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

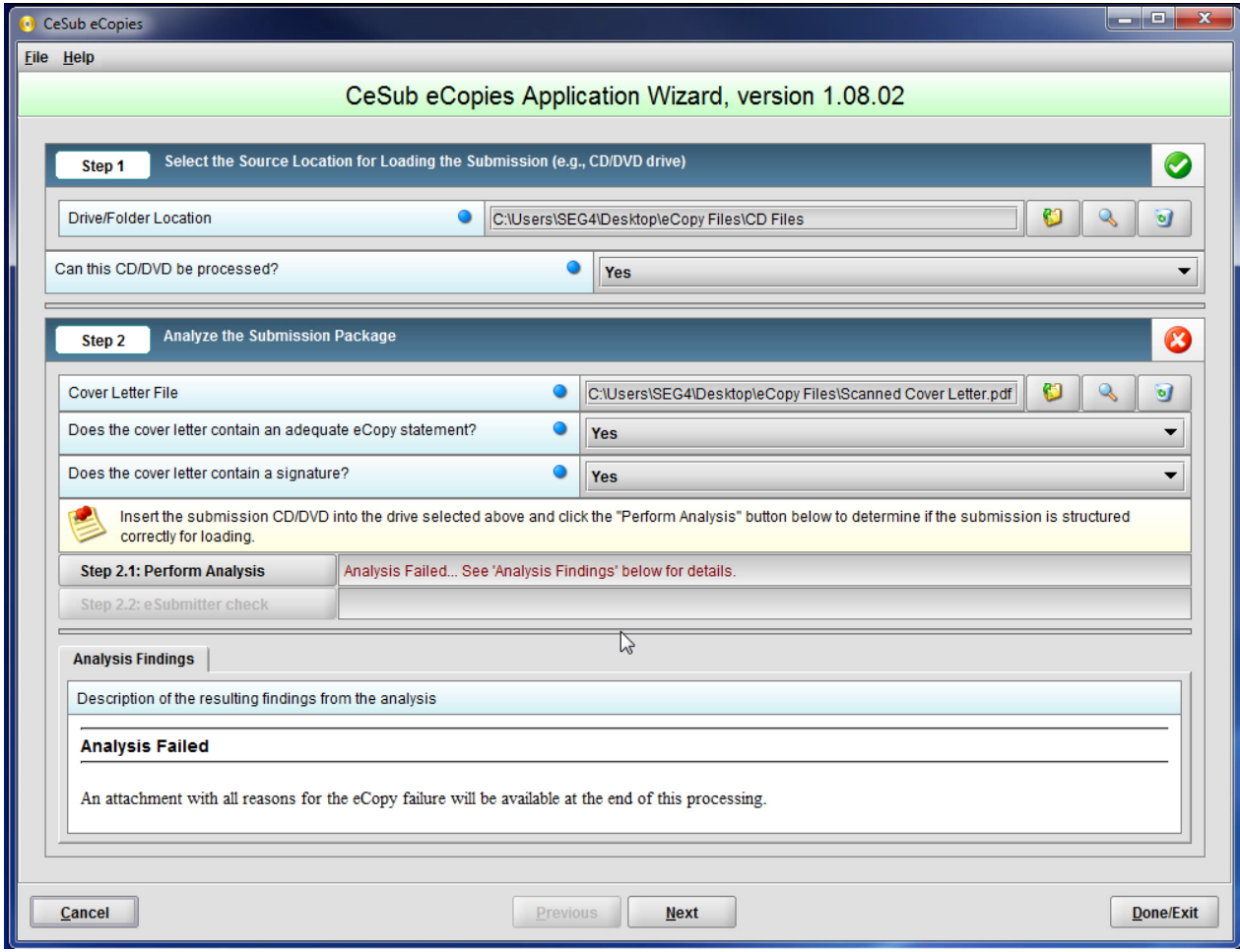
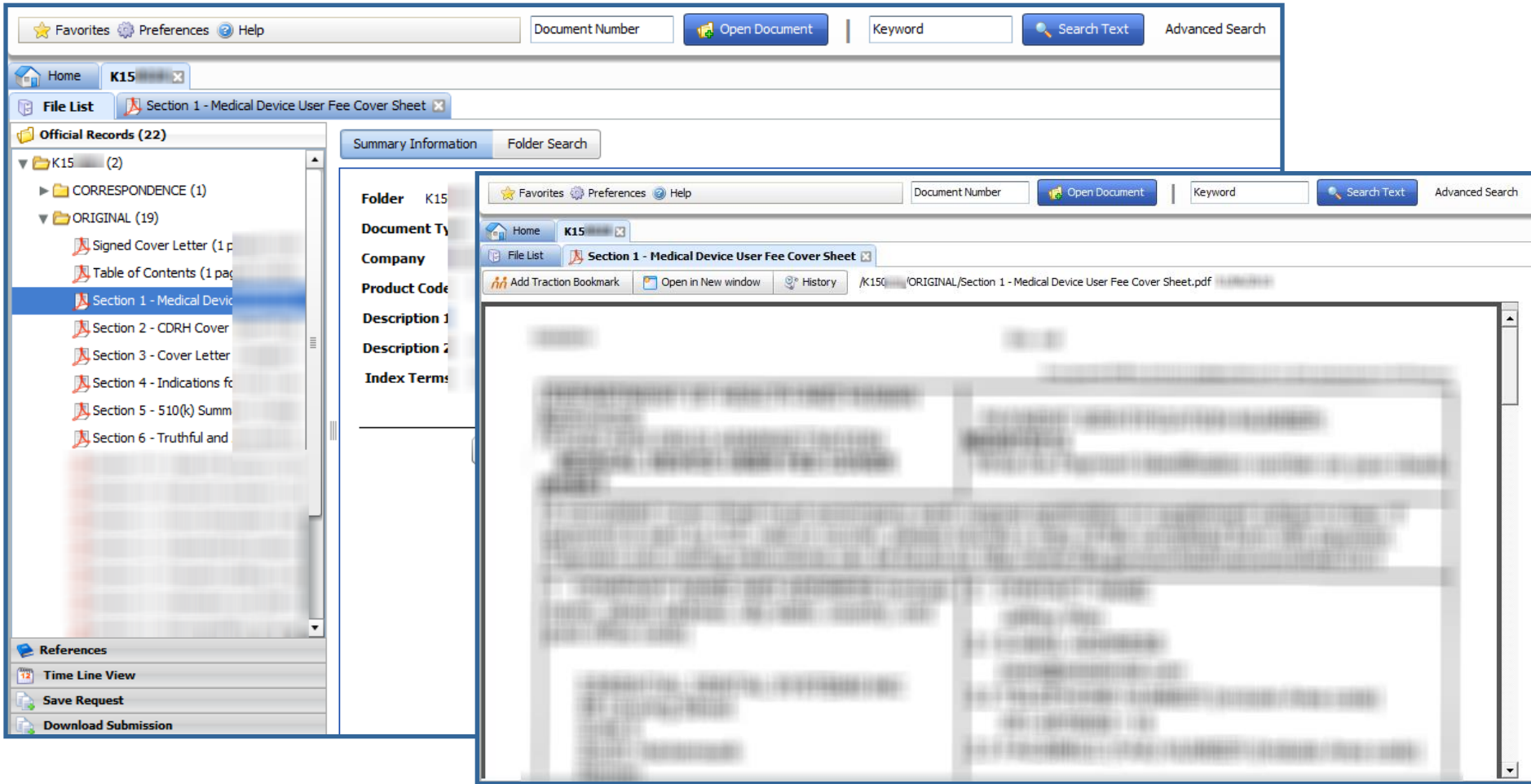


