

# eCopy Program for Medical Device Submissions

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## Guidance for Industry and Food and Drug Administration Staff

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This document supersedes the guidance of the same title dated December 31, 2012.

For questions regarding this document, contact CDRH's eCopy Program Coordinators at 240-402-3717 or [cdrh-eCopyinfo@fda.hhs.gov](mailto:cdrh-eCopyinfo@fda.hhs.gov) or CBER's Office of Communication, Outreach and Development, at 1-800-835-4709 or 301-827-1800.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

# Preface

## Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to <http://www.regulations.gov>. Identify all comments with the Docket No. FDA-2012-D-1056. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. Please use the document number (1797) to identify the guidance you are requesting.

Additional copies of this guidance document are also available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, by emailing [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov), or from the Internet at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

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# eCopy Program for Medical Device Submissions

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## Guidance for Industry and Food and Drug Administration Staff

### 1. Introduction

This is an updated version of the guidance that was issued on December 31, 2012. It provides clarification to the processing and technical standards for eCopies based on FDA's experience to date with the program.

The purpose of this guidance is to explain the new electronic copy (eCopy) Program for medical device submissions. Section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), requires the submission of eCopies with the issuance of this final guidance. This guidance describes how the Food and Drug Administration (FDA) is implementing the eCopy Program under section 745A(b) of the FD&C Act. The inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version.

This guidance provides, among other things, the standards for a valid eCopy under section 745A(b)(2)(A) of the FD&C Act. In accordance with section 745A(b), submission types identified in this final guidance must include an eCopy in accordance with the standards provided by this guidance for the submission to be processed and accepted for review by FDA, unless they have been identified as being exempted or waived. Submissions submitted without an eCopy and eCopy submissions that do not meet the standards provided in this guidance will be placed on hold until a valid eCopy is submitted to FDA and verified to meet the standards, unless a waiver or exemption has been granted. While the submission is on hold, the review clock will not begin and the submission will not be reviewed.

In section 745A(b), Congress granted explicit statutory authorization to FDA to implement the statutory eCopy requirement by providing standards, criteria for waivers, and exemptions in guidance. Accordingly, to the extent that this document provides such requirements under section 745A(b) of the FD&C Act (i.e., standards, criteria for waivers, and exemptions), indicated by the use of the words *must* or *required*, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

However, this document also provides guidance on FDA's interpretation of the statutory eCopy requirement and the Agency's current thinking on the best means for implementing other aspects of the eCopy program. Therefore, to the extent that this document includes provisions that are

not “standards,” “criteria for waivers,” or “exemptions” under section 745A(b)(2), this document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, but does represent the Agency’s current thinking on this topic. The use of the word *should* in such parts of this guidance means that something is suggested or recommended, but not required. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff listed on the title page of this guidance.

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because it is not an accurate description of all of the effects of this guidance. This guidance contains both binding and nonbinding provisions. Insofar as this guidance provides “standards,” “criteria for waivers,” and “exemptions” pursuant to section 745A(b) of the FD&C Act, it will have binding effect.

The eCopy program is not intended to impact (reduce or increase) the type or amount of data the applicant<sup>1</sup> includes in a submission to support clearance or approval. Please refer to other FDA device or program-specific guidance documents from [CDRH](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>) and [CBER](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm214106.htm) (<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm214106.htm>) for the appropriate contents for submissions.

For additional eCopy Program resources, please refer to FDA’s webpage entitled, [eCopy Program for Medical Device Submissions](#).

## 2. What is an eCopy?

An electronic copy (eCopy) is defined as an exact duplicate of the paper submission, created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive. An eCopy is accompanied by a paper copy of the signed<sup>2</sup> cover letter and the complete paper submission.<sup>3</sup>

Note that inclusion of individual CDs for just certain sections of the paper submission (e.g., a CD of the data line listings added to a sleeve in some attachment) will no longer be accepted because

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<sup>1</sup> For the purposes of this guidance, applicant includes “submitter,” “sponsor,” or “holder.”

<sup>2</sup> The cover letter signature may be a wet (i.e., ink) signature or a valid digital signature. Please note that other forms submitted within an IDE or premarket submission (e.g., Truthful and Accurate Statement for 510(k)s) can also be signed with either a wet signature or digital signature.

<sup>3</sup> An eCopy is not considered to be an electronic submission. For information on eSubmissions, refer to “[FDA eSubmitter](http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm)” (<http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>) and “[Regulatory Submissions in Electronic Format for Biologic Products](http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm163685.htm)” (<http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm163685.htm>).

such CDs will not meet the requirements for a valid eCopy as outlined in this guidance. Any CD provided must be an eCopy as defined above for the submission to be accepted.

### **3. Are differences between the contents of an eCopy and paper submission acceptable?**

While an eCopy is defined as an exact duplicate of the paper copy, there are limited cases in which differences between the eCopy and the paper copy may be justified because a paper copy is not practical or appropriate for analysis purposes (e.g., raw data and statistical analysis programs,<sup>4</sup> data line listings to facilitate a bioresearch monitoring review) or is not feasible (e.g., videos, x-rays). The critical attribute of an eCopy is that it must include in electronic form all data required for that submission type.<sup>5</sup> In other words, the eCopy must include all of the required information for FDA review, whereas the paper copy can include a placeholder cross-referencing the location of certain information in the eCopy.

The cover letter must contain the modified eCopy statement described in [Attachment 1](#) and describe any differences between the paper version and the eCopy. If information is included in the eCopy that is not in the paper copy, then the paper copy must have a placeholder to redirect the reviewer (e.g., a piece of paper with a statement directing the reviewer to a particular section in the eCopy).

FDA will consider the eCopy, with the cover letter, loaded into the appropriate Center's official document repository to be the official record. Any undisclosed differences between the eCopy and the paper version may need to be rectified and could delay the review of the submission.

### **4. For what submission types is an eCopy required?**

Section 745A(b) of the FD&C Act, as added by section 1136 of FDASIA, requires an eCopy for the following submission types:

- Premarket notification submissions (510(k)s), including third party 510(k)s;
- Evaluation of automatic class III designation petitions (de novos);
- Premarket approval applications (PMAs), including Transitional PMAs;<sup>6</sup>
- Modular PMAs;
- Product development protocols (PDPs);
- Investigational device exemptions (IDEs) [see partial [Exemptions](#) below];

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<sup>4</sup> For information on electronically submitted data, refer to “[Clinical Data for Premarket Submissions](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm>).

<sup>5</sup> For example, the content requirements for a 510(k) submission are found in 21 CFR 870.87 and 807.92; those for original PMA submissions are found in 21 CFR 814.20.

<sup>6</sup> This includes all PMA submission types, including, but not limited to, original PMAs, panel-track supplements, 180-day supplements, manufacturing site change supplements, 30-Day Notices, 135-Day Supplements, and post-approval study supplements and reports, as well as amendments involving changes in the correspondent or ownership and requests for extensions.

- Humanitarian device exemptions (HDEs)<sup>7</sup>
- Emergency Use Authorizations (EUAs)<sup>8</sup> [see [Exemptions](#) below];
- Certain investigational new drug applications (INDs);<sup>9</sup>
- Certain biologics license applications (BLAs);<sup>10</sup> and
- Pre-Submissions.<sup>11</sup>

eCopies for all subsequent submissions to an original submission, including amendments (amendments include add-to-files, CLIA categorization add-to-files, and appeals), supplements, and reports (reports include annual/periodic and post-approval reports)<sup>12</sup> to the submission types identified above would also be required even if the original was submitted to FDA prior to implementation of the eCopy requirements.

The size of the submission is irrelevant. Whether it is a single-page submission (i.e., the company cover letter is the only content) or a multi-volume submission, the eCopy requirements apply.

Responses to deficiency letters are required to be formally submitted to CDRH's or CBER's Document Control Center<sup>13</sup> (DCC) to be logged in as an amendment or a supplement and, thus, are subject to the eCopy requirements.

