



U.S. Food and Drug Administration
Protecting and Promoting Public Health



eCopy Program Update

FDA-Industry IVD Roundtable Meeting
June 2, 2016

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FDA/CDRH/OIR/DPOM

Overview

- eCopy Processing at CDRH
- eCopy Guidance
- eCopies That Help Review Staff
- Improvements for Industry
- Questions

Valid and Usable eCopies foster a common goal...

Timely access to safe, effective, and high-quality medical devices

eCopy Processing

1. Packages come to White Oak campus
2. Packages are couriered to Fully Integrated Records Facility (FIRF) in Landover, MD, for same day processing
3. Document Control Center (DCC) logs the submission into our tracking systems
4. DCC scans signed letter and loads scanned letter and the eCopy using the eCopy Loader tool
5. DCC updates tracking system with eCopy status and sends acknowledgement letter to applicant/sponsor
6. If the submission is ready to review (i.e., not user fee or eCopy hold), submission is immediately available to staff through Image 2000+ (Image)

Note: Staff do **not** receive the package that was submitted

eCopy Loader Tool

- eCopy Loader tool validates eCopy and then loads files to Image
- Files are not loaded to Image if they don't pass validation
- USB drives go through additional security check

CeSub eCopies Application Wizard, version 1.08.02

Step 1 Select the Source Location for Loading the Submission (e.g., CD/DVD drive)

Drive/Folder Location: C:\Users\SEG4\Desktop\Copy Files\CD Files

Can this CD/DVD be processed? Yes

Step 2 Analyze the Submission Package

Cover Letter File: C:\Users\SEG4\Desktop\Copy Files\Scanned Cover Letter.pdf

Does the cover letter contain an adequate eCopy statement? Yes

Does the cover letter contain a signature? Yes

Insert the submission CD/DVD into the drive selected above and click the "Perform Analysis" button below to determine if the submission is structured correctly for loading.

Step 2.1: Perform Analysis Analysis Failed... See 'Analysis Findings' below for details.

Step 2.2: eSubmitter check

Analysis Findings

Description of the resulting findings from the analysis

Analysis Failed

An attachment with all reasons for the eCopy failure will be available at the end of this processing.

Cancel Previous Next Done/Exit

Image 2000+

- Review staff views/download submission files from Image

The screenshot displays the Image 2000+ web application interface. The top navigation bar includes links for Favorites, Preferences, and Help, along with search and document management tools like Document Number, Open Document, Keyword, Search Text, and Advanced Search. The main content area is divided into several sections:

- File List:** A sidebar on the left showing a hierarchical view of folders and files. The 'K15' folder is expanded, showing subfolders like 'CORRESPONDENCE (1)' and 'ORIGINAL (19)'. Under 'ORIGINAL', several files are listed, including 'Signed Cover Letter (1 p...', 'Table of Contents (1 pag...', and 'Section 1 - Medical Device User Fee Cover Sheet' (which is highlighted).
- Summary Information:** A section on the right side of the file list, containing fields for Folder, Document Type, Company, Product Code, Description 1, Description 2, and Index Terms.
- Document Preview:** A large window on the right showing the content of the selected document, 'Section 1 - Medical Device User Fee Cover Sheet'. The preview is currently blurred.
- References:** A section at the bottom left with links for Time Line View, Save Request, and Download Submission.

