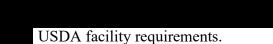
Internal Guidance on NCAH Portal Access for New Firms

This guidance is designed to help Reviewers determine when to request that a new firm be enabled for use of the National Centers for Animal Health (NCAH) Portal from the Center for Veterinary Biologics (CVB) Program Information Management and Security (PIMS) Section. New firms will typically ask for access to the NCAH Portal because it is a much more efficient way to communicate with CVB compared to paper documents delivered by the United States Postal Service (USPS) or other mail carriers. Using the NCAH Portal speeds up communication, allows for efficient movement of large documents, and prevents the loss of incoming documents and outgoing correspondence. The disadvantage of granting early access to the NCAH Portal is that firms must learn the system and use it regularly to keep their access accounts active and up to date.

The following are points to consider when offering new firms access to the NCAH Portal:

- All firms must make their initial submissions using signed paper copies.
- If the firm has made multiple (5-10) submissions within a year to CVB and it appears there is going to be a long term relationship with the firm during product development, the Reviewer (after consulting with Section Leader) could request for the firm to have NCAH Portal access.
- The firm will need to meet all the current guidance on NCAH Portal access as found in: <u>https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-</u> biologics/sa_ncah_portal_guidance/ct_vb_ncah_portal_access
 - The product falls under CVB jurisdiction
 - Product is suitable for licensure/permitting
 - Submission of Facility documents that are likely to meet USDA requirements.



- Permitted firms must have established an active US quarantine site in LSRTIS that is documented by the submission of acceptable facility documents. This is needed to assure there is a responsible party within the US. Simply having a US based liaison and a United States Post Office box as an address is <u>not</u> acceptable. A verified identity eAuthentication account is only provided within the United States or a US Embassy.
- USDA Establishment Code has been assigned
 - Note it is acceptable for firms to be recognized by an alphabetical abbreviation in LSRTIS, and not yet have a final Establishment Number



- Firm has properly trained their staff on the applicable NCAH Portal procedures.
- Firm has a liaison at an **active** site for the Establishment in LSRTIS, as well as, a filed 2007 with their eAuthentication username and applicable roles provided.
- Firms should be warned in advance that if they are unable to competently use the NCAH Portal submissions may be returned unprocessed with guidance on resubmission and their NCAH Portal access could be suspended or revoked.
- Below is a template letter that can be used to offer firms NCAH Portal access that sets the expectations of using the NCAH Portal:

Dear Name:

You have requested access to the NCAH Portal. Before this access is provided, the Center for Veterinary Biologics (CVB) would like to ensure you have read and understood the principles of using the NCAH Portal.

First, it is imperative to read the NCAH Portal User Guides and view the training videos prior to making submissions. These guides contain CVB business rules, as well as information on the mechanics of navigating the portal. The business rules are essential for proper formatting, submission, and routing within the CVB. Improperly prepared and submitted items will be returned unprocessed. <u>https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/SA NCAH Portal Guidance</u>

Next, you need to ensure the correct form is being submitted to the correct CVB unit. Some documents are sent to CVB, Policy, Evaluation, and Licensing (PEL) unit and others are sent to the CVB, Inspection and Compliance (IC) unit. Failure to send the documents to the correct unit based on the submission type, will result in documents being returned unprocessed. The submission type you need will determine which NCAH Portal User Guide(s) you will need to utilize.

Each employee at the firm you would like to use the NCAH Portal must have a USDA verified identity eAuthentication account username, have an APHIS Form 2007 submitted to CVB, and eAuthentication username and applicable role(s) entered into CVB's LSRTIS database. For more information see the NCAH Portal User Guide: *Description of Portal Roles and Privileges*. In addition, the firm should have an email address that is monitored on a frequent basis. Notification of submission status changes will be sent to this address along with other applicable notifications. This may be your only form of notification – so this is something the CVB suggests is a group email for the firm, **not** just an individual. If this email address needs to be updated, it is up to the firm to contact the CVB at <u>CVB.PIMS@usda.gov</u>.

Please remember that the CVB cannot alter any information for your USDA verified identity eAuthentication account. Those are the credentials (username and password) that grant your access to the NCAH Portal. You will need to contact the <u>USDA Service Center</u> to modify that information. CVB has information regarding <u>eAuthentication</u> on the NCAH Portal Guidance pages on the CVB website. You will need to regularly access the NCAH Portal to keep your credentials active.

The expectation is that your firm will be fully capable of using the NCAH Portal with minimal technical support. The CVB has very limited resources available to provide you additional guidance on the use of the NCAH Portal, beyond what is available on the website. If you are not able to successfully utilize the NCAH Portal, your access to the NCAH Portal may be suspended or revoked, and you will be required to make paper copy submissions.

Sincerely,