**Please note that eCopy requirements do not apply to information obtained during the Interactive Review process (via email, phone, and/or fax) once a submission is under review, if that information is not mailed to FDA.** However, should an applicant choose to mail a response to an Interactive Review request (which should only occur if the size of the response makes communication by email or fax infeasible), it will be logged in as an amendment and be subject to the eCopy requirements.

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<sup>7</sup> This includes all HDE submission types, including, but not limited to, original HDEs, 180-day supplements, manufacturing site change supplements, 30-Day Notices, 135-Day Supplements, and post-approval study supplements and reports, as well as amendments involving changes in the correspondent or ownership and requests for extensions.

<sup>8</sup> Refer to the guidance entitled, "[Emergency Use Authorization of Medical Products](#)"

(<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>) for more information on EUAs.

<sup>9</sup> Applicable only to those devices that are regulated by CBER as biological products under Section 351 of the Public Health Service (PHS) Act and that also require submission of an IND prior to submission of a BLA. Such devices are generally those intended for use in screening donated blood for transfusion transmissible diseases.

<sup>10</sup> Applicable only to those devices that are regulated by CBER as biological products under Section 351 of the PHS Act, including those that do not require submission of an IND prior to the submission of the BLA. Such devices generally include those reagents used in determining donor/recipient compatibility in transfusion medicine.

<sup>11</sup> Refer to the draft guidance entitled, "[Medical Devices: The Pre-Submission Program and Meetings with FDA Staff](#)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm>).

FDA's draft guidance represents FDA's proposed approach to Pre-Submissions.

<sup>12</sup> Section 745A(b) of the FD&C Act does not apply to Medical Device Reports submitted under 21 CFR Part 803.

<sup>13</sup> Refer to 21 CFR 807.90 for the DCC addresses for CDRH and CBER.

## **Exemptions**

Above, FDA identified the submission types cited in the legislation as being subject to the eCopy requirements. However, the legislation also allows for FDA to set forth criteria for exemptions from eCopy requirements. Accordingly, due to the potentially urgent nature of the following types of submissions, FDA considers these to be exempt from the requirement for an eCopy:

- two specific types of IDEs - compassionate use IDE submissions and emergency use IDE submissions;<sup>14</sup> and
- all EUAs.

Although these submission types do not require eCopies as per this exemption, FDA encourages you to submit eCopies of these submissions, when feasible, in order to facilitate the review process.<sup>15</sup> If you choose to submit an eCopy, it must meet the technical standards outlined in [Attachment 1](#).

## **Waivers**

FDA believes that, given the widespread availability of software to enable the creation of an acceptable eCopy at little to no cost, all applicants should have the ability to provide an eCopy.

## **5. Are there other submission types not subject to the eCopy legislation for which eCopies may be submitted?**

Although an eCopy is not required under Section 745A(b) of the FD&C Act, FDA also accepts and strongly encourages you to submit eCopies for:

- Master Access Files (MAFs);
- 513(g) Requests for Information (513(g)s); and
- Clinical Laboratory Improvement Act (CLIA) Categorization – Exempt Device submissions (CLIA “X” files).

eCopies for these three submission types are voluntary; however, if you choose to submit an eCopy, it must meet the technical standards outlined in [Attachment 1](#).

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<sup>14</sup> Please refer to CDRH’s device advice page entitled “[IDE Early/Expanded Access](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse>) and FDA’s “[Guidance on IDE Policies and Procedures](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm>) for additional details on compassionate and emergency use IDE submissions.

<sup>15</sup> If submission of an eCopy is not feasible, but there is pertinent electronic information, such as imaging data, to supplement the information in the paper copy, please contact the lead reviewer to submit this information via Interactive Review.



## 6. How many copies of a submission are needed?

The eCopy Program does not change the overall number of copies to submit to FDA. [Table 1](#) below provides the number of copies associated with each submission type for which an eCopy is either required or voluntary.

**Table 1 – Number of Copies for Submission**

Submission Type	Required or Voluntary eCopy	Total Number of Copies
510(k)s	Required	2 <sup>16</sup>
Third Party 510(k)s	Required	2 <sup>16</sup>
De Novos	Required	2
PMA, including Transitional PMAs		
• Original PMAs	Required	6 <sup>17</sup>
• Panel-Track Supplements	Required	6 <sup>17</sup>
• All other PMA supplement types (e.g., 180-Day Supplements, Real-Time Supplements, 30-Day Notices, 135-Day Supplements)	Required	3 <sup>18</sup>
• PMA reports (annual reports and post-approval study reports)	Required	2
PDPs	Required	See PMAs for corresponding type
HDEs	Required	See PMAs for corresponding type <sup>19</sup>
Modular PMAs	Required	3
IDEs		
• Compassionate use IDEs	Voluntary	3 <sup>20</sup>
• Emergency use IDEs	Voluntary	3 <sup>20</sup>
• All other types of IDE submissions	Required	3 <sup>20</sup>
EUAs	Voluntary	2
Pre-Submissions	Required	2
MAFs	Voluntary	2
513(g)s	Voluntary	2
CLIA X Files	Voluntary	2
INDs	Required	3 <sup>21</sup>
BLAs	Required	3

<sup>16</sup> See 21 CFR 807.90(a)(3)(c).

<sup>17</sup> See 21 CFR 814.20(b)(2).

<sup>18</sup> See 21 CFR 814.39(c).

<sup>19</sup> See 21 CFR 814.104(b)(4).

<sup>20</sup> See 21 CFR 812.20(a)(3).

<sup>21</sup> See 21 CFR 312.23(d).

For submission types for which eCopy requirements apply:

- If a total of two copies are required, you must submit one full paper copy and one eCopy (with a cover letter with a signature and an adequate eCopy statement).
- If more than two copies are required, then you must submit one full paper copy and all remaining copies as eCopies (with a single cover letter with a signature and an adequate eCopy statement). For example, for an original PMA, you must submit one paper copy and five eCopies.<sup>22</sup>

On the other hand, for compassionate use IDE submissions, emergency use IDE submissions, EUAs, MAFs, 513(g)s, and CLIA X files, you may choose to submit only paper copies because an eCopy is voluntary. However, if you choose to submit an eCopy for one of these submission types, it must meet the technical standards outlined in [Attachment 1](#).

## 7. What are the processing steps for an eCopy?

Below are the processing steps for the submission and acceptance of an eCopy.

### a. What are the technical standards for an eCopy?

The technical standards for an eCopy are detailed in [Attachment 1](#). An eCopy that does not meet the technical standards in [Attachment 1](#) will not be accepted.

### b. Are there special considerations when developing an eCopy for an original submission versus a response to a review hold notification?

There are no special considerations because the eCopy program does not dictate the content of a document (original, supplement, amendment, or report). Each eCopy is its own entity, and the same technical standards in [Attachment 1](#) apply to each eCopy. This means that volume (if applicable) and PDF numbering start over with each new eCopy rather than continuing from a previously-submitted eCopy. Do not provide previously-submitted information in a cumulative fashion. Only include content pertinent to the current submission (e.g., an eCopy for a response to a 510(k) hold notification only includes the response content, not the original 510(k) content plus the response content). FDA recommends that you first determine what your content is, and then provide an eCopy that matches both in content and flow and meets the technical standards in [Attachment 1](#).

### c. Are there any issues to consider when choosing the eCopy media?

It is up to each applicant whether to burn your eCopy onto a CD, DVD, or flash drive. However, please be aware that certain brands of media, particularly flash drives, come pre-loaded with files that may lead to your eCopy failing the loading process. You should check the media for pre-loaded files and delete them before you burn your eCopy to the media.

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<sup>22</sup> FDA review staff should not request an additional eCopy or paper copy of a submission from the applicant.

**d. What if there is another submitting party involved?**

In the case that another party (e.g., law firm, consultant) submits a submission on behalf of an applicant, the eCopy must still meet the technical standards in [Attachment 1](#) in order to be successfully processed by FDA. The eCopy requirements are the same regardless of who is submitting the eCopy. While the applicant may or may not include their own company cover letter as part of the eCopy, our technical standards require that the submitting party include a company cover letter (with an eCopy statement and signature), as described in [Section A of Attachment 1](#).

