CVB Notice 24-13: Field Studies with Nonviable, Non-replicating Veterinary Vaccines Targeting Highly Pathogenic Avian Influenza in Livestock

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The Center for Veterinary Biologics (CVB) recently added a new notice to its website regarding the acceptance of licensure applications for products used to vaccinate livestock for Highly Pathogenic Avian Influenza (HPAI) H5N1, and the authorization of a field trial under specific conditions: CVB Notice 24-13: Field Studies with Nonviable, Non-replicating Veterinary Vaccines Targeting Highly Pathogenic Avian Influenza in Livestock.

As one part of several USDA vaccine licensure requirements, provided the application meets the requirements, the Department has authorized the start of an initial field study of nonviable, non-replicating vaccine against HPAI H5N1 to be administered to dairy cattle to evaluate safety. This would be the first field safety study for a bovine specific H5N1 vaccine and the first time a HPAI vaccine field study would be conducted outside a laboratory setting or on any type of commercial farm in the United States.

Studies that are limited to non-viable, non-replicating vaccines do not cause virus shedding. Vaccinated cattle will not transmit virus to other animals, milk, meat, people or into the environment. Therefore, these cattle and their products do not present a risk to human health and will stay in normal production.

This allows for the first authorized field safety study. USDA anticipates requests from other interested vaccine manufacturers and will use these criteria for approval.