



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 16-05

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Initiation of the National Centers for Animal Health (NCAH) Portal  
for the Center for Veterinary Biologics

### I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) is beginning the process of accepting submissions via the web-based NCAH Portal for APHIS Form 2007, *Qualifications of Veterinary Biologics Personnel*; APHIS Form 2008, *Veterinary Biologics Production and Test Report*; and APHIS Form 2020, *Shipment and Receipt of Biologics Samples*.

### II. BACKGROUND

The CVB has been working internally and with manufacturers from stakeholder groups since 2014 to produce requirements and business processes for a system that enables electronic submissions to the CVB. The NCAH Portal fulfills this goal and also allows the CVB to respond electronically.

The implementation of the NCAH Portal will consist of a multiphase roll-out. During the phased implementation, there will be a period of time in which some submissions will be electronic, while others remain paper based. An initial four-week pilot implementation, with selected licensees and permittees, will precede the implementation for all licensees and permittees.

### III. ACTION

Beginning in June 2016, all licensees and permittees may submit data through the NCAH Portal in lieu of submitting hard copy data on the APHIS forms listed above. Veterinary biologics establishments must do the following to gain access to the NCAH Portal:

1. Each **employee** must have USDA Level 2 eAuthentication. Detailed instructions are found at <https://www.eauth.usda.gov>.
2. Each employee also must have an APHIS Form 2007 on file with the CVB.

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3. At a minimum, each **firm** must have employees who serve in the following CVB-authorized roles:
  - Liaison
  - Government Sampler

Other employees from the firm may be added as NCAH Portal users as desired. Various roles, having different read/edit/submit privileges, are available.

A user without a specified NCAH Portal role will be able to enter limited data and edit that data but will not be able to submit anything to the CVB.

4. There will be mandatory annual information security awareness training for each designated NCAH Portal User. Details regarding this annual training will be made available on the CVB website.
5. Each time an authorized NCAH Portal User logs on to the Portal, they will be presented with a warning banner that displays the following information:
  - You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.
  - Unauthorized or improper use of this system may result in civil and criminal penalties.
  - By using this information system, you understand and consent to the following:
    - You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, the Government may for any lawful Government purpose monitor, intercept, search and seize any communication or data transiting or stored on this information system.
    - Any communications or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.
    - Your consent is final and irrevocable. You may not rely on any statements or informal policies purporting to provide you with any expectation of privacy regarding communications on this system, whether oral or written, by any other official, except USDA's Chief Information Officer.
6. Rules of behavior specific for submitting information via the NCAH Portal include the following:
  - You will accept all CVB responses via the NCAH Portal and understand responses will only be available for 60 days after the CVB response is completed.

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- You will promptly report any IT security incidents involving the use of the NCAH Portal to the CVB.

Guidance for submission of information may be found in the related Veterinary Services Memoranda: 800.53, *Release of Biological Products*; 800.59, *Veterinary Biological Product Samples*; 800.63, *Personnel at Licensed Establishments*; 800.69, *Guidelines for Autogenous Biologics*; and 800.101, *U.S. Veterinary Biological Product Permits for Distribution and Sale*. In addition, there is a link to a Portal User Guide located within the footer of the NCAH Portal website.

The Portal website may be found at <https://ncahappspub.aphis.usda.gov/NCAHPortal/public/>. The Portal and applicable training materials may also be accessed through the CVB website at [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/ct\\_cvb\\_portal\\_guidance](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/ct_cvb_portal_guidance).

#### IV. IMPLEMENTATION/APPLICABILITY

Phased implementation of the NCAH Portal for APHIS Forms 2007, 2008, and 2020 is scheduled to begin April 25, 2016, with selected licensees and permittees. Implementation for all licensees and permittees is scheduled for June 2016. Electronic submission is strongly encouraged; however, paper-based submissions will continue to be accepted for those who choose not to submit electronically or need a hard copy signature from APHIS.