**e. What if this is a Third Party 510(k)?**

There are two distinct parties involved in the generation of a Third Party 510(k): (1) the Accredited Person and (2) the applicant. Each party is subject to the eCopy requirements. Accordingly, each party (i.e., the Accredited Person and the applicant) must provide their own:

- eCopy (on a single CD, DVD, or flash drive) that meets the standards in [Attachment 1](#); and
- company cover letter with an eCopy statement and signature as described in [Section A of Attachment 1](#).

Therefore, there will be two separate eCopies provided for a given Third Party 510(k). Given this, it is essential that each eCopy be clearly marked as belonging to the Accredited Person or the applicant.

FDA recognizes that an applicant may interact with the Accredited Person multiple times prior to the Third Party 510(k) being submitted to FDA. Regardless of the number of interactions prior to the Third Party 510(k) being submitted to FDA, the applicant's eCopy must be on a single CD, DVD, or flash drive in order to be loaded by our software. This could be accomplished by, for example, organizing each round of interaction as different volumes in the eCopy (e.g., VOL\_001\_Original Review, VOL\_002\_Round 2 Review). The Accredited Person must also provide their eCopy on a single CD, DVD, or flash drive for the same reason.

Although the Accredited Person is FDA's point-of-contact and is the party that will be sent the eCopy hold notification if there are any issues with either eCopy, each party is responsible for meeting the eCopy requirements.

**f. What if this is a bundled submission?**

For bundled submissions, there should be only one version of the company cover letter (with an eCopy statement and signature) and only one eCopy that apply to all submissions in the bundle. There should not be different company cover letters or eCopies associated with each submission in the bundle. The company cover letter should include a list or table of all submissions that are part of the bundle. The list or table should specify the submission

number, trade name, and, as applicable, the model number, of each device impacted by the change.

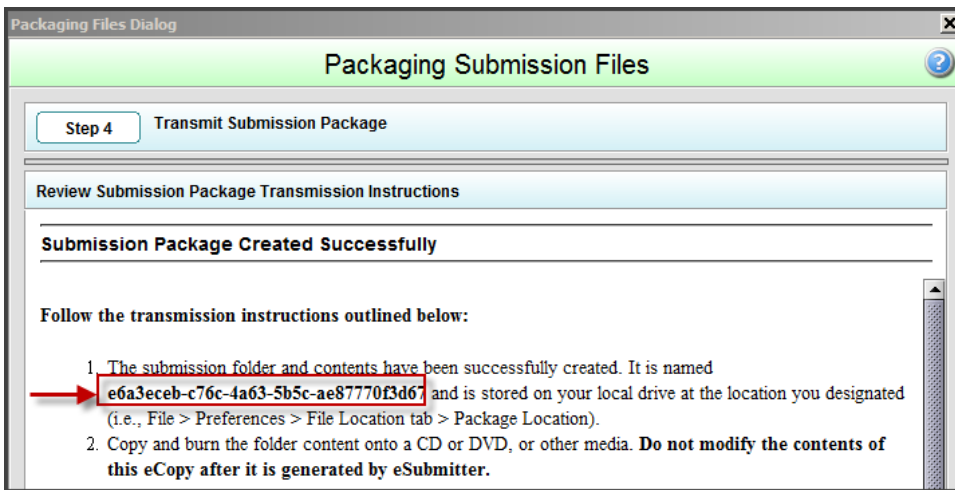
**g. How do you know if an eCopy meets the technical standards before you send it to FDA?**

At this time, there is no FDA tool available to pre-validate an eCopy that has already been developed by an applicant. However, there is a free eSubmitter-eCopies tool available on [FDA's website](http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm) at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm>, which we strongly encourage applicants to use regardless of the Center to which you will be sending your submission. Use of this tool is optional; however, one of the benefits of the tool is that it creates an eCopy in real-time that is consistent with the technical standards described in [Attachment 1](#). The tool guides you through the steps of adding the content and will add any required prefixes to volumes/folders and PDFs.

As an additional resource, there is a [quick reference guide](#) specific to the eSubmitter-eCopies tool available at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm>. It is important that you use only this reference guide when using the eSubmitter-eCopies tool and not the generic eSubmitter guides that are available.

Please note that the eSubmitter-eCopies tool does not transmit the eCopy through the FDA Gateway. Instead, as shown in [Figure 1](#), the eSubmitter-eCopies tool provides the formatted eCopy content for you to download onto your local computer drive and then burn onto a CD, DVD, or flash drive. The eCopy content is saved in a folder with a long alpha-numeric name. You need to open up the folder with the long alpha-numeric name that was saved on your local computer drive and burn those contents onto your CD, DVD, or flash drive. Do not add any of the files that the eSubmitter-eCopies tool saves on your local computer drive outside of that folder with the long alpha-numeric name, as those additional files created by the eSubmitter-eCopies tool are for your records only.

Figure 1: Snapshot of final packaging screen from eSubmitter-eCopies tool



Should you have any technical questions regarding the eSubmitter-eCopies tool, please contact [cdrhesub@cdrh.fda.gov](mailto:cdrhesub@cdrh.fda.gov) prior to submission of the eCopy to FDA.

## **h. How do you submit an eCopy to FDA?**

An eCopy is submitted as part of a package to CDRH's or CBER's DCC. The package includes:

- one or more eCopies burned to a CD, DVD, or flash drive with a paper copy of your company cover letter. The company cover letter must include an eCopy statement and signature as described in [Section A of Attachment 1](#). If more than one eCopy is to be submitted, then a single company cover letter for all eCopies is sufficient; and
- one complete paper copy.

For Third Party 510(k)s, refer to [Section 7e](#) for the specifics of the eCopy and company cover letter associated with each of the two parties involved.

## **i. How does FDA process an eCopy?**

The determination as to whether or not an eCopy passes the loading process will be made by the appropriate staff at the same time the submission is received by FDA and logged into our database.<sup>23</sup>

If an eCopy passes the loading process, the company cover letter and eCopy contents will be loaded into the appropriate Center's official submission repository.

If an eCopy fails the loading process, we will notify you in writing (e.g., by letter, email, and/or fax) that your submission is on eCopy hold. The eCopy hold notification will describe the reasons for the eCopy failure and the logistics for submitting a replacement eCopy. It is important that you follow these directions to avoid delays in processing the replacement eCopy. **The submission will be placed and remain on eCopy hold until a valid replacement eCopy is submitted to FDA and verified to meet the technical standards of [Attachment 1](#).**<sup>24</sup>

## **j. What do you provide to FDA in response to an eCopy hold?**

As stated above, you will receive a notification that states the specific reason(s) why your eCopy failed the loading process. In response to the eCopy hold notification, you must provide:

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<sup>23</sup> At CDRH, it is managed by the DCC staff. At CBER, it is managed jointly by the DCC staff and the Regulatory Project Manager (RPM).

<sup>24</sup> Do not confuse an "eCopy hold" with a User Fee hold; a submission may be placed on User Fee hold for failure to pay the User Fee even if a valid eCopy is submitted. In addition, do not confuse an "eCopy hold" with FDA decisions such as Refuse to Accept or Refuse to File. An eCopy hold takes place before a submission is subject to any review process. Once under review, if applicable for that submission type, acceptance and/or filing reviews will be performed. See also Section 7m of this guidance.

- a company cover letter with an eCopy statement and signature (preferably with a revised date); and
- a replacement eCopy (CD, DVD, or flash drive) that meets the technical standards of [Attachment 1](#). Be sure to label the media with the full submission number and identify it as a “replacement eCopy.”

Be sure that you provide a complete eCopy for the submission at hand and not just the corrected files or folders.<sup>25</sup>

The company cover letter (with an eCopy statement and signature) is required regardless of whether or not the eCopy failure was related to the company cover letter, because the DCC needs to be able to date stamp the company cover letter to record the receipt date of the replacement eCopy.