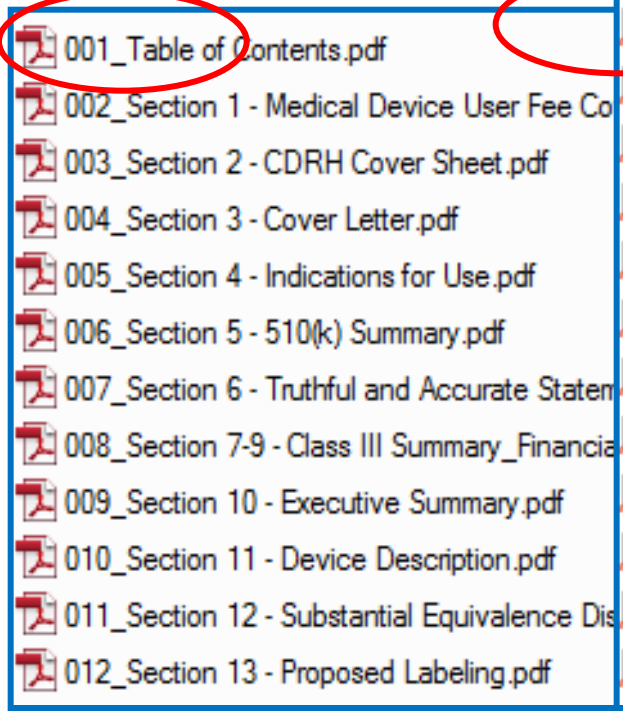
Image 2000+

- Review staff views/download submission files from Image

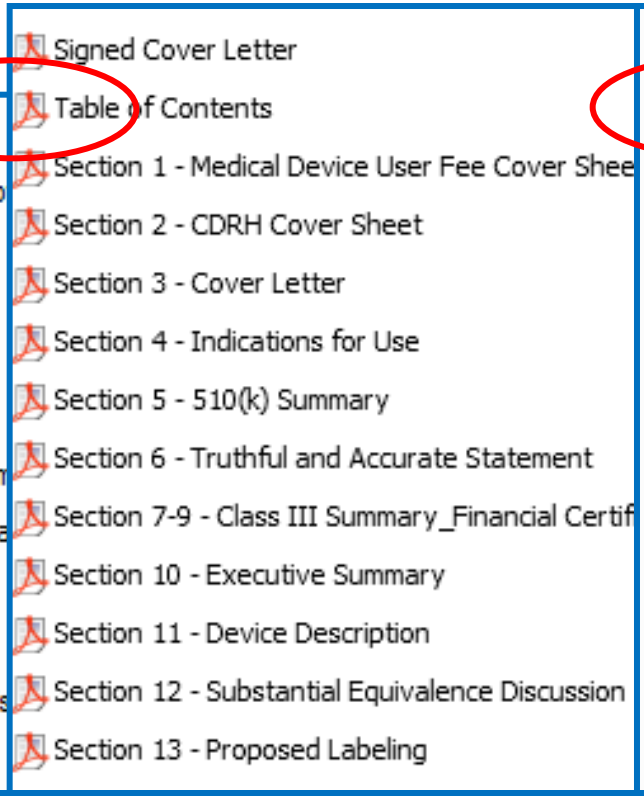


Challenge with CDRH Systems

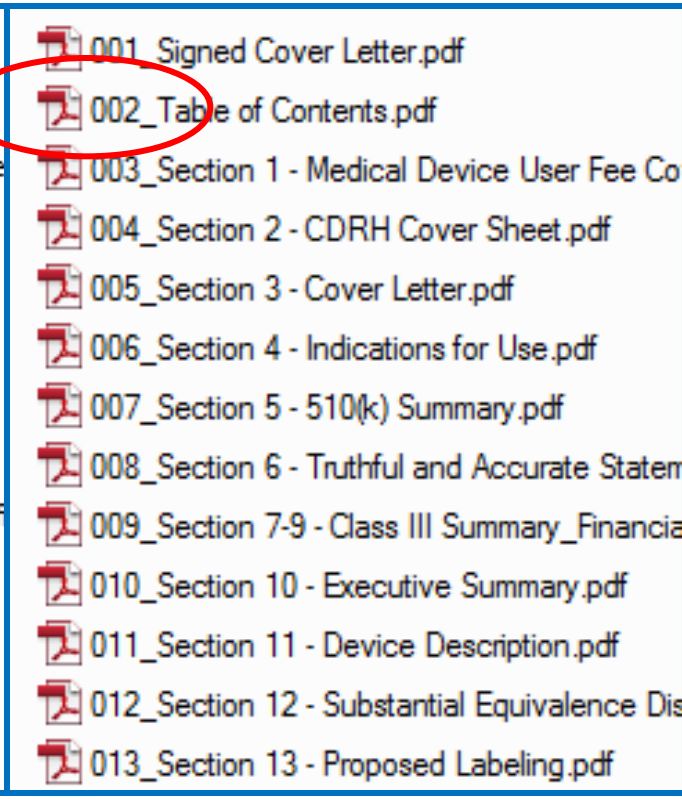
Files on eCopy disc