Challenge with CDRH Systems

Files on eCopy disc

Files on Image web page

Files downloaded from Image

001_Table of Contents.pdf 002_Section 1 - Medical Device User Fee Co 003_Section 2 - CDRH Cover Sheet.pdf 004_Section 3 - Cover Letter.pdf 005_Section 4 - Indications for Use.pdf 006_Section 5 - 510(k) Summary.pdf 007_Section 6 - Truthful and Accurate Statem 008_Section 7-9 - Class III Summary_Financia 009_Section 10 - Executive Summary.pdf 010_Section 11 - Device Description.pdf 011_Section 12 - Substantial Equivalence Dis 012_Section 13 - Proposed Labeling.pdf	Signed Cover Letter Table of Contents Section 1 - Medical Device User Fee Cover Shee Section 2 - CDRH Cover Sheet Section 3 - Cover Letter Section 4 - Indications for Use Section 5 - 510(k) Summary Section 6 - Truthful and Accurate Statement Section 7-9 - Class III Summary_Financial Certif Section 10 - Executive Summary Section 11 - Device Description Section 12 - Substantial Equivalence Discussion Section 13 - Proposed Labeling	001_Signed Cover Letter.pdf 002_Table of Contents.pdf 003_Section 1 - Medical Device User Fee Co 004_Section 2 - CDRH Cover Sheet.pdf 005_Section 3 - Cover Letter.pdf 006_Section 4 - Indications for Use.pdf 007_Section 5 - 510(k) Summary.pdf 008_Section 6 - Truthful and Accurate Statem 009_Section 7-9 - Class III Summary_Financia 010_Section 10 - Executive Summary.pdf 011_Section 11 - Device Description.pdf 012_Section 12 - Substantial Equivalence Dis 013_Section 13 - Proposed Labeling.pdf
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PDF links would be helpful, but links across files break in CDRH Systems

eCopy Guidance

- eCopy Guidance:

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>

- eCopy Program Page:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm>

eCopy Program for Medical Device Submissions

[f SHARE](#)
[t TWEET](#)
[in LINKEDIN](#)
[p PIN IT](#)
[e EMAIL](#)
[p PRINT](#)

An electronic copy (eCopy) is an electronic version of your medical device submission stored on a compact disc (CD), digital video disc (DVD), or a flash drive. Including an eCopy with your submission has been required since January 1, 2013. A submission with an eCopy that does not meet the technical standards outlined in the [eCopy guidance](#) will be placed on eCopy hold until a valid eCopy is received.

The following resources will help you in understanding the eCopy program and how to successfully create and submit your eCopy:

- [eCopy guidance](#)
- [How to Submit an eCopy - Instructional Video](#)
- [Frequently Asked Questions](#)
- [eSubmitter-eCopies Tool](#) (a voluntary tool that formats your eCopy content and allows you to download onto a local drive)
- [eCopies Validation Module](#) (a voluntary tool that verifies the format of an eCopy you have already developed on your local drive)

If you have questions about the eCopy program, please contact the eCopy Program Coordinators at CDRH-eCopyinfo@fda.hhs.gov or 240-402-3717.

Avoid Common Mistakes

- Review Attachment 1 of eCopy Guidance
- Only PDF or .zip files
 - Watch out for hidden files on the CD (e.g., preloaded on flash drive)
 - .zip files only under “MISC FILES” or “STATISTICAL DATA” folder – .zip files are for other information, not a second copy of the PDFs
- Follow Naming Conventions in Section B
 - eCopy with single PDF still needs to have prefix of 001_
 - Do not mix up Volume and Non-volume (PDF file) naming structures
 - No subfolders in Volume-Based eCopy
- No security settings to open PDF file
 - Many people need to review files to make a decision
 - Need to be able to open PDFs for years (records management req's)
 - If you do not trust USPS, FedEx, UPS, etc., you can have your package delivered via courier service directly to White Oak
- 001_.pdf and 002_.pdf are not descriptive names

Including non-PDF
files is #1 reason
for eCopy Hold

eCopies That Help Review Staff

- Valid eCopies can still be a challenge for review staff

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission: 9/18/2015
User Fee Payment ID Number: [blank]
FAKE PAYMENT ID: [blank]
Form Approval: QMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.
FDA Submission Document Number (if known): [blank]

SECTION A

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	TYPE OF SUBMISSION PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? ☐ Yes ☐ No (If Yes, please complete Section I, Page 5)

