

Secondary Review of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection)

Export Manager

A. Receipt of Export Documents from the Biologics Compliance Assistant (BCA), Export Document Examiner, or Student Intern:

1. Review and consider any special request submitted in the cover letter.

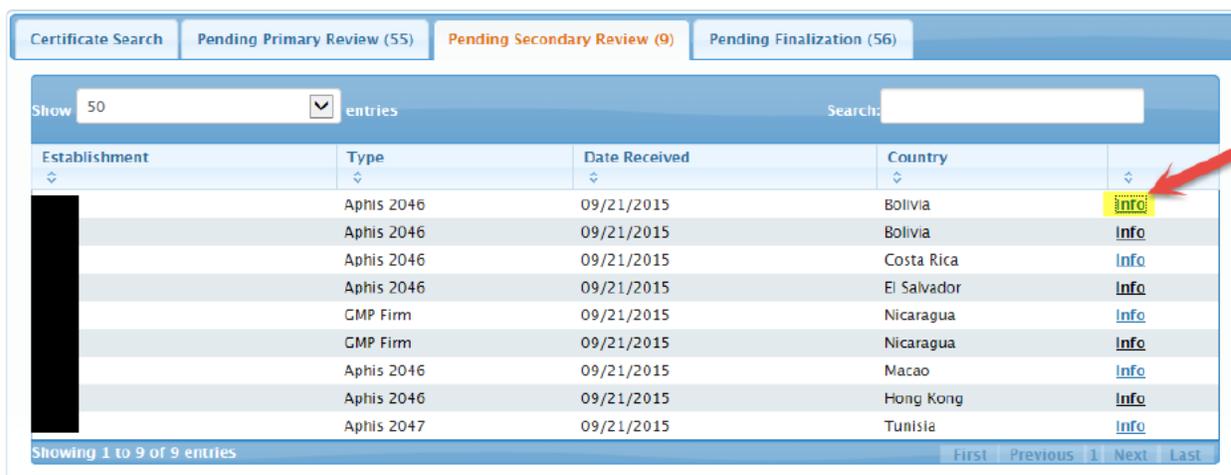
B. Search the Record in LSRTIS

1. Go to Export Module in LSRTIS, under IC heading (green circle)
2. Click on Pending Secondary Review (yellow highlight)
3. Alternatively, you may use the Certificate Search Tab to find the certificate in LSRTIS.



C. Conduct Secondary Review

1. Confirm the certificate (hard copy) is available in LSRTIS
2. Click on Info



Establishment	Type	Date Received	Country	
	Aphis 2046	09/21/2015	Bolivia	Info
	Aphis 2046	09/21/2015	Bolivia	Info
	Aphis 2046	09/21/2015	Costa Rica	Info
	Aphis 2046	09/21/2015	El Salvador	Info
	GMP Firm	09/21/2015	Nicaragua	Info
	GMP Firm	09/21/2015	Nicaragua	Info
	Aphis 2046	09/21/2015	Macao	Info
	Aphis 2046	09/21/2015	Hong Kong	Info
	Aphis 2047	09/21/2015	Tunisia	Info

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3. Review the certificate, note that the items have been checked by the primary reviewer, and verify that information listed on the certificate is accurate.
 - a. If the primary reviewer has listed a discrepancy/question, investigate discrepancies between the certificate and the Product License Profile report, and verify the accuracy of all remaining information on the certificate by comparison with the official hard copy documents in the CVB File Room or SharePoint. Unverifiable discrepancies will be audited in accordance with **ICWI0075, Audits and Reference Slips for IC Documents**.
 - b. Table 1: Hard Copy Source Documents

Item	Source Document	Location
Establishment Name, Address, Date of License, and Original Date of License	Establishment License	CVB File Room or SharePoint
Product True Name, Product Date of License, Original Date of Product License, and License Restrictions	Product License	CVB File Room or SharePoint
Trade Names Spanish True Name	Active Labels on File	CVB File Room or SharePoint

4. Note any flags in LSRTIS and investigate

Certificate

- Product ██████ Establishment ██████ License has restriction 46 - Export distribution shall be limited to authorized recipients designated by proper animal health regulatory officials--under such additional conditions as these authorities may require.
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Info

Establishment	298
Site	1730 Olympic Drive, Athens, GA - Manufacturing Site

Ensure that product or products on the certificate are not subject to a stop sale action or hold release that prevents the sale of the product in the United States.

5. Review product restriction for APHIS Forms 2047 and 2047-S

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6. The CVB will review the appended formulation based on the information available in the Outline of Production. In general, the ingredients will be evaluated based on how the product is batched (Section IV). The firm has the option to describe the ingredients based on how the product is diluted and ready to use or based on the amount in the individual vessel. Additional options may be considered. Optional calculations must be accurate.
7. Spanish true names in APHIS Forms 2046-S and 2047-S will be based on active labels on file for the specific code. Special request to use Spanish true names may be considered.
8. The address of the U.S. manufacturer must be on the Certificate of Licensing and Inspection; but as an internal policy for permitted products, CVB may allow the inclusion of the address of the U.S. quarantine site. Adding the quarantine address is acceptable. Certificates using the address of foreign manufacturers is not considered.
9. In accordance with Veterinary Services Memorandum No. 800.208, CVB will not issue certificates for product that is not released through our process, and the only labels/claims we will certify are those on file to support the U.S. license.
 - a. If a company has a Special Label approved, CVB will not issue any certificates for product to move or be registered with labels/claims depicted in those Special Labels. The stamp on the special labels indicate: Center for Veterinary Biologics Authorized Solely on Basis of Importing Country's Consent, Not For Use On Product Distributed in the United States.
 - b. The CVB may consider the authorization of an appended Export Only labels, Special Labels or Claims as long as the disclaimer "Authorized Solely on Basis of Importing Country's Consent, Not For Use On Product Distributed in the United States" is included.
10. Review all requests for attestations and other non-standard information. A listing can be found in the current version **ICSOP0044**, *Export Certificates and Certificates of Licensing and Inspection*, Sections 4 and 5.

D. Record Secondary Review

If all of the information on the certificate is successfully verified,

- a. Record the date of the secondary review and initials of the responsible person on the Product License Profile and/or cover letter, if applicable.

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- b. Click Secondary Review in LSRTIS

Action History



Action	Employee	Timestamp	Info
Initial Creation	Mattocks, David	2015-09-22 06:29:11.0	
Primary Reviewed	Mattocks, David	2015-10-08 08:41:38.0	

Buttons: Edit, Secondary Review, Audit, Reference Slip

- c. Sign the certificate(s) - If the certificate contains more than one page, sign all pages that contain a signature line. (For Certificates of Licensing and Inspection, a signature line is required only on the first page, but depending on the requirements of the country of destination, licensees/ distributors may request a signature on each page.) For Portal submissions, just push the certificate forward for finalization. The wet signature of Portal submissions will be added during the finalization of the certificate.
- d. Route the submission to the Export Document Examiner for finalization under **ICWI0070**, *Finalization and Mailing of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection)*.