Please note that if the only reason your eCopy failed is because of a lack of a signature or an adequate eCopy statement on your company cover letter, then all you need to provide is a paper copy of your revised company cover letter in response to the eCopy hold notification.

#### **k. How does FDA process a replacement eCopy?**

When FDA receives a replacement eCopy, it is processed in the same manner as the initial eCopy. More specifically, a determination is made as to whether or not the replacement eCopy passes the loading process. If it does not, then the submission will be placed on eCopy hold again, and an eCopy hold notification will be issued to you.

#### **l. What timeframes need to be considered?**

If you are submitting a new submission and receive an eCopy hold notification, you should respond to that eCopy hold notification within 180 days. If FDA does not receive a replacement eCopy within 180 days of the eCopy hold notification, FDA may consider your submission withdrawn and closed in our database.

If you are submitting a response to a review hold notification (e.g., a response to an Additional Information letter for a 510(k)), you should allow for mail delivery and eCopy processing times in order to ensure that you meet review hold notification deadlines. You risk withdrawal and closure of your submission if your response is mailed very close to or at 180 days.

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<sup>25</sup> For eCopies submitted to CBER only, in some cases only those files that could not be uploaded need to be resubmitted. If you have been advised by the CBER RPM that a submission tracking number has been assigned to your submission, the new eCopy and its company cover letter should clearly identify the assigned submission tracking number and state that the eCopy is an amendment to that submission.

**m. When does review of a submission begin?**

Review of a submission will begin only after a valid eCopy has been received and, if applicable, the user fee has been paid.<sup>26</sup>

**n. If you submitted an eCopy for a submission type that did not require an eCopy and you received an eCopy hold letter, what are your options?**

If you submitted an eCopy for a compassionate use IDE, emergency use IDE, EUA, MAF, 513(g), or CLIA X file, and it did not meet the technical standards in [Attachment 1](#), your submission will be placed on eCopy hold. However, unlike the other submission types that require a valid eCopy, you have the option of responding to that eCopy hold notification with an additional paper copy in lieu of a replacement eCopy.

**8. What if your device is regulated by CBER?**

**a. Will the new eCopy requirements apply?**

Yes, unless your submission is an entirely electronic submission exempted under this guidance, as described below. With the implementation of the statutory requirement, all medical device submission types listed in Section 4 must be in the form of an eCopy regardless of the Center in FDA in which the submission will be reviewed unless the requirement is waived or exempted. Accordingly, submissions for devices subject to review by CBER must be in the form of an eCopy, except where exempted as described below.

Submissions for devices that are subject to licensure under the Public Health Service (PHS) Act, including biologics license applications and supplements, investigational new drug applications, and EUAs for these devices, may be submitted as true electronic submissions as detailed in [Section 8b](#) and [Section 8c](#) below. FDA will exempt such true electronic submissions from the eCopy requirement.

**b. Can you submit an electronic submission instead of an eCopy?**

Yes, you can choose to make true electronic submissions (described below) and submit them through the FDA Gateway.

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<sup>26</sup> As applicable for the submission type, acceptance or acceptance and filing reviews will then be conducted. Otherwise, the substantive review of the submission will begin. For more information, please see the guidances “[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>) and “[Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Approval Applications \(PMAs\): Effect on FDA Review Clock and Goals](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089733.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089733.htm>).



### **c. How do you prepare and submit an electronic submission to CBER?**

CBER has several resources available to applicants who choose to submit electronic submissions as outlined in the document “[Regulatory Submissions in Electronic Format for Biologic Products](#).” (<http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm163685.htm>). Thus, specific details are available in the cited references and will not be repeated in this guidance.

In addition, for devices that are regulated under the PHS Act and require the submission of a BLA, consult the guidance document entitled “[Providing Regulatory Submissions to the Center for Biologics Evaluation and Research \(CBER\) in Electronic Format - Biologics Marketing Applications](#)” (<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM192413.pdf>) for details on preparing your electronic submission. Note that certain sections of this guidance, for example, those on pharmacology and toxicology, are generally not pertinent to licensed devices.

Also note that true electronic submissions, as described in the above-referenced guidance documents, cannot include zip files, as can be done with eCopies.

You can submit questions pertaining to the preparation of submissions in electronic format for submission to CBER at [ESUBPREP@fda.hhs.gov](mailto:ESUBPREP@fda.hhs.gov).

You may also contact CBER at [CBER.CDISC@fda.hhs.gov](mailto:CBER.CDISC@fda.hhs.gov) to discuss the potential for [submission of data in CDISC format](#) (<http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm>).

CBER will accept true electronic submissions via electronic transmission (i.e., through the FDA Electronic Submissions Gateway<sup>27,28</sup>) or on physical media through CBER’s Document Control Center. CBER will accept eCopies only on physical media through our DCC; they cannot be submitted through the FDA Gateway.

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<sup>27</sup> Refer to “[Food and Drug Administration Electronic Submissions Gateway \(Federal Register Notice\) - 8/9/2006](#)” (<http://www.gpo.gov/fdsys/pkg/FR-2006-08-08/html/E6-12808.htm>).

<sup>28</sup> Refer to “[Electronic Submissions Gateway](#)” (<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>).



## Attachment 1 – Technical Standards for eCopies

Below are the standards that are written into the FDA eCopy software coding. If an eCopy does not meet all of the required standards identified in Sections A through D below, then the eCopy will not pass FDA’s eCopy loading process. On the other hand, Sections E through G provide recommendations to consider when developing an eCopy.

### **The basic steps for developing an eCopy are as follows:**<sup>29</sup>

1. Determine the content of your document (original, supplement, amendment, or report). This is not dictated by the eCopy program.
2. Create your company cover letter following the specific requirements in [Section A](#). Make sure your company cover letter includes an eCopy statement and signature.
3. Based on the content, determine whether you want to have a volume-based or non-volume-based structure for your eCopy. This determination is made independently for each eCopy and is not dependent on the format chosen for any previous document. See [Section B](#) below.

If you chose a volume-based submission, then add your volumes to the eCopy following the naming convention in [Section B](#) below.

4. Create your PDFs and add them to the eCopy. PDFs are the main file type, if not the only file type, that comprises your eCopy. Please note that PDFs should be created by converting the files from the native format (e.g., Microsoft Word) using Adobe Acrobat PDF Version 11 or below whenever possible, rather than creating them as scanned versions of the printed files, which are far inferior in quality.

For the naming convention for PDFs, follow the specifics in [Section C, Part 1](#). Do not name a PDF using the volume/folder naming convention as the two differ from each other.

PDFs can only be added to the root level<sup>30</sup> of the eCopy or under a volume/folder as shown in Figures 2 through 11 below. If you have a volume-based submission, then your PDFs must be named with the prefix count starting with “001\_” in each volume (001\_, 002\_, etc.) as shown in [Figure 9](#) and [Figure 10](#) below.

You may have a single PDF that comprises your eCopy if it meets all of the standards in [Section C](#), including the naming convention. The single PDF must have a “001\_” prefix.

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<sup>29</sup> This section is a simple summary of the process for creating an eCopy. It is critical that you read and understand all of the technical standards addressed in Attachment 1.

<sup>30</sup> The “root level” of an eCopy is defined as the main level that you see when you open a CD, DVD, or flash drive.

Please note that the file size limit, in particular, must be taken into consideration if you are contemplating using a single PDF; see [Section C, Part 4](#) below for details.

Aside from naming convention, do not forget the other PDF standards that you need to meet: (1) Adobe Acrobat PDF version 11 or below; (2) no embedded attachments; (3) no security settings; and (4) 50MB or smaller in size.

5. If you need to add non-PDFs to your eCopy, follow the instructions in [Section D](#). Non-PDF files are added by zipping them and placing the zip file(s) under a “MISC FILES” or “STATISTICAL DATA” folder. Do not place any PDFs in either of these two folders. Please note that it is preferable that statistical data be provided in a structured format readable by common statistical analysis software packages.
6. Prepare your package for DCC. The package includes: (1) your eCopy(ies) burned to a CD, DVD, or flash drive with a paper copy of your company cover letter as described in [Section A](#) below and (2) one full paper copy.
7. Mail your package to the DCC.

