

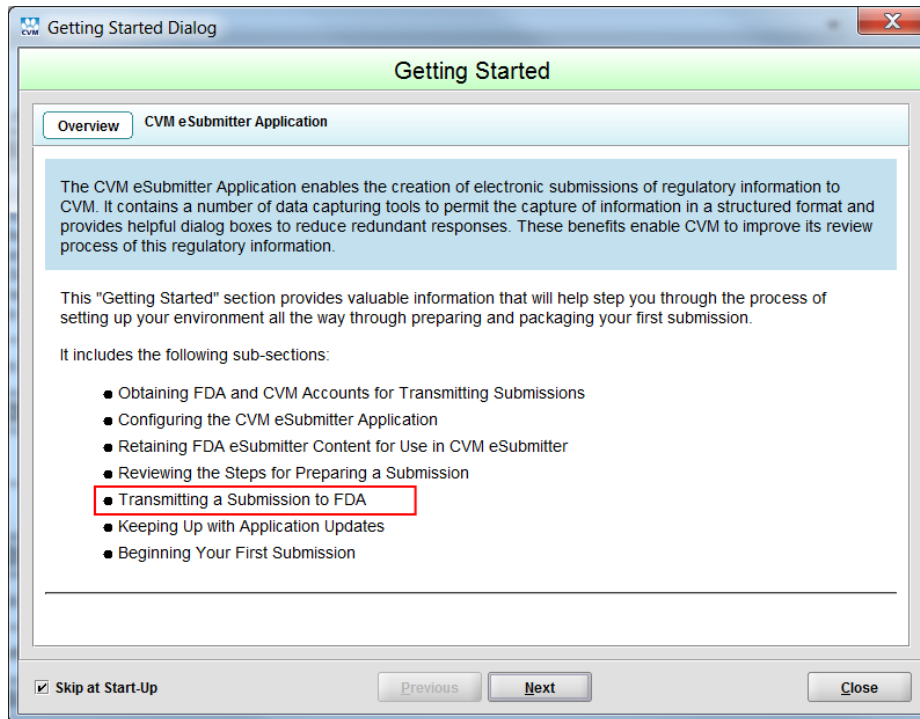
CCR Number	ESUB-025
Title	Add section to “Getting Started” on transmitting a submission to FDA
Business Owner	CVM
Change Type	Enhancement
Components	CVM eSubmitter Application
Severity	Low
Application Release	Version 1.05.00 – 2/12/2018

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.

Updated Getting Started Overview



New Getting Started Step 5: Transmitting a Submission to FDA