SECTION B

Company / Institution Name: NotARcal Company
Division Name (if applicable): [blank]

SUBMITTER, APPLICANT OR SPONSOR

Establishment Registration Number (if known): [blank]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Establishment Registration Number (if known): [blank]

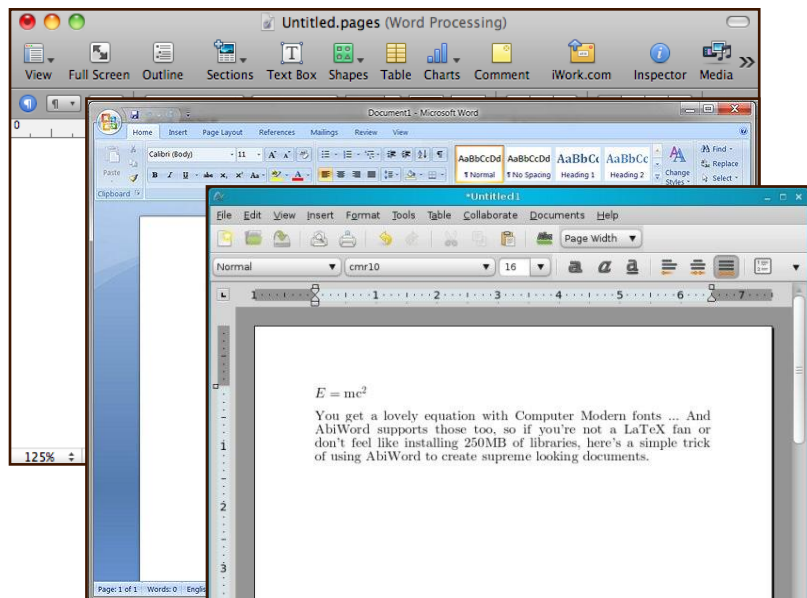
it for Evaluation of Automatic Class III Designation
De Novo Request
510(k) Number: Non-Applicable
Name of Company: Not-A-Real Company
Name of Representative: Jerry Logue
Company Address: Silver Spring, MD

- Valid eCopies that are unusable may go on RTA Hold

eCopies That Help Review Staff



Save electronic files directly to PDF.
Do not print and scan.