## A. Company Cover Letter Requirements

To meet the standards of the eCopy program, the cover letter must also include both:

- a signature (may be a wet (i.e., ink) signature or a valid digital signature); and
- one of the following eCopy statements:
  - standard text – “The eCopy is an exact duplicate of the paper copy.”; or
  - modified text – “The eCopy is an exact duplicate of the paper copy except [specify all differences].”

Do not confuse a company cover letter with Form FDA 3514 ([CDRH Premarket Review Submission Cover Sheet](#)). A company cover letter is the document that is on your letterhead and includes information such as the purpose of your submission,<sup>31</sup> contact information (including phone number and email address), along with the eCopy statement and your signature.

We expect the vast majority of the submissions to include the first statement (standard text). However, as described in [Section 3](#) above, for those submissions that contain certain clinical datasets, or other types of data/information that are not feasible or practical to put in paper form, the second statement (modified text) would apply. If you include the second eCopy statement (modified text), you must specify the differences between the eCopy and paper submission. In addition, you must include a placeholder in the paper submission referring to the eCopy for that

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<sup>31</sup> When describing the purpose of your submission, please use characteristics such as the submission type (e.g., 510(k), PMA, Pre-Submission), stage of review (i.e., original, amendment, supplement, or report), and any other key words or information that will assist in FDA’s processing of the submission. It is especially important to include the submission tracking number if one has already been assigned and provided to you.

specific information (e.g., “The eCopy is an exact duplicate of the paper copy except that data line listings were only provided in the eCopy. A placeholder was provided in Volume 4 of the paper copy referring back to the eCopy for that information.”).

Please also note that it is FDA’s preference that responses to deficiencies identified during submission review not be incorporated into the company cover letter for ease of processing on both the part of the applicant and FDA. Instead, please incorporate your responses into the main body of your submission.

It is recommended that your company cover letter (with the eCopy statement and signature) also be included as a PDF in your eCopy, but it is not required.

## B. Volume or Non-Volume Structure Requirements

The structure of an eCopy is highly dependent on the overall size of the submission and can be organized as a volume-based or non-volume-based submission as described below.

### 1. Non-Volume-Based eCopy

A non-volume based eCopy is generally recommended for small submissions. This eCopy structure includes one or more PDFs at the root level. **See [Section C](#) for required PDF file technical standards, particularly the required PDF naming convention.** Examples of non-volume-based eCopies are shown in Figures 2 through 8 below.

Figure 2: Pre-Submission for which all content was placed in a single PDF


Name ^	Size	Type	Date modified
 001_Pre-Submission for ABC Device.pdf	16,555 KB	Adobe Acrobat Doc...	1/9/2013 3:45 PM

Figure 3: PMA annual report for which all content was placed in a single PDF


Name ^	Size	Type	Date modified
 001_P130001 - 2013 annual report.pdf	16,555 KB	Adobe Acrobat Doc...	1/9/2013 3:45 PM

Figure 4: Original 510(k) submission for which all content was placed in a single PDF


Name ^	Size	Type	Date modified
 001_510(k) Content.pdf	16,555 KB	Adobe Acrobat Doc...	1/9/2013 3:45 PM

Figure 5: Original 510(k) submission for which the content was added as individual PDF files

Name ^	Size	Type	Date modified
 001_Medical Device User Fee Cover Sheet Form 3601.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 002_CDRH Premarket Review Submission Cover Sheet.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 003_510(k) Company Cover Letter.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 004_Indications for Use Statement.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 005_510(k) Summary.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 006_Truthful and Accuracy Statement.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 007_Class 3 Summary and Certification.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 008_Financial Certification or Disclosure Statement.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 009_Declarations of Conformity and Summary Reports.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 010_Executive Summary.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 011_Device Description.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 012_Substantial Equivalence Discussion.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 013_Proposed Labeling.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 014_Sterilization and Shelf Life.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 015_Biocompatibility.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 016_Software.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 017_Electromagnetic Compatibility and Electrical Safety.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 018_Performance Testing - Bench.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 019_Performance Testing - Animal.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 020_Performance Testing - Clinical.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM
 021_Other.pdf	131 KB	Adobe Acro...	2/5/2013 12:01 PM

Figure 6: Response to 510(k) RTA hold letter for which each item being responded to was added as an individual PDF file





Name ^	Size	Type	Date modified
 001_Item 5 - Signed Truthful & Accuracy Statement.pdf	807 KB	Adobe Acro...	4/10/2013 9:28 AM
 002_Item 13 - List of Components.pdf	641 KB	Adobe Acro...	4/10/2013 9:17 AM
 003_Item 13 - List of Accessories.pdf	395 KB	Adobe Acro...	4/10/2013 9:17 AM
 004_Item 22 - Sterilization.pdf	929 KB	Adobe Acro...	4/10/2013 9:17 AM

Figure 7: Response to a 510(k) deficiency letter for which for which all content was placed in a single PDF






Name ^	Size	Type	Date modified
 001_K130001s1 - dated 1.1.2013.pdf	16,555 KB	Adobe Acrobat Doc...	1/9/2013 3...

Figure 8: Response to a deficiency letter with each response as its own PDF

Name ^	Size	Type	Date modified
 001_Cover Letter.pdf	807 KB	Adobe Acrobat Doc...	4/10/2013 9:28 AM
 002_Question 1 response.pdf	641 KB	Adobe Acrobat Doc...	4/10/2013 9:17 AM
 003_Question 2 response.pdf	395 KB	Adobe Acrobat Doc...	4/10/2013 9:17 AM
 004_Question 3 response.pdf	929 KB	Adobe Acrobat Doc...	4/10/2013 9:17 AM

## 2. *Volume-Based eCopy*

A volume-based eCopy is generally recommended for large or complex submissions in order to facilitate the review of the submission. This eCopy structure includes volumes (i.e., folders) at the root level. Each volume, in turn, includes one or more PDF files. No other file types but PDFs can be placed in these volumes.

A naming convention for the volumes is required in order to assure that the system can create a sort order of the folders. Without this sort order, the volumes will load in alphabetical order and, thus, be out of order.

**Each volume must have the following naming convention:**

- **VOL\_XXX\_Descriptive Name** (e.g., VOL\_001\_Mechanical Testing); or
- **VOL\_XXX** (e.g., VOL\_001).

**The volume numbering must have a non-repeating, consecutive prefix. The first volume has the prefix of VOL\_001. The second volume has a prefix of VOL\_002, etc. If this volume naming convention is not followed, the eCopy will fail the loading process.**

The Descriptive Name part of the name of the volumes is optional. However, if a Descriptive Name is used for a volume, it should be descriptive of its content and meaningful to the reviewer. The Descriptive Name can be up to 125 characters and can have spaces, dashes (not elongated dashes), underscores, and periods. **However, the Descriptive Name must not contain any of the following special characters or it will fail the loading process:**

- tilde (~)
- asterisk (\*);
- elongated dash (–);
- apostrophe (’);
- single quotation mark (‘);
- double quotation marks (“);
- colon (:);
- pound sign (#);
- vertical bar (|);
- forward slash (/);
- backward slash (\);
- greater than sign (>);
- less than sign (<);
- question mark (?); and
- various other symbols (e.g., →, \*, β, α, ∞, ±, ™).

**No Subfolders:** Under this eCopy structure, you must avoid placing any subfolders under a volume or the eCopy will fail the loading process. Even if you have non-PDF documents that are associated with a particular volume, you cannot embed the “MISC FILES” or “STATISTICAL DATA” folder within one of these volumes or it will fail the eCopy loading.

**NOTE:** A slight variation of a volume-based eCopy structure includes both volumes and at least one PDF file at the root level. This structure commonly occurs when an applicant adds a PDF of the company cover letter at the root level with all other PDFs organized under multiple volumes. See [Figure 11](#) as one example.

