CCR Number	ESUB-025
Title	Add section to "Getting Started" on transmitting a submission to FDA
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 provided instructions from obtaining accounts to packaging your first submission. However, it did not reference how to transmit your submission to CVM. While transmitting a submission to CVM is not a capability of eSubmitter, and is performed by using the FDA Electronic Submission Gateway (ESG), it is still applicable to include as part of the end-to-end process.

With the latest change, we have inserted a new Step 5: "Transmitting a Submission to FDA" that provides additional information related to using the FDA ESG.

🔛 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 Close				

Updated Getting Started Overview

New Getting Started Step 5: Transmitting a Submission to FDA

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Getting Started				
Step 5 Transmitting a Submission to FDA				
Submissions generated within CVM eSubmitter must be transmitted using FDA's Electronic Submission Gateway (ESG) and validated using CVM's Electronic Submission System (ESS).				
There are two approaches to transmitting content through the FDA ESG: • The FDA ESG Web Interface (i.e., WebTrader) • An AS2 Gateway-to-Gateway Connection				
Instructions on both approaches are provided within Chapters 4 and 5 of the online ESG User Guide.				
The following link will display the online ESG User Guide – Table of Contents FDA ESG User Guide 				
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