Where were changes made in the 3/22/2024 version?
1. Page 3, in Entering label-specific information section, a step was added to click "Add Row" to enter labels to replace.

Where were changes made in the 3/27/2020 version?
1. Page 2, in the Attaching Label Documents section, a new option for using a PDF version of the label template was added and the Word template was updated.
    - CVB supplied Word template Label Mounting Sheet - Template A
    - CVB supplied PDF template Label Mounting Sheet - Template C

Where were changes made in the 5/9/2017 version?
1. Page 2, a footnote was added regarding submission of FDA-EREA labels.
    [1] Submit FDA-EREA labels as "Incoming Core Documents" attached to a "Correspondence" submission.

2. Page 3, in the Entering label-specific information section, #4 - Distributor:
    Distributor: Enter ONLY if the label is a container or a box label. For export labels, the entity responsible for distributing the vaccine in the country of destination may be variably identified as the distributor, importer, marketer, or equivalent. Consider all of these roles as distributors for this data field. Type any part of the Distributor name to display a list of choices in the CVB Distributor list. If the desired Distributor is not displayed, select "Not Listed." Upon receipt of a "Not Listed" submission, the CVB will add the new Distributor to the picklist for future use.

Where were changes made in the 3/15/2017 version?
1. Page 2, in the Creating a Label Submission section, a new statement was added to the list:
    Tag: Select "Single Tier Labeling" if submitting labeling in full compliance with single-tier rule (APHIS Final Rule 2011-0049)

Where were changes made in the 2/22/2017 version?
1. Page 2, in the Creating a Label Submission section, a new statement was added to the list:
    Product Code: This must be an assigned code. The labeling functionality for the NCAH Portal will not accept the "Unassigned" placeholder for uncoded products. (If you wish to obtain feedback on preliminary labeling ideas for a product that has not yet been coded, submit as Correspondence per User Guide 10 and do not place on a mounting sheet.)

Where were changes made in the 10/28/2016 version?
1. Page 2, in the Attach Labels section, a new statement was added to the list:
    Do not attach more than 5 labels to a single submission. If you need to submit more than 5, please contact your reviewer for guidance on the best way to group them.

Where were changes made in the 10/24/2016 version?
1. Page 2, in the Attach Labels section, a clarifying statement was added to the 3rd bullet:
    *Use the attachment type "Incoming postlicense label" for each actual label submitted for approval. ***Do not use this attachment type for anything other than items submitted on a label mounting sheet.****

Submitting Labels to Policy, Evaluation and Licensing (PEL)

This is a detail guide to be used in conjunction with the 2049 General User Guide. It is not intended for stand-alone use.
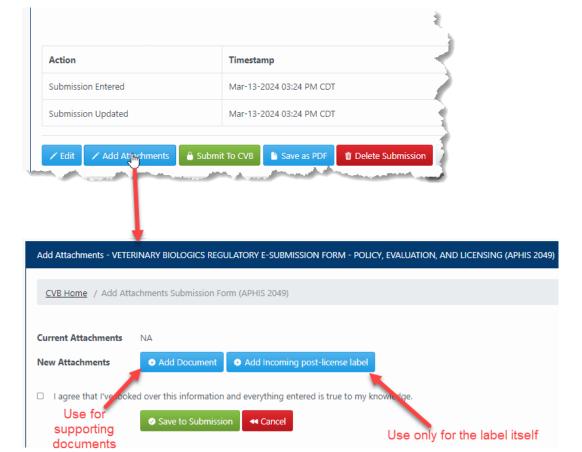
This guide pertains to submitting labels that are intended for *use* on licensed product.
It doesn't matter if the label submission is made before, or after, the product license is granted.
Do NOT use this guide for experimental labels OR labels to be used on unlicensed product exported under the Food and Administration's Export Reform and Enhancement (FDA-EREA) Act of 1996.[1]

Creating a label submission

Use the 2049 portal interface to submit labels to Policy, Evaluation, and Licensing, per the instructions in the General User Guide. Use the following values:

- Product Code: This must be an assigned code. The labeling functionality for the NCAH Portal will not accept the "Unassigned" placeholder for uncoded products. (If you wish to obtain feedback on preliminary labeling ideas for a product that has not yet been coded, submit as Correspondence per User Guide 10 and do not place on a mounting sheet.)

- Submission type = Labels, postlicense (Remember: this submission type pertains whether labels for use on postlicense product are submitted before, or after, a product license is issued)

- Submission subtype = leave blank

- Tag: Select "Single Tier Labeling" if submitting labeling in full compliance with single-tier rule (APHIS Final Rule 2011-0049)

After saving, attachments can be added. Portal users are given the option to upload an Incoming Post-License Label or other kind of document.

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[1] Submit FDA-EREA labels as "Incoming Core Documents" attached to a "Correspondence" submission.

Submitting Labels to Policy, Evaluation and Licensing (PEL)

Attaching label documents

- Multiple labels may be attached to one label submission, *provided that* they are for the same product.

- Each label must be a separate attachment.

