

## VS Memorandum (VSM) 800.75

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### Reissuance of Product Licenses for Products Under Conditional Licenses

#### 1. Purpose and Background

This memorandum provides guidelines for reissuing licenses for products under conditional U.S. Veterinary Biological Product Licenses upon approach of the termination date of the conditional license according to title 9, *Code of Federal Regulations* (CFR), part [102.6\(a\)](#).

To meet an emergency condition, limited market, local situation, or other special circumstance, APHIS may issue a conditional United States Veterinary Biological Product License for a veterinary biological product under expedited procedures that ensure purity, safety, and a reasonable expectation of efficacy. APHIS may require establishments issued a conditional product license to do additional efficacy studies on the product or to develop additional data to support the validity of a proposed potency test for the product or both.

Each conditional product license carries a termination date. Conditional licenses are typically issued for 1 or 2 years. During the period the conditional license is in effect, the Center for Veterinary Biologics (CVB) expects the licensee either to make satisfactory progress toward completing the requirements for a regular product license or to fully complete the requirements for a regular product license.

#### 2. Document Status

- A. Issue Date: 07/14/2022
- B. This document replaces Veterinary Services Memorandum 800.75 dated October 27, 1999, which is cancelled.

#### 3. Reason for Reissuance

This document is reissued to be consistent with current guidance.

#### 4. Authority and References

##### A. Authorities

- 9 CFR [102.6](#)

##### B. References

- [Veterinary Services Memorandum 800.126](#) Efficacy and Safety Studies for Cancer Immunotherapeutics

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- [Veterinary Services Memorandum 800.213](#) Licensing Guidelines for Production Platform-Based, Non-Replicating, Nonviable Products

### 5. Audience

VS employees and members of the biologics industry.

### 6. Guidance

At the approach of a conditional product license termination date, CVB may reissue the product license as a conditional product license or as a regular product license or allow the product license to terminate. This depends on the degree to which the licensee has demonstrated progress toward completing the requirements for a regular license.

#### A. Requests for Reissuance of a Product License

Before the date the conditional product license is to terminate, the licensee must send CVB a request to reissue the product license. The request should include all available data and information demonstrating progress the licensee has made toward completing the requirements for a regular license for the product. The request should be submitted 90 days prior to the date of the conditional license termination to allow time for processing.

#### B. CVB Actions

CVB will respond to a request to reissue the product license for a product under a conditional license by doing one of the following:

1. *Reissue the Product License as a Regular Product License* – If the licensee satisfies all the requirements for a regular product license, CVB will issue a regular product license for the product.
2. *Reissue the Product License as a Conditional Product License* – CVB will reissue a conditional product license in the following situations:
  - a) If the licensee makes satisfactory progress toward completing the requirements for a regular product license but does not complete all the requirements for a regular product license, CVB will reissue a conditional product license for the product.
  - b) If minimal progress has been made toward completing requirements for a regular product license but CVB determines there is still a need for the conditionally licensed product, CVB will reissue a conditional license.
3. *Allow the Product License to Terminate* – CVB will allow a conditional product license to terminate in the following situations:

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- a) If the licensee does not demonstrate satisfactory progress toward completing the requirements for a regular product license, CVB will allow the product license to terminate.
  - b) If the product has qualified for a regular product license by another manufacturer since the conditional product license was last issued, CVB may consider the reissuance of a conditional product license only if assured that the licensee can satisfy all requirements for issuance of a regular product license within that 6-month period. If the licensee cannot provide such assurance, CVB may allow the product license to terminate.
4. *Actively Terminate the Product License* – CVB may proactively terminate a conditional license in cases of safety or efficacy concerns.
  5. *Conditional Licenses for Cancer Immunotherapies* – CVB will generally allow initial conditional licensure and reissuance regardless of the availability of a fully licensed similar product due to the heterogeneity within tumor types and variable patient responses to seemingly similar cancer immunotherapies. Additional guidance regarding the requirements for the reissuance of conditionally licensed cancer immunotherapies are found in VSM [800.126](#) Section 5.E.
  6. *Conditional Licenses for Platform and Prescription Platform Products* – Refer to VSM [800.213](#) Section V.A for guidance regarding reissuance of conditionally licensed platform products.

### 7. Implementation/Applicability

Updated policy in this memorandum is effective immediately.