United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-04

Subject: Autogenous Vaccine Use in Turkeys

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

The purpose of this notice is to inform interested parties of the procedure required to permit limited use of autogenous avian influenza (AI) vaccine in turkeys.

AI is considered an exotic disease by the Animal and Plant Health Inspection Service (APHIS). Therefore, the requirements and restrictions applicable to conditionally licensed AI vaccine outlined in Veterinary Services Memoranda 565.12 dated July 24, 1995, and 800.85 dated July 23, 1999, apply also to autogenous vaccine produced from avian influenza isolates.

Generally, vaccine from any H5 or H7 serotype should not be prepared or used unless specifically authorized by APHIS. AI vaccine from serotypes other than H5 and H7 may be produced for use in turkeys only. In either case, vaccine should only be used in facilities with proper biocontainment and sentinel systems.

Prior to shipping each serial (including the first serial) of autogenous AI vaccine for use in turkeys, veterinary biologics manufacturers must submit to the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC):

1. Data and/or reports documenting compliance with all requirements specified in 9 CFR 113.113.

2. A description of the product (including H type), the serial number, location of premises, and quantity of the product to be used (number of doses) at that location.

3. One copy of a letter of permission from state animal health officials authorizing vaccine use and specifying any conditions of that use.

For the first serial of autogenous vaccine produced from an isolate, the information specified in items 1 and 2 should be sent to CVB-IC in letter format (along with item 3).
When the APHIS Form 2008, Veterinary Biologics Production and Test Report, is submitted to CVB-IC at the completion of product testing, the information in items 1 and 2 should also be included on that form. For subsequent serials, the information specified in items 1 and 2 should be recorded on APHIS Form 2008, attached to the letter of permission signed by the appropriate state animal health official, and submitted to CVB-IC.

Veterinary biologics manufacturers are reminded that VS Form 16-6A, United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors, must be obtained prior to shipping/transporting AI isolates from one location to another. Refer to 9 CFR Part 122 or contact the National Center for Import and Export at *www.aphis.usda.gov/vs/import_export.htm* for information concerning permit application procedures.

/s/ Steven A. Karli

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Director
Center for Veterinary Biologics