- Do not attach more than 5 labels to a single submission. If you need to submit more than 5, please contact your reviewer for guidance on the best way to group them.

- Use the attachment type "Incoming postlicense label" for each actual label submitted for approval.
  Do not use this attachment type for anything other than items submitted on a label mounting sheet.

- Use one of the following CVB supplied templates and the template instructions found in User Guide #13 for the mounting sheet upon which the label is submitted. Customization of templates is not permitted.

  CVB supplied Word template Label Mounting Sheet - Template A

  CVB supplied PDF template Label Mounting Sheet - Template C

Entering label-specific information

After electing to add an incoming post-license label, the following information is requested:

Label Document   REMOVE

File
1 Select file ...   Browse ...

Type*
Incoming post-license label

Label Type*
2 [dropdown]

Tradename
3 [text field]

Division/Subsidiary
4 [dropdown]

Distributor
5 [text field]

Comments
6 [text field]

This Label Replaces

Label Number*	Use Remaining Inventory?	

7 ⊕ Add Row

This Label Replaces

Label Number*	Use Remaining Inventory?	
8 [text field]	**9** [checkbox]	Remove

⊕ Add Row

Note: May not have multiple attachments with the same name.

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1 **File:** Identify the file to be uploaded.

2 **Label type:** Select from dropdown picklist (e.g., Container, Box)

3 **Tradename:** Enter ONLY if the label is a container or a box label. Type any part of the Tradename to display a list of choices in the CVB Tradename list. If the desired Tradename is not displayed, select "Not Listed." Upon receipt of a "Not Listed" submission, the CVB will add the new Tradename to the picklist for future use.

Submitting Labels to Policy, Evaluation and Licensing (PEL)

④ Division/Subsidiary: Enter ONLY if the given label lists a subsidiary or division of the establishment. Select from a picklist of divisions/subsidiaries recognized on the establishment license.

⑤ Distributor: Enter ONLY if the label is a container or a box label. For <u>export</u> labels, the entity responsible for distributing the vaccine in the country of destination may be variably identified as the distributor, importer, marketer, or equivalent. Consider all of these roles as distributors for this data field. Type any part of the Distributor name to display a list of choices in the CVB Distributor list. If the desired Distributor is not displayed, select "Not Listed." Upon receipt of a "Not Listed" submission, the CVB will add the new Distributor to the picklist for future use.

⑥ Comments: Enter any comments specific to the *individual label* being uploaded.

⑦ Add Row: Click the Add Row button to enter the following information for the label needing replaced.

⑧ Label Number: If the current label replaces label(s) already on file with the CVB, provide the CVB label # of the label being replaced (NOT the mail log # under which it was processed). If more than one label is replaced by the current label, additional rows may be added.

⑨ Use Remaining Inventory: For each label being replaced, check whether permission is being requested to use existing inventories of the replaced labels. Typically, use of replaced labels is authorized for an additional year, unless other arrangements are specifically requested and authorized by the CVB. If there is no need to use remaining inventories once the replacement label is approved, leave the checkbox blank.

Submitting Labels to Policy, Evaluation and Licensing (PEL)

Attaching other supporting documents

- Documents other than the actual labels on mounting sheets may be added with the attachment type "Incoming (Core) Document".

- Such supporting documents may include, but are not limited to, proof of foreign registration, English translations of foreign text (if not included on mounting sheet), or any other necessary background information.

- **Do NOT attach APHIS Form 2015**, as this is not necessary for portal submissions.

Appearance in portal once submitted:

Once a label submission is submitted to the CVB, the portal user sees the following:

- The mail log number for the entire submission.
- CVB label numbers for each label attachment.
- Click on Label Info to see specific details entered about each label.

Appearance in portal once processed:

Each new label processed, as well as any labels replaced, will show in the Labels Impacted section. This listing reflects CVB's official actions, which may not correspond exactly to requested actions. The Labels Note: Impacted table will reflect real-time status of the labels for as long as the entry can be viewed via portal and not a fixed status at the point in time the submission was completed.

Labels Impacted	Label #	Type	Current Status	Current Disposition	Current Stamp Date	Current Expiration Date
	91157	Container	Active	EXTENDED USE	Jan-01-2016	Jun-30-2018
	91197	Container	Inactive			
	91205	Box	Inactive			
	91215	Box	Active	SKETCH	Jun-06-2016	Jun-06-2017
	91216	Circular	Active	TEMPORARY	Jun-06-2016	Jun-30-2017
	91217	Container	Active	PERMANENT	Jun-06-2016	

Submitting Labels to Policy, Evaluation and Licensing (PEL)

Appearance in portal once processed: *(continued)*

There also will be a file returned for each label submitted. There also may be a comments document; if there are no comments, there will be a "No Return Form Comments" statement in the CVB Response section.

CVB Response Files			
File		**CVB Label #**	**Type**
Testlabel1outgoing.docx		91215	Outgoing Post-License Label
Testlabel2outgoing.docx		91216	Outgoing Post-License Label
Testlabel3outgoing.docx		91217	Outgoing Post-License Label