

December 11, 2006

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-24

Subject: Exemptions to allow live poultry vaccines administered via wing web to be tested for detection of extraneous viable bacteria and fungi via Title 9, Code of Federal Regulations, Part 113.27 (e).
To: Biologics Licensees, Permittees, and Applicants

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

I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) will allow exemptions for live poultry vaccines of chicken embryo origin, administered via wing web to be tested for extraneous viable bacteria and fungi via Title 9, Code of Federal Regulations, Part 113.27 (e).

II. BACKGROUND

The 9 CFR 113.27 (a) currently indicates:

"Each serial and subserial of live viral vaccine shall be tested for purity as prescribed in this paragraph. However, products of chicken embryo origin recommended for administration other than by parenteral injection may be tested as provided in paragraph (e) of this section."

Though wing web inoculation is a parenteral administration, CVB finds it acceptable to consider allowing products administered by wing web inoculation to be tested for extraneous viable bacteria and fungi by 9 CFR 113.27 (e) instead of 113.27 (a).

III. ACTION

Exemptions will be considered to allow testing of live viral vaccines of chicken embryo origin that are administered by wing web injection to be tested under 9 CFR 113.27(e). Establishments already utilizing the exemption are requested to indicate that an exemption has been granted. Include the date and name of the authorizing official, if

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United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

510 S. 17th Street, Suite 104 Ames, IA 50010 (515) 232-5785 FAX (515) 232-7120 available. These additions should be made at or before the annual review of the Outline. Requests for exemptions to these regulations should be addressed to the reviewer assigned to the establishment and be accompanied by the appropriate page amendments to the Outline.

/s/ Richard E. Hill

Richard E. Hill, Jr. Director