Examples of volume-based eCopies are shown in Figures 9 through 11 below.

Figure 9: Original PMA with the PDF content of VOL\_001 and VOL\_002 shown

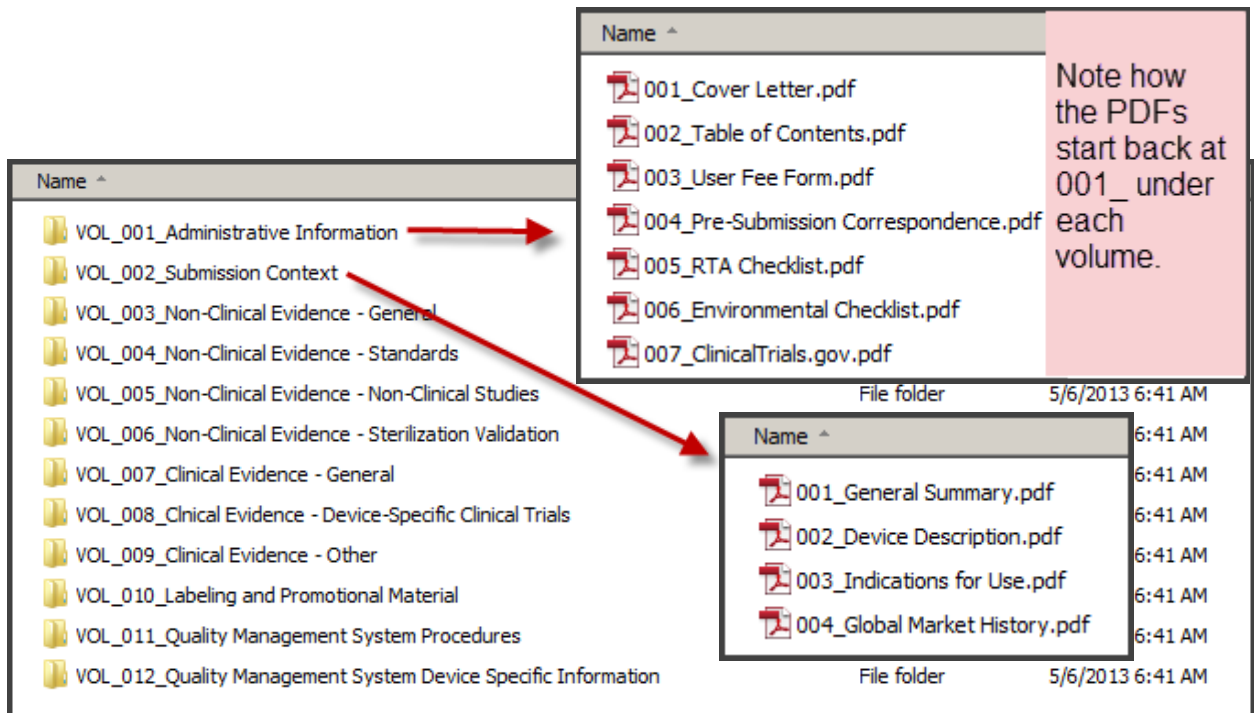


Figure 10: Original IDE with the PDF content of VOL\_002 and VOL\_003 shown

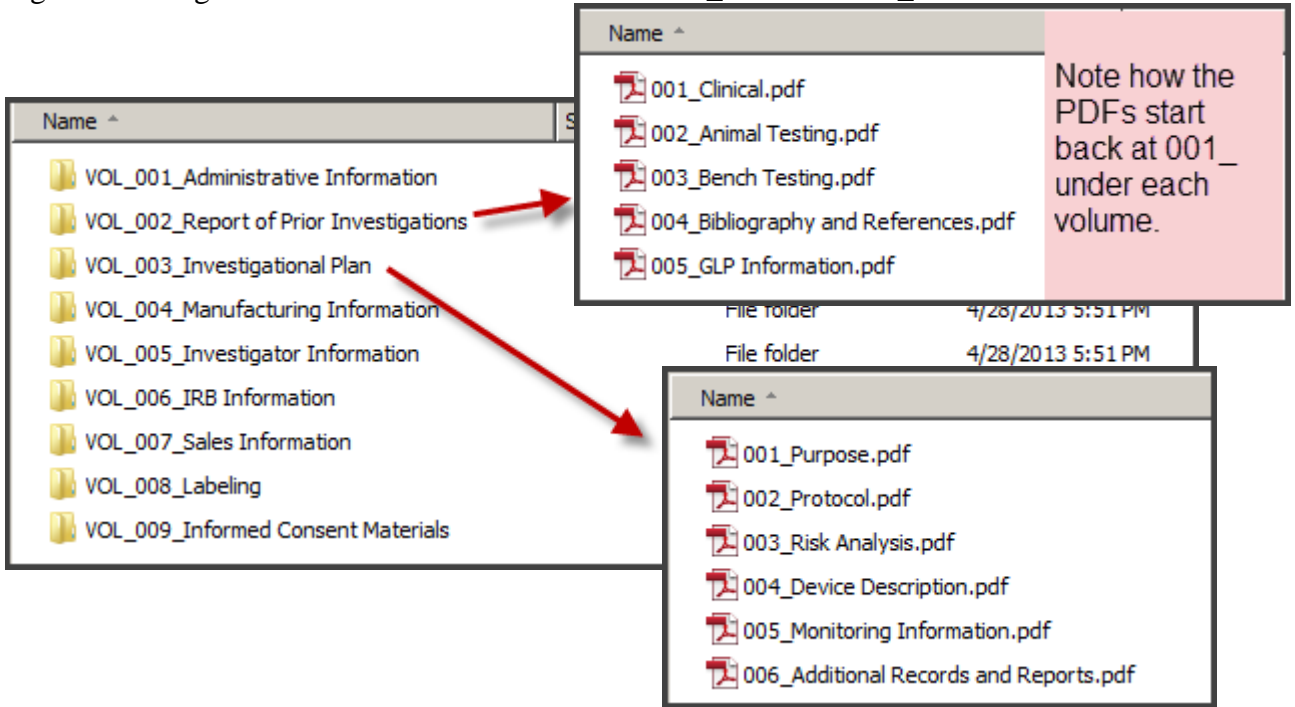
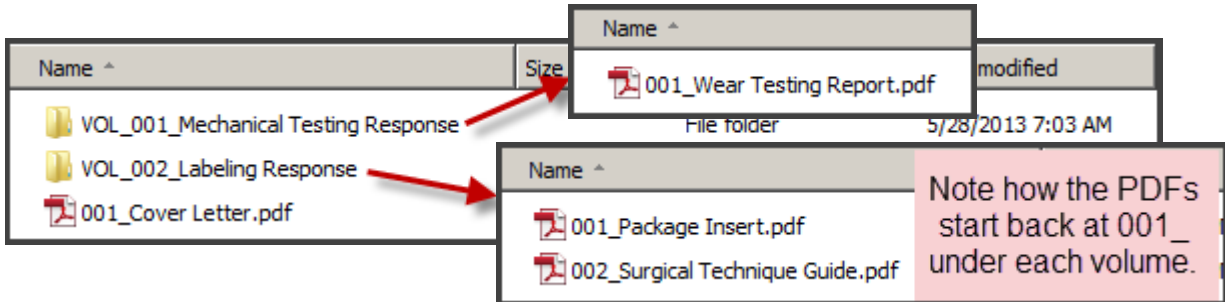


Figure 11: Response to RTA hold notification for which the responses were grouped by topic



### C. PDF File Requirements

Whether you choose a volume-based or non-volume-based eCopy structure, PDF is the primary file format used for an eCopy. (See [Section D](#) for how to add non-PDF files to an eCopy.)

**Below are the requirements for PDF files. If you do not follow them, your eCopy will fail the loading process.**

**NOTE:** You may choose to have a single PDF that comprises the entire submission, as long as all PDF file requirements below are met. However, it is important to note that, as described in [Section C, Part 4](#) below, no individual PDF file may exceed 50MB. Also keep in mind that large files take longer to open and search than do small files. A very large file can be difficult for reviewers to work with, unless there are bookmarks or hyperlinks. See [Section C, Part 4](#) below for details.