Files on Image web page



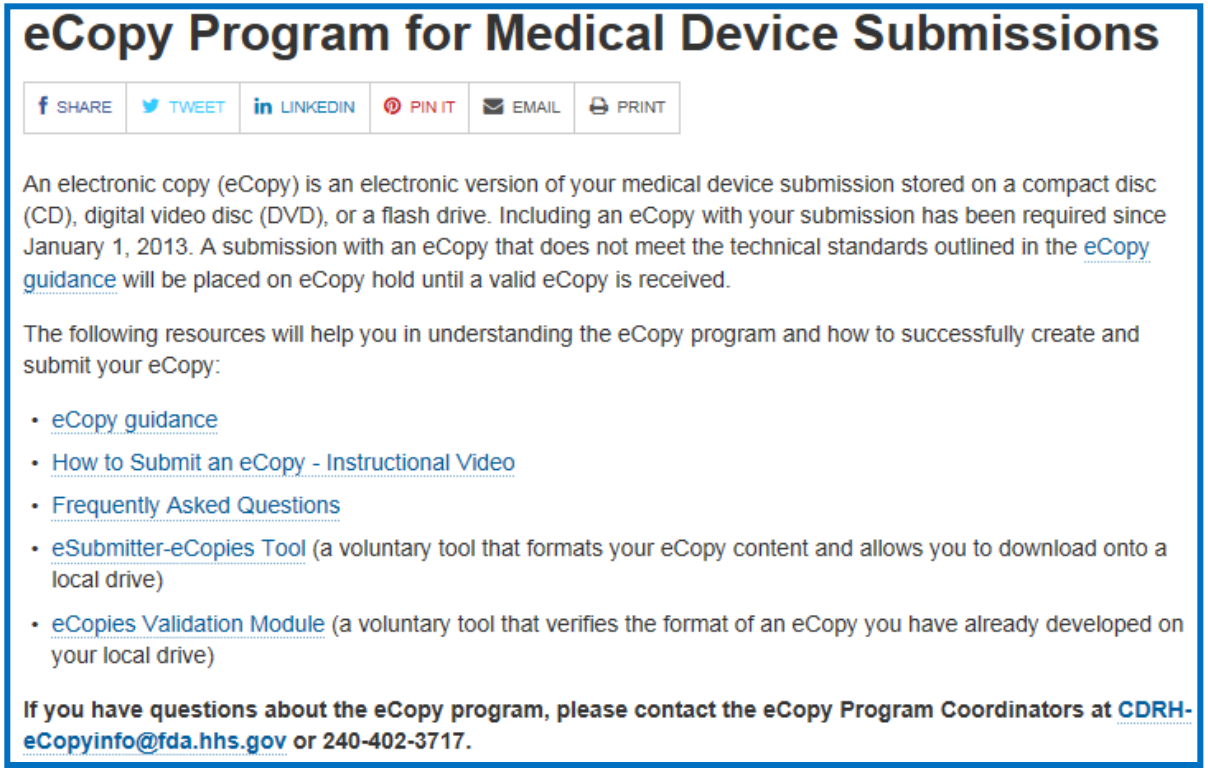
Files downloaded from Image



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

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | 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.

