



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE 20-12

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Veterinary Vaccines Targeting SARS-CoV-2 Virus in Mink

### I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is accepting veterinary biologics product license and permit applications for veterinary biological products used to vaccinate mink against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the etiologic agent of coronavirus disease 2019 (COVID-19).

### II. BACKGROUND

SARS-CoV-2 is a positive single-stranded enveloped RNA coronavirus that causes mild to lethal respiratory illness in some species of animals and is responsible for the COVID-19 pandemic disease in humans. Mink are highly susceptible to SARS-CoV-2, and there is evidence of high transmissibility between mink and mink farms causing high morbidity and mortality. The disease has been reported on mink farms in several countries including the United States.

Although there is evidence for spread of viral infection from humans to cats and dogs, at this point there is very limited evidence indicating disease spread between cats and dogs in non-laboratory settings. Currently CVB is not accepting license applications for SARS-CoV-2 vaccines for use in dogs or cats because data do not indicate such a vaccine would have value. At this time, CVB will support research and development activities for SARS-CoV-2 veterinary biologics in any species, such as requests to ship experimental product. CVB is closely monitoring the situation and may re-evaluate as additional information becomes available. However, veterinary biologics licenses or permits will not be granted for species other than mink without more evidence of transmission and clinical disease in other species.

### III. ACTION (or POLICY)

Parties interested in licensing or permitting a SARS-CoV-2 for use in mink should refer to title 9, *Code of Federal Regulations*, Chapter I, Subchapter E; Veterinary

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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](http://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.