Animal and Plant **Health Inspection** Service

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-03

Veterinary Services

TO: Biologics Licensees, Permittees, and Applicants

Center for Veterinary **Biologics**

Directors, Center for Veterinary Biologics

Veterinary Services Leadership Team

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Veterinary Vaccines and Veterinary Diagnostic Products Targeting

Avian Metapneumovirus (all subtypes)

I. PURPOSE

SUBJECT:

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is accepting veterinary biologics product license and import permit applications for veterinary biological products used to vaccinate for avian metapneumovirus (aMPV) and veterinary diagnostic products for aMPV. Products targeting subtypes A and B are of greatest interest but given the current status of aMPV in the United States, CVB will accept information related to all subtypes for review. Although CVB is open to receiving applications for both modified live and inactivated products, the preference for use will be the latter.

II. BACKGROUND

aMPV has been reported on turkey farms in several states in the United States, and the situation is dynamic. Subtypes A and B have currently been detected; the United States has had subtype C since at least 1997.

III. ACTION (or POLICY)

Parties interested in licensing or permitting an aMPV vaccine or diagnostic product should refer to Title 9, Code of Federal Regulations, Chapter I, Subchapter E; Veterinary Services (VS) Memorandum 800.50, Basic License Requirements and Guidelines for Submission of Materials in Support of Licensure; and VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale. This information is available on the CVB website: www.aphis.usda.gov/animalhealth/cvb regsandguidance

IV. IMPLEMENTATION/ APPLICABILITY

Applications and supporting materials may be submitted to the CVB-Policy, Evaluation, and Licensing for review effective immediately.