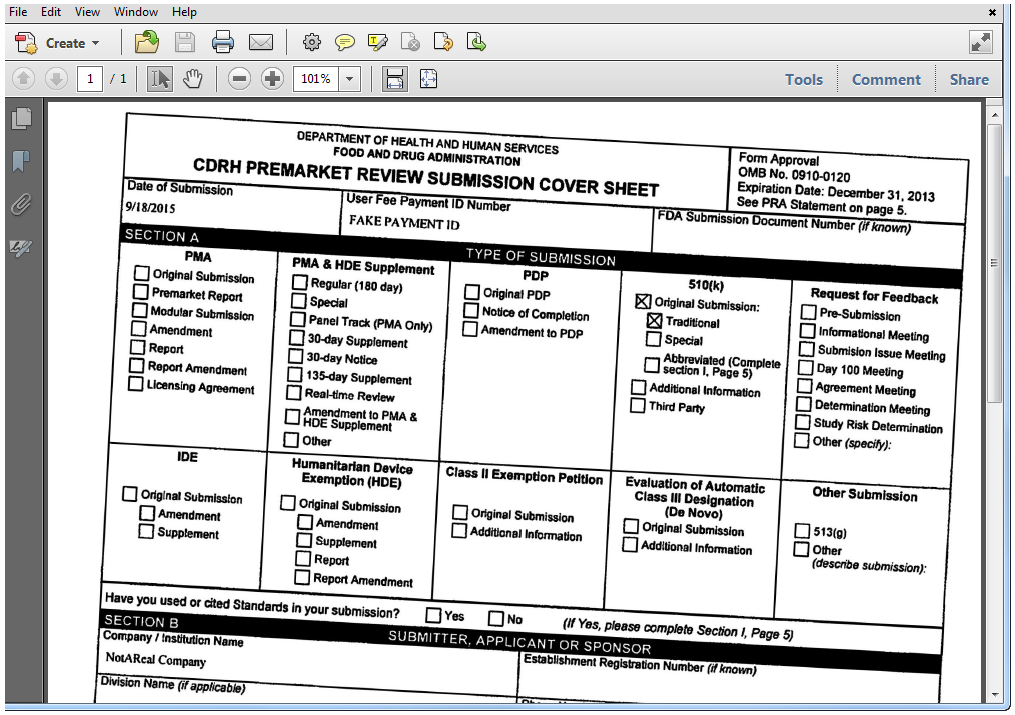
Avoid Common Mistakes

- 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

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
9/18/2015	FAKE PAYMENT ID	

SECTION A — TYPE OF SUBMISSION

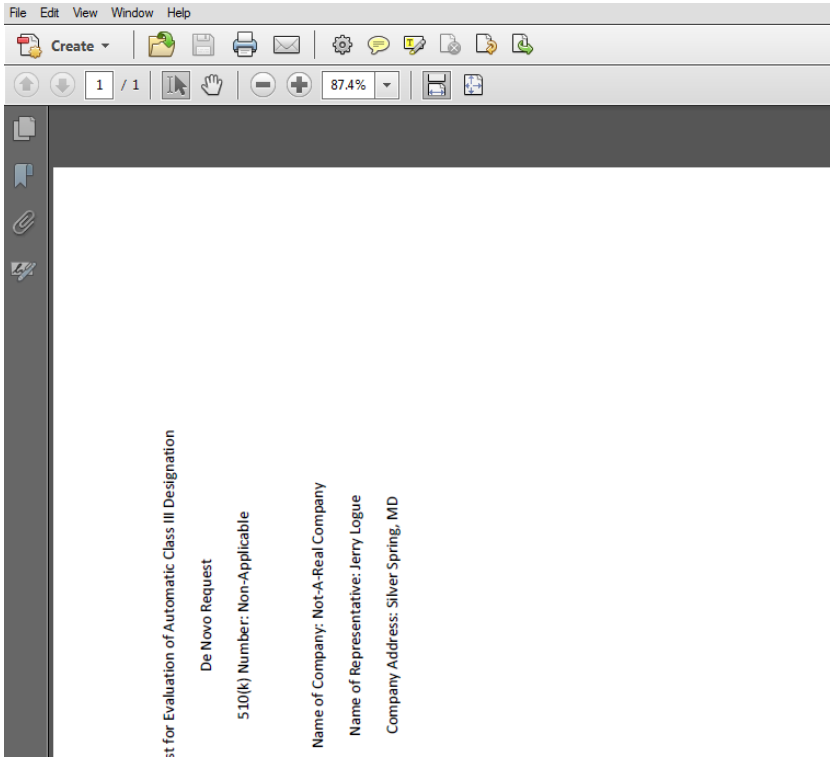
PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*
NotARea Company	
Division Name *(if applicable)*	



