these requirements and is prohibited. The Center for Veterinary Biologics (CVB) will not release autogenous AI vaccines without authorization from both the relevant State authorities, responsible officials of APHIS, VS, and if necessary, required permits for interstate transport.

/s/ Steven A. Karli

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Director
Center for Veterinary Biologics