

## Submitting Outlines to Policy, Evaluation and Licensing (PEL)

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## Submitting Outlines to Policy, Evaluation and Licensing (PEL)

This is a detail guide to be used in conjunction with the [2049 General User Guide \(User Guide 10\)](#) and [Creating/Revising Electronic Outlines \(User Guide 18\)](#). It is not intended for stand-alone use.

This guide pertains to submitting Outlines of Production and Special Outlines for licensed or prelicense product. **\*\*\*Do NOT use this guide for Outlines for unlicensed product exported under the Food and Administration's Export Reform and Enhancement Act of 1996.\*\*\***

### Creating an Outline Submission

Use the 2049 portal interface to submit Outlines to Policy, Evaluation, and Licensing, per the instructions in the [General User Guide](#). Use the following values.

- Submission type
  - If this is the 1<sup>st</sup> electronic submission for a particular Outline or Special Outline, then select either "Outline (Baseline Version Only)" OR "Special Outline (Baseline Version Only)" respectively
  - For all document revisions *subsequent* to receiving a filed Baseline (version Baseline-CVB) from the CVB select "Outline" OR "Special Outline"
- Submission subtype - leave this field blank

When adding attachments, portal users are given the option to upload an Incoming Outline or other kind of document.

The screenshot shows a user interface for adding attachments. At the top, it says "Current Attachments NA". Below that, under "New Attachments", there are two blue buttons: "+ Add Document" and "+ Add Incoming Outline". Below the buttons is a checkbox that is currently unchecked, followed by the text "I agree that I've looked over this information and everything entered is true to my kn". At the bottom, there are two buttons: a green "Save to Submission" button and a red "Cancel" button.

### Attaching Outline documents

- Attach only one Outline or Special Outline per submission. Only new documents or complete revisions are accepted. The CVB will not process individual page changes.
- Use the attachment type "**Incoming Outline**" for the actual Outline/Special Outline submitted for approval. **\*\*\*Do not use this attachment type for anything other than the Outline.\*\*\***
- Use the [CVB-supplied template](#) and [formatting instructions](#) for the Outline.

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### Entering Outline-Specific Information

After electing to add an incoming outline, the following information is requested:

The screenshot shows a form titled "Outline Document" with three main input areas:
 

- 1** File: A text input field with a "Browse ..." button.
- 2** Comments: A text input field.
- 3** Outline Version #: A text input field.

 To the right of these fields are labels: "Type\*" (with "Incoming Outline" selected below it) and "Outline Version #\*" (with "3" entered below it). A red note at the bottom left of the form reads: "Note: May not have multiple attachments with the same name."

- 1 File:** Identify the file to be uploaded.
- 2 Comments:** Enter any comments specific to the *individual Outline* being uploaded.
- 3 Version #:** Enter the version number assigned to the Outline being uploaded. See [User Guide 19](#) for details on versioning.

### Attaching Other Supporting Documents

- Documents other than the actual Outlines may be added with the attachment type “Incoming (Core) Document”.
- Such supporting documents may include, but are not limited to, additional instructions/requests for your reviewer.
- **Do NOT attach APHIS Form 2015**, as this is not necessary for portal submissions.
- It is not necessary to submit a compiled Summary of Changes (as all changes are tracked in-line). If, however, you wish to submit a Summary of Changes *in addition to* in-line tracking, submit the Summary as a separate document. Do not insert it to the Outline.

### Appearance In Portal Once Processed:

There will be an Outline file returned with an updated version number. If the Outline was approved (digitally signed), the outgoing version will be designated as the incoming version + “-CVB”. If the Outline was returned unprocessed, it will not be digitally signed and the outgoing version number will be the incoming version + “-UP”.

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.

Submitted Files		File	Type	Submitter's Study ID	Outline Version #	Comments	Date Added
		test.docx	Incoming Outline		3		12/08/2016

  

CVB Response Files		File	Outline Version #	Type
		Tested2.docx	3-CVB	Outgoing Outline

  

CVB Response	Response
	No Return Form Comments