eCopies That Help Review Staff

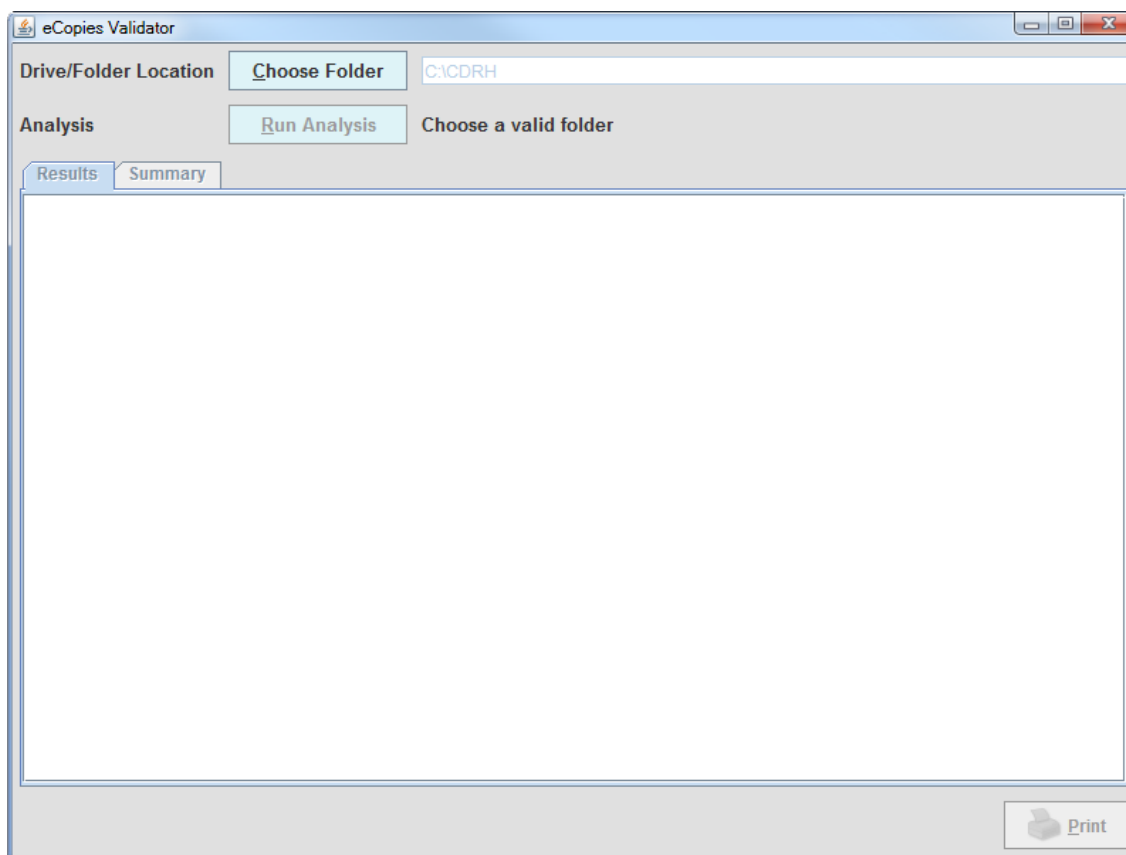
- If you have to scan files, use OCR features available in most scanning software to enable searching in the PDF file
- If you have an invalid eCopy, send a full replacement
 - 001_Attachment1_Replacement.pdf would be a valid eCopy and would not go on eCopy hold
 - Since the other files were never loaded in Image and review staff doesn't have the rest of the submission, it goes on RTA hold, and goes through all the concurrence steps
- Rotate pages so that files are viewable
 - Staff can **not** modify files in Image
 - If PDF files have rotated pages, every person who views that PDF (reviewer, branch chief, medical officers, etc.) has to rotate them
- If using large PDFs, include bookmarks to locations within the PDF

eCopies That Help Review Staff

- Very large .zip files present technical challenges
 - Keep files under 1GB zip. 1 GB files take a while to download from Image; 2GB zip files cannot be downloaded from Image.
 - Better to have four (4) 500MB zip files than one (1) 2GB file
- PDF Security settings may slow down review
 - Some reviewers and applicants find it easier to use PDF “stickies” than long references (Doc_1, Page 40, Table 1, Column 2, Row 6)
- HHS Security Policies prohibit staff from inserting portable media into their laptop (there are a few exceptions)
 - Very large files during Interactive Review can be sent as an eCopy amendment
 - Mail eCopy to DCC address (not reviewer) since the reviewer cannot load file into Image

Best Practices

1. **Run the eCopy through the Validation tool** before submitting to confirm that eCopy meets validation rules



Best Practices

2. Much like it is good to have someone in your company, not on the project team, review the submission before it is sent in, it is also good to **have someone in your company review the final eCopy** to check usability before submitting:
 - Do all the files have useful names (e.g., not 001_001.pdf)?
 - Can you use the files without a password?
 - Can you open the file without downloading additional PDF add-ins?
 - Are all pages in the PDF viewable?
 - Are all pages in the PDF oriented so that they can be read without rotating?
 - Can you search for text in the PDF?
 - Are .zip files less than 1 GB?
 - Can you extract the contents of the .zip file?

Improvements for Industry

- CDRH is working on near-term improvements to make it less cumbersome for industry to submit eCopies
- Considering future enhancements



Questions?

Future questions can be sent to
CDRH eCopy Program Coordinators

CDRH-eCopyinfo@fda.hhs.gov

240-402-3717