## 1. *Specific PDF File Naming Convention*

Regardless of which eCopy structure is used, a naming convention is required in order to assure that the loading system can create a sort order of PDF files that matches the order of files to be read by review staff. Without this sort order, the files will load in alphabetical order and, thus, be out of order.

**You must use the following naming convention for all PDF files, whether part of a volume-based or non-volume-based eCopy:**

- **xxx\_Descriptive Name**

**The PDF file name has a non-repeating, consecutive 3-digit number prefix followed by an underscore (\_). The first PDF has the prefix of 001\_, the second PDF has a prefix of 002\_, etc.** Keep in mind that if you have a volume-based submission, you need to start over with the numbering of the PDFs at 001\_, 002\_, etc. within each volume, as shown in [Figure 9](#) and [Figure 10](#) above. **If this PDF file naming convention is not followed, the eCopy will fail the loading process.**

**eCopies that are comprised of only a single PDF need to have the 3-digit prefix of 001\_.**

The Descriptive Name part of the file name should be descriptive of its content and meaningful to the reviewers. The Descriptive Name can be up to 125 characters and can have spaces, dashes (not elongated dashes), underscores, and periods. **However, the Descriptive Name must not contain any of the following special characters or it will fail the loading process:**

- tilde (~)
- asterisk (\*);
- elongated dash (–);
- apostrophe (’);
- single quotation mark (‘);
- double quotation marks (“);
- colon (:);
- pound sign (#);
- vertical bar (|);
- forward slash (/);
- backward slash (\);
- greater than sign (>);
- less than sign (<);
- question mark (?); and
- various other symbols (e.g., →, \*, β, α, ∞, ±, ™).

Examples of the PDF file names are throughout the figures in [Attachment 1](#).

**NOTE:** There is no correlation between the 3-digit file name prefix and the content or section location of the PDF file (e.g., a Section 10 response does not need a “010\_” prefix). The 3-digit prefix is only used by the loading software to load the PDFs in the correct order; otherwise, the system would load the PDF files alphabetically. Depending on the Center involved, the review staff may or may not even see the 3-digit prefix after it is loaded into the official repository.



This is why it is important that you have meaningful Descriptive Names for your PDF files so that it is clear to review staff what the content of the file involves. You can use the Descriptive Name to also refer to Section or Tab numbers or review deficiency items. It is recommended that you use Descriptive Names that are consistent with the language used in published guidance documents.<sup>32</sup> This will facilitate the review process by allowing the reviewer to easily navigate through the information. Examples of the varying Descriptive Names for the PDF files are throughout the figures in [Attachment 1](#).

## 2. *No Embedded Attachments or Attributes*

Our previous version of the eCopy software rejected PDF files with embedded attachments and attributes. We found that the rejected PDF files were due to embedded attachments or attributes that the applicant did not intentionally embed and of which they were unaware. Accordingly, in order to streamline the eCopy processing, we have updated our software to not reject PDFs with embedded attachments or attributes. **However, do not intentionally embed attachments to PDF files because those embedded attachments are not compatible with our official repository, which can result in this information being missed during the review (e.g., we cannot search for content in an embedded attachment in a PDF; the attachment is removed when a PDF is downloaded from the official repository).**

**NOTE:** Do not confuse embedded attachments or attributes with hyperlinks or bookmarks, as these are very different. Hyperlinks and bookmarks are not only permitted, but are also encouraged, because they facilitate navigation of the submission by the reviewer; they are described in [Section E](#) below.

## 3. *No PDFs that Require a Password to Open*

We previously rejected PDF files with any type of security setting that met either of the following two scenarios: (1) security settings that allowed anybody to open the file but protected the content from modification (which appears to be a common practice with independent laboratories) and (2) security settings that required passwords to open them.

We found that all of the rejected PDF files were due to the first scenario (i.e., PDFs that could be opened but the content was protected). Accordingly, in order to streamline the eCopy processing, we will now allow PDFs with this type of security setting.

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<sup>32</sup> Examples of published guidances with helpful descriptions of submission contents include the recently published Refuse to Accept guidances available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm>, CBER's Guidance for Industry: [Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological \*In Vitro\* Diagnostic Product](#) (<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm080819.pdf>), and [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#), (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm>) as well as many others.


**However, you must not include any PDF that requires a password to open it or we will put the submission on eCopy hold. eCopies must not include PDF files that require passwords to view the content.**

#### **4. PDF File Size Limited to 50MB or Below**

While there is no limitation on the total size of an eCopy, each PDF file must be limited to 50MB or smaller.



Be careful to look at the file size after you have added it to your eCopy media (CD, DVD, or flash drive), as shown in [Figure 12](#). The file size shown here is what the loading software will use to determine if the size technical standard has been met. Do not use the size limit in the file properties or the size limit that appears when you hover the cursor over a PDF file, as both of these sizes will be smaller and will mislead you as to whether or not the PDF size technical standard has been met.

Figure 12: PDF that has exceeded the 50MB size limit and will fail the eCopy loading process

Name ^	Size	Type	Date modified
 001_Mechanical Testing.pdf	50,663 KB	Adobe Acrobat Doc...	1/24/2013 4:16 PM

If a file size is greater than 50MB, then you must split the contents into multiple files. We recommend that you name the files in a way that clearly reflects that it was originally a single file that was split into multiple files. One suggested way of accomplishing this is by naming the files as Parts 1 and 2 as shown in [Figure 13](#) below.

Figure 13: Example of how you can split and label a PDF greater than 50MB into multiple files

Name ^	Size	Type	Date modified
 001_Mechanical testing - Part 1.pdf	25,210 KB	Adobe Acrobat Doc...	2/8/2013 12:56 PM
 002_Mechanical testing - Part 2.pdf	25,442 KB	Adobe Acrobat Doc...	2/8/2013 1:00 PM

#### **5. Adobe Acrobat PDF Version 11 or Below**

Only eCopies submitted using Adobe Acrobat 11 or below will be accepted.<sup>33</sup> If you have a new version of Adobe Acrobat greater than 11, you must save the PDF as a reduced size PDF or the eCopy will fail the loading process.

<sup>33</sup> As we test and validate new versions of Adobe Acrobat, we will update this guidance accordingly.

## D. Requirements for How to Add Non-PDF Files via “STATISTICAL DATA” and “MISC FILES” Folders

[Section B](#) describes how both a volume-based and non-volume-based eCopy include PDF files. However, in addition to PDF files, an eCopy may also include non-PDF files, if applicable for a particular submission.

The three required steps for adding non-PDF files to an eCopy are as follows:

- Add a “STATISTICAL DATA” or “MISC FILES” folder to the root level of the eCopy. These folders must be spelled precisely, but they are not case sensitive.
- Zip all non-PDF content into one or more zip file(s). There are no limitations/restrictions on the naming convention for a zip file(s) or any of the content that you add to the zip file(s). In addition, there is no size limit for the zip files; however, it is recommended that you limit the size to 50MB or less in order to prevent potential problems, such as time delays when uploading the files.
- Add the zip file(s) to the “STATISTICAL DATA” or “MISC FILES” folder.

**If you do not follow these requirements, the eCopy will fail the loading process.**

**NOTE:** Depending on the type of non-PDF files that you want to add to your eCopy, you may determine that it is appropriate to have both the “STATISTICAL DATA” and “MISC FILES” folders in your eCopy. [Figure 15](#) below illustrates this.

Below describes the type of information appropriate as part of a “STATISTICAL DATA” or “MISC FILES” folder.

### 1. “STATISTICAL DATA” folder

The “STATISTICAL DATA” folder is used to add types of statistical information, including metadata<sup>34</sup> and data line listings, to the eCopy in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. There are no restrictions on the format used; however, file formats that include variable labels and dictionary information (such as SAS XPORT) are encouraged.<sup>35</sup>

**Do not forget to zip the content before placing it within the STATISTICAL DATA folder.**

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<sup>34</sup> Metadata includes data dictionaries and terminologies, formats, annotated case report forms, statistical analysis details, and any other information that contributes to understanding and using the data.

