



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS DRAFT NOTICE NO. 21-03

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Issuance of Inspection Certificate

### I. PURPOSE

This Notice informs regulated entities of the new process for Issuance of Inspection Certificates. Inspection certificates will be issued for in-depth inspections of U.S. Veterinary Biologics Establishment Licensed sites.

### II. BACKGROUND

Veterinary Services (VS) Memorandum 800.91 was updated on December 11, 2020, to include the issuance of Inspection Certificates. These certificates are issued to indicate the manufacturing site or sites have been inspected under U.S. laws and determined to comply with USDA's good manufacturing practices (GMP).

### III. POLICY

#### A. Issuance of Inspection Certificates

1. Inspection Certificates will be issued for in-depth inspections for domestic sites (Licensees).
  - a. All sites visited during the inspection will be listed on the certificate.
  - b. Inspection Certificates will not be issued for U.S. quarantine sites for permitted product.
2. The Inspection Certificate will be digitally signed and sent back to the liaison for the Establishment via the NCAH Portal in the same Mail Log Item as the inspection report for the site.
3. No additional copies of the Inspection Certificate will be granted for the site inspection. Attestations of GMP may still be requested as indicated in VS Memorandum 800.52.

#### B. Issuance of Retroactive Inspection Certificates

1. Due to Covid-19 travel restrictions, in-depth inspections of licensed establishments have been postponed and the practice of issuing

Inspection Certificates based on a current in-depth inspection has not been initiated.

2. Issuance of an Inspection Certificate based on the last in-depth inspection conducted at the establishment site can be requested by the U.S. Veterinary Biologics Establishment Licensee.
  - a. Request the Inspection Certificate through a formal submission via the NCAH Portal.
  - b. Use Submission Type – Inspection.
  - c. Enter Establishment Site and, if needed, Additional Sites for which the certificate is requested.
  - d. The Brief Description should indicate “Request for Inspection Certificate”.
  - e. Enter the Mail Log Item listing the in-depth inspection report the certificate will reference.
3. No Inspection Certificates will be issued for inspection of foreign manufacturing sites for permittees or for the related quarantine site located in the United States.
4. These certificates are valid for five years from the date of the initiation of the on-site inspection.

#### IV. IMPLEMENTATION/ APPLICABILITY

This change will be effective immediately. Once an on-site inspection has been conducted for a site, the option to request issuance of a retroactive Inspection Certificate will no longer be available for that site.