

CCR Number	ESUB-024
Title	Add section to "Getting Started" on transferring working files from FDA eSubmitter to CVM eSubmitter
Business Owner	CVM
Change Type	Enhancement
Components	CVM eSubmitter Application
Severity	Low
Application Release	Version 1.05.00 – 2/12/2018

Change Description

Previously, the "Getting Started" dialog was missing instructions on transferring working files originally created within FDA eSubmitter so that they could be reused within CVM eSubmitter. Specifically, contact and address information, as well as previously created submissions that could be reused to create new submissions in CVM eSubmitter through the "Save-As" operation.

With the latest change, we have inserted a new Step 3: "Retaining FDA eSubmitter Content for Use in CVM eSubmitter."

Getting Started Dialog		
Getting Started		
Overview CVM e Submitter Application		
The CVM eSubmitter Application enables the creation of electronic submissions of regulatory information to CVM. It contains a number of data capturing tools to permit the capture of information in a structured format and provides helpful dialog boxes to reduce redundant responses. These benefits enable CVM to improve its review process of this regulatory information.		
This "Getting Started" section provides valuable information that will help step you through the process of setting up your environment all the way through preparing and packaging your first submission.		
It includes the following sub-sections:		
 Obtaining FDA and CVM Accounts for Transmitting Submissions 		
 Configuring the CVM eSubmitter Application 		
 Retaining FDA eSubmitter Content for Use in CVM eSubmitter 		
 Reviewing the Steps for Preparing a Submission 		
 Transmitting a Submission to FDA 		
Keeping Up with Application Updates		
Beginning Your First Submission		
Skip at Start-Up Previous Next		

Updated Getting Started Overview

New Getting Started Step 3: Retaining FDA eSubmitter Content for Use in CVM eSubmitter

Getting Started Dialog		
Getting Started		
Step 3 Retaining FDA e Submitter Content for Use in CVM e Submitter		
The CVM eSubmitter application is backward compatible with the FDA eSubmitter application. Specifically, with respect to submission and address/contact information prepared in FDA eSubmitter before the launch of the CVM eSubmitter application.		
The following link will provide guidance on moving existing information from FDA eSubmitter to CVM eSubmitter: • <u>CVM eSubmitter Retaining Information from FDA eSubmitter Quick Guide</u>		
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