st for Evaluation of Automatic Class III Designation

De Novo Request

510(k) Number: Non-Applicable

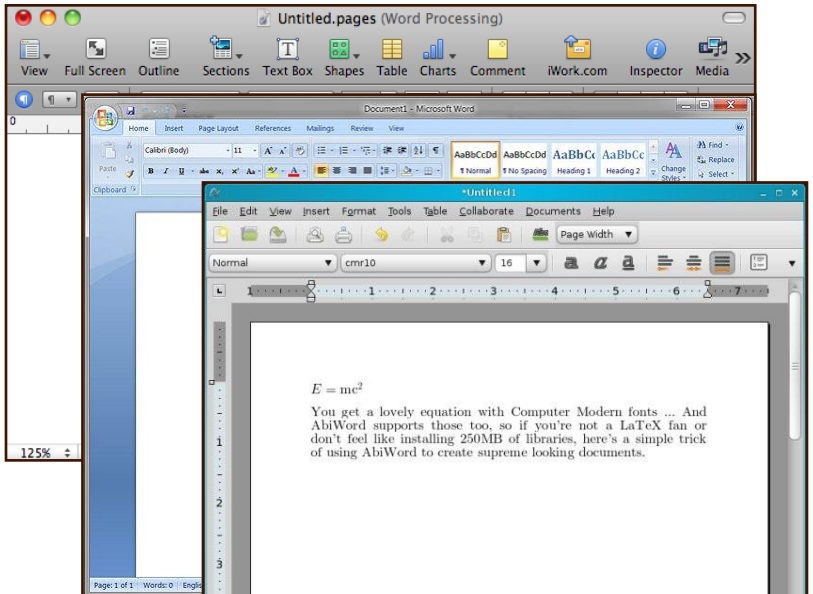
Name of Company: Not-A-Real Company

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

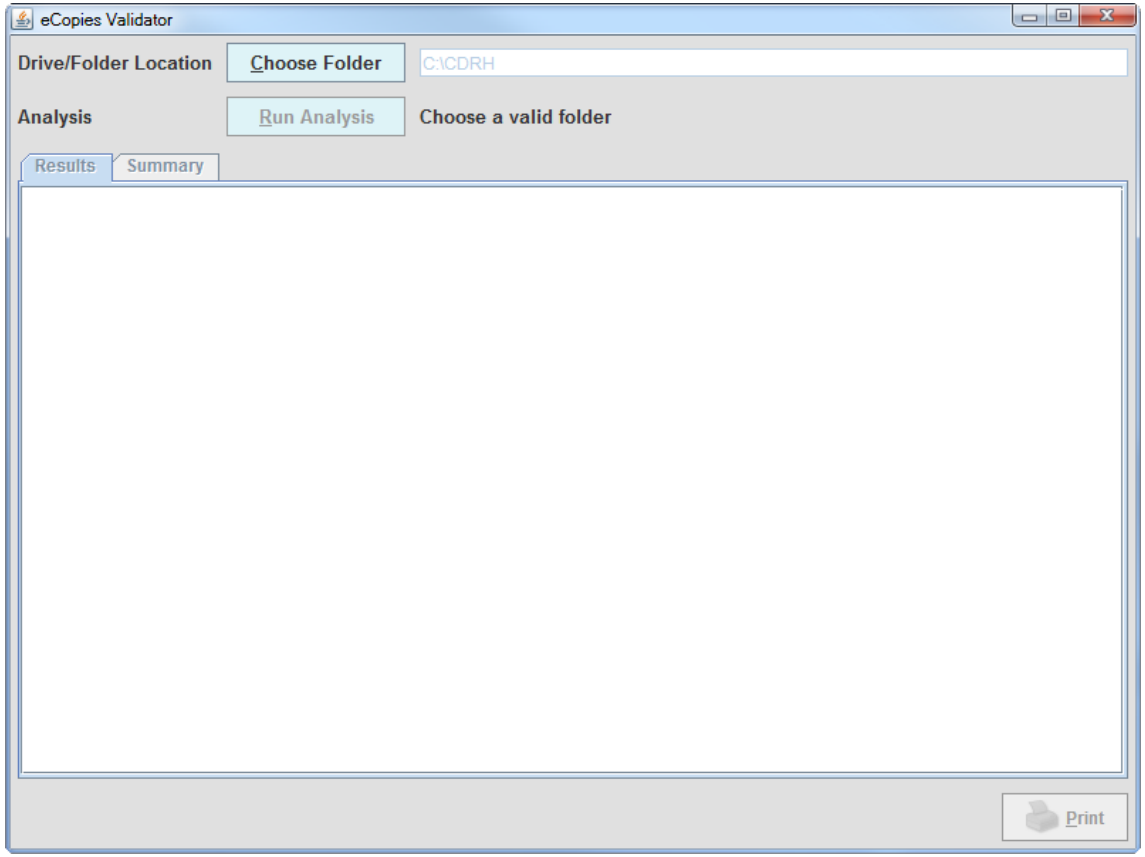
- If you have to scan files, use OCR features available in most scanning software to enable searching in the PDF file
- If you have an invalid eCopy, send a full replacement
  - 001_Attachment1_Replacement.pdf would be a valid eCopy and would not go on eCopy hold
  - Since the other files were never 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