<sup>35</sup> For further information, see the draft guidance, “Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Standardized Study Data” (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334.pdf>).

## 2. “MISC FILES” folder

The “MISC FILES” folder is used to add types of files that cannot be submitted (or should not be submitted) in PDF format and are not statistical in nature (e.g., videos, x-rays, machine readable software source code). These miscellaneous files may be included in the eCopy under the MISC FILES folder in their native formats, such as, but not limited to: .gif; .tif; .jpg; .avi; .mpeg; .wmv; and .txt. There are no restrictions on the native format.

In addition, for the purposes of streamlining the review process, FDA encourages you to also include, under the MISC FILES folder, Microsoft Word versions of certain documents or pieces of information that were also provided in the main body of the eCopy as PDFs. In other words, include the PDF version in the main body of the eCopy as part of the volume-based or non-volume-based eCopy structure and include a Microsoft Word version in the MISC FILES folder to assist the reviewer. **Do not include Microsoft Word versions in lieu of the PDF versions.** Documents such as those listed below are commonly requested via Interactive Review to enable FDA feedback to the applicant and/or completion of the review. Inclusion of these documents within the MISC FILES folder in an eCopy can help to minimize potential delays during the substantive review of the submission. Suggested documents include, as applicable:

- Labeling for any submission [preferably with each piece (e.g., physician labeling, patient labeling, operators manual) as a separate file];
- Predicate device comparison table for 510(k)s;
- 510(k) Summary;
- Summary of Safety and Effectiveness Data (SSED) for PMAs; and
- Summary of Safety and Probable Benefit (SSPB) for HDEs.

There are no limitations/restrictions on the naming convention for any files you add to the zip files for the MISC FILES folder. However, for Microsoft Word documents included in the MISC FILES folder, it is recommended that you use a naming convention similar to the PDF equivalent files so that reviewers can easily make the correlation.

**Do not forget to zip the content before placing it within the MISC FILES folder.**

[Figure 14](#) provides an example of non-volume-based eCopy with a MISC FILES. [Figure 15](#) provides an example of a volume-based eCopy that includes both the STATISTICAL DATA and MISC FILES folders. Both figures show the zip file(s) directly under the folder.

Figure 14: Example of a non-volume-based submission with a “MISC FILES” folder

Name ^	Date modified	Type	Size
MISC FILES			
001_Medical Device User Fee Cover Sheet.pdf			KB
002_CDRH Premarket Review Submission.pdf			KB
003_510(k) Company Cover Letter.pdf			KB
004_Indications for Use Statement.pdf			KB
005_510(k) Summary.pdf			KB
006_Truthful and Accuracy Statement.pdf			KB
007_Class III Summary and Certification.pdf			KB
008_Financial Certification or Disclosure Statement.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
009_Declarations of Conformity and Summary.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
010_Executive Summary.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
011_Device Description.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
012_Substantial Equivalence Discussion.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
013_Proposed Labeling.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
014_Sterilization and Shelf Life.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
015_Biocompatibility.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
016_Software.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
017_Electromagnetic Compatibility and Electromagnetic Interference.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
018_Performance Testing - Bench.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
019_Performance Testing - Animal.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
020_Performance Testing - Clinical.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB
021_Other.pdf	2/5/2013 12:01 PM	Adobe Acrobat Doc...	131 KB

Note that the "MISC FILES" folder is at the root level. Directly under this folder is where you put one or more zip files. Nothing but zip files can be placed in this folder.

In this example, there is only one zip file.

MISC FILES			
Device Description section - surgical procedure.zip			

Figure 15: Example of a volume-based submission with “MISC FILES” and “STATISTICAL DATA” folders

Name ^	Size	Type	Date modified
MISC FILES			:34 PM
STATISTICAL DATA			:22 AM
VOL_001_Introduction			:28 PM
VOL_002_Device Description and Mechanism of Action			:28 PM
VOL_003_Labeling			:28 PM
VOL_004_Other Supporting Information			:28 PM

Note that both "Misc Files" and "Statistical Data" folders were used for this example submission. Both folders are at the root level. Nothing but zip files can be placed in these two folders.

MISC FILES			
Images.zip			
WORD copy of SSED.zip			
STATISTICAL DATA			
SAS data.zip			

## **E. Bookmarks and Hyperlinks within PDFs**

Bookmarks and hyperlinks within a single PDF file should be used to assist the reviewers in navigating through the content of the submission. However, these are not required elements for an eCopy. If you use either bookmarks or hyperlinks, consider the following:

### **1. Bookmarks**

Bookmark references can be created for the heading of a section, subsection, or title of figures and tables within a single PDF file. In general, including a meaningful bookmark to the main table of contents for a submission or item is helpful, and will aid the reviewer in locating information and navigating the submission.

### **2. Hyperlinks**

Hyperlinks are used to improve navigation through individual PDF documents and are encouraged. Hyperlinks can be designated by rectangles using thin lines or by blue text or you can use invisible rectangles for hypertext links in a table of contents to avoid obscuring text.<sup>36</sup> Hyperlinks throughout the body of the document to support annotations, related sections, references, appendices, tables, or figures that are not located on the same page are helpful and improve navigation efficiency.

Hyperlinks to other sections within an individual PDF document are permitted and maintained within a given PDF file when added to a Center's official document repository. However, hyperlinks from one PDF to another PDF file (or across other file types) are not supported and will not work at this time.<sup>37</sup>

## **F. Creating a PDF File from the Source Document (Preferred)**

When creating a PDF from the source document (e.g., Microsoft Word document), please consider the following:

### **1. Adobe Plug-Ins**

If you use Adobe plug-ins to create PDF files and/or capture or display data, there is a risk that information may not display correctly because reviewers may not have access to certain plug-ins to review content being displayed by a plug-in.

### **2. Fonts**

One of the following fonts should be used in your source document: Times New Roman; Verdana; Arial; Tahoma; or Helvetica. You should avoid using customized fonts and multiple fonts within the same document.

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<sup>36</sup> Note that use of blue text for hyperlinks is the most widely recognized style.

<sup>37</sup> Note that CBER can accommodate hyperlinks from one PDF to another and encourages their use.

We recommend the use of a black font color. Blue font may be used for hypertext links. If a font color other than black is used, avoid light colors that do not print well on grayscale printers. It is advised that you test the color reproduction prior to submission by printing sample pages from the document using a grayscale printer. In addition to font colors, keep formatting simple in tables.

We recommend a font size of 12; however, we will accept smaller fonts.

## **G. Creating a PDF File from a Scanned Document**

The applicant should create all PDF files directly from the source documents whenever feasible rather than creating them by scanning. **PDF documents produced by scanning paper documents are far inferior to those produced directly from the source document, such as a Microsoft Word document, and, thus, should be avoided if at all possible.** Paper documents that include a watermark, such as DRAFT or COPY, are not suitable for scanning as the watermark makes the scanned document difficult or impossible to read. Scanned documents, particularly tables and graphs, are more difficult to read and do not allow the reviewers to copy and paste text for editing.

For any scanned document, we highly recommend that you perform optical character recognition (OCR) so that the text is searchable. Check to see that the content has been correctly converted by: (1) highlighting an area of text and (2) searching for a word or phrase. If the word or phrase is not returned in the search, then the OCR did not recognize the text. FDA recognizes that use of OCR may not be feasible in some cases for documents with figures and images.

Scanned documents, particularly those with images and photographs, tend to be large in file size, so be careful not to exceed 50MB for a single file or your eCopy will fail the loading process.

Please note that FDA recognizes there may be cases in which it is appropriate to have scanned documents added to an eCopy. For example, if you do not digitally sign the Truthful & Accuracy Statement for a 510(k), then a scanned PDF copy of that signed document would be added to the eCopy.