



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-10

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Geetha B. Srinivas, DVM, PhD.
Director, Center for Veterinary Biologics

SUBJECT: Veterinary Vaccines and Veterinary Diagnostic Products Targeting
Avian Metapneumovirus (all subtypes)

I. PURPOSE

This Notice supersedes Notice 24-03. 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 limited to two specific types of vaccine products/developmental materials:

1. Experimental Autogenous Products: These are defined as domestically produced, inactivated veterinary biological products that are similar to autogenous products in that they are produced from an isolate of the current outbreak strains. However, they differ from autogenous products in that these unlicensed, experimental products will be distributed under 9 CFR 103.3 to meet the current need for product related to avian metapneumovirus (aMPV). These products will undergo purity and safety testing, and the firm must conduct testing to verify inactivation. CVB will require approved manufacturers to submit frequent, detailed accounting on number and locations of doses distributed, require orders from veterinarians with a valid veterinarian-client-patient relationship, State Animal Health Official (SAHO) approval to use the unlicensed product in their state, and distribution will be limited to affected states. The submitted Form 2071 and SAHO approval letters must include a requirement that movement of vaccinated birds to unaffected states will be prohibited. Progress toward licensure will be expected for experimental autogenous products; they will only be allowed for sale and distribution until more traditional vaccines are licensed.
 - a. Interested firms should contact CVB for product code assignment and create an Outline of Production similar to an outline for autogenous products.

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-10

Page 2

- b. CVB will consider requests from the firm for concurrent CVB Laboratory testing of the Master Cell Stocks (MCS) used to propagate the virus. Firms should contact their Reviewer.
2. Imported developmental materials: Import permits for Master Seed Virus (and perhaps MCS) will be considered for products produced internationally in order to facilitate domestic licensure and production of modified live viral or inactivated products. Such products will be considered for conditional licensure to meet the emergency condition.
 - a. CVB will consider requests from the firm for concurrent CVB Laboratory testing of the Master Seed Virus (MSV) and MCS. Firms should contact their Reviewer.
 - b. The imported MSV will be considered the pre-Master, and the MSV+1 produced domestically will be used as the starting MSV for domestic manufacture and use.

License or import permit applications for veterinary diagnostic products for aMPV are also still of interest to the CVB.

Products targeting subtypes A and B are of greatest interest but given the current status of aMPV in the United States, information related to all subtypes will be accepted for review.

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; subtype C was also recently detected. A novel subtype was also described in 2019 in the United States.

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:

<https://www.aphis.usda.gov/veterinary-biologics/regulations-guidance>

IV. IMPLEMENTATION/ APPLICABILITY

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-10

Page 3

Applications and supporting materials may be submitted to CVB-Policy, Evaluation, and Licensing for review effective immediately. If your firm is not portal enabled, you can email responses using the subject line: "Products Targeting Avian Metapneumovirus" to the USDA Center for Veterinary Biologics at CVB@usda.gov.