

Formatting Documents for 2049 Submissions

Where were changes made in the 6/18/2020 version?

1. [Page 3, Section C - Incoming Outlines, information was added for the respective User Guides.](#)
 - o User Guide 17 "Requirements for Electronic Outline of Production and Special Outline Templates" reference was removed because that process is no longer used.
 - o Links to User Guides 18, 19, 20 and Template B were added.

Where were changes made in the 5/9/2017 version?

1. [Page 3, Section C - Incoming Outlines, information was added for the respective User Guide.](#)
 - o See User Guide 17 "Requirements for Electronic Outline of Production and Special Outline Templates" for important details.

Where were changes made in the 11/15/2016 version?

1. [A change was made in Section A, bullet 6, sub-bullet 1.](#)
 - o For requests to ship experimental product under 9CFR 103.3, merge all supporting documents *except* APHIS Form 2071 and experimental labels. Because we return copies of acceptable labels along with the signed Form 2071, we would like each of these in separate pdf files.

Formatting Documents for 2049 Submissions

A. Incoming Core Documents

Convert documents to PDF format unless there is a specific need to keep them in their native format.

- Whenever possible, create PDF files directly from the application in which the document was created, rather than printing and rescanning, even if you have optical character recognition (OCR) capability on the scan. This creates cleaner copy, eliminates the potential for OCR errors, and facilitates our use of Adobe Acrobat review tools.
Images of handwritten signatures on individual documents are not necessary.
- If you must scan print copy, such as handwritten data capture sheets or laboratory notebook pages, PDF files should have optical character recognition so that any typed text is searchable. Avoid creating photographic images of print copy.
- When converting image-containing files to pdf, ensure that the image quality remains at least 220 pixels per inch (ppi).
 - In MS Word 2010 and 2013, this may be set by going to File→Options→Advanced→Image Size and Quality. Set Target Default Output to 220 ppi.
 - In Adobe Acrobat XI, this may be set by going to Edit→Preferences→Convert to PDF. Select the source file type (such as MS Word) and click on Edit Settings...Select "Smallest File Size" from the subsequent dialog box, then click Edit...Within the Edit screen, select Images. On the Images page, update the downsampling of color and greyscale images so they do not go below 220 ppi.
- It may be helpful to compress large (i.e., numerous megabytes) PDF files, especially if they are scanned from print copy, which often produces a larger file than direct conversion from the source application. As when converting from a source application, it is also important to retain image quality when compressing files that are already in pdf format. With the pdf document open in Adobe Acrobat XI, select File→Save As...→Save as Other...→Optimized PDF. Within the PDF Optimizer screen, set the color and greyscale image settings so they are at least 220 ppi. It is not necessary to provide backward compatibility.
- Individual files should not exceed 20 MB. If you have a large report that will exceed this limit, which practically speaking is only expected to occur if there are numerous raw data capture sheets, create a separate file for the data capture sheets.
- More likely you will start with numerous small files to submit. In most cases we prefer that you merge small documents into one pdf file, as each document must be opened from our mail log separately and merged documents increase our efficiency of review. The following exceptions apply:
 - For requests to ship experimental product under 9CFR 103.3, merge all supporting documents *except* APHIS Form 2071 and experimental labels. Because we return copies of acceptable labels along with the signed Form 2071, we would like each of these in separate pdf files.
 - Merge APHIS 2071 with any continuation sheets necessary to complete Blocks 4 and 5 of the form. This is important to facilitate the return of processed continuation sheets with the processed form.
 - If you elect to resubmit previously reviewed items for historical reference, create a separate pdf file for historical information. (In general, it should not be necessary to resubmit prior items, but it is especially redundant if you can cite the mail log number under which they were originally reviewed.)

Formatting Documents for 2049 Submissions

A. Incoming Core Documents *(continued)*

- When combining files, please use the Adobe Acrobat option to *Combine Files into a Single PDF* or to *Insert Page From File*. Then each added page becomes a new page in the file to which it was added. **Refrain from** creating Adobe portfolios, in which files are grouped but retain their individual identity and have to be opened separately once the portfolio is opened.
- For reports and protocols, we encourage you to create descriptively named “bookmarks,” using Adobe Acrobat, for main document headings. This will increase our review efficiency by improving navigation among document sections. If you use MS Word “headings” for report sections, you can opt to have bookmarks automatically created from those headings when you convert the Word file to pdf.
- Although file names are left largely to the discretion of the submitter, we do request that the file name reflect the document content, so that CVB users do not have to open the document to have a general idea what it contains.

B. Incoming Postlicense Labels



See [User Guide 13 “Using the CVB Template for a Label Mounting Sheet”](#) for important details



This applies to labels to be *affixed to* licensed product, regardless whether the label submission is made after licensure OR in anticipation of licensure.



Do not use this for labels to be affixed to experimental product or labels to be affixed to product exported under FDA-EREA. Such labeling is submitted as Incoming Core Documents.

C. Incoming Outlines

- See the following user guides for important details.
 - [User Guide 18 "Creating and Revising Electronic Outlines"](#)
 - [User Guide 19 "Versioning Electronic Outlines"](#)
 - [User Guide 20 "Submitting Outlines to Policy, Evaluation and Licensing \(PEL\)"](#)
 - [Template B "Outline Templates"](#)

D. Data for Statistics

- Follow the instructions in the [CVB Data Guide](#)

E. Genetic Sequences

- Can be pdf or text file.
- Submit only the top strand sequence.
- Numbered lines are acceptable in the file, but make sure that line identifications do not include letters, as these can be mistaken for part of the sequence by reader software.