



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-11

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

FROM: Geetha B. Srinivas, DVM, PhD.
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SUBJECT: Veterinary Vaccines Targeting Highly Pathogenic Avian Influenza in Livestock

I. PURPOSE

The purpose of this Notice is for the Center for Veterinary Biologics (CVB) to provide an update to interested parties regarding veterinary biologics product licenses for veterinary biological products used to vaccinate livestock for Highly Pathogenic Avian Influenza (HPAI) H5N1, clade 2.3.4.4b. This Notice includes current information for evaluation of efficacy and current considerations for vaccine use in the United States.

II. BACKGROUND

Highly Pathogenic Avian Influenza (HPAI) H5N1 was first confirmed in U.S. dairy cattle on March 25, 2024, by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service's (APHIS) National Veterinary Services Laboratories (NVSL). The recent HPAI H5 clade 2.3.4.4b strain was made available from the NVSL as noted in [Notice 24-06](#). CVB previously posted a related request for information on H5 HPAI vaccines and status of development in [Notice 24-09](#).

III. ACTION (or POLICY)

USDA acknowledges the veterinary biologics industry's interest in the development of vaccines for potential use in livestock or other animal species against H5 HPAI. CVB is providing the following updates but also noting that this is a rapidly evolving situation. These points should be considered current unless this CVB Notice is cancelled or superseded.

1. CVB is currently accepting license applications for vaccines to protect livestock against H5 HPAI.

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2. Conditional Licensure – CVB will consider serological response in vaccinated target species as data to support a reasonable expectation of efficacy. Serological testing should focus on antibodies to the H5 clade 2.3.4.4b hemagglutinin using an assay such as or similar to the hemagglutination inhibition assay. Study protocols including proposed serologic testing details should be submitted to CVB for review.
3. Full Licensure – Currently CVB will only consider studies using vaccination-challenge with H5 HPAI in the target species, along with all other licensure requirements, to obtain full licensure. Note the recent [Select Agent Exemption for H5 HPAI](#). Study protocols should be submitted to CVB for review.
4. CVB strongly encourages applications for licensure, with the caveat that U.S. licensure is distinct from authorization for U.S. use. At the time of this CVB Notice, USDA has not authorized the use of H5 vaccines in the United States. Any products that are licensed will carry a restriction prohibiting U.S. sale, distribution, and use until further notice.
5. If USDA authorizes HPAI vaccine use or stockpile purchasing, preference may be given to products that best fit national program objectives. Example objectives could include eradication of H5 HPAI from cattle, compliance with surveillance testing, or addressing international trade concerns. Vaccine characteristic considerations could include licensure data and status, viability of the final product (e.g. live vs inactivated), and specific compatibilities to differentiate infected from vaccinated animals (DIVA).

Parties interested in licensing an H5 HPAI vaccine should contact CVB for further discussion. 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

Applications and supporting materials may be submitted to the 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 HPAI" to the USDA Center for Veterinary Biologics at CVB@usda.gov.