

Webinar 3: Follow-up Question and Answer Session

September 19, 2018

Agenda

- Introductions/Agenda: 9:00 – 9:05 am
- Brief Overview of Previous Webinars: 9:05 – 9:15 am
- Open Question and Answer Session: 9:15 - End

eSubmitter Webinar 1

- Webinar 1: FDA ESG and CVM ESS Registration Process held May 23, 2018
 - Overview of electronic submission process
 - How to complete registration with FDA ESG
 - How to complete registration with CVM ESS
 - Types of connections (AS2 v. Webtrader)
 - Webtrader basics

eSubmitter Webinar 2

- Webinar 2: How to Use the eSubmitter Tool held August 22, 2018
 - Downloading and installing CVM eSubmitter
 - Launching eSubmitter and basic navigation
 - Creating a new submission
 - Finalizing and packaging a submission
 - Submitting to CVM and viewing CVM Responses
 - Afternoon Breakout Sessions on building specific submission types

Location of Webinar Information

- Webinar Agendas, recordings, and meeting materials are available on the CVM eSubmitter page of FDA.gov
 - <https://www.fda.gov/ForIndustry/FDAeSubmitter/cm226814.htm>

Important Announcement

- Changes made to the eSubmitter templates to support the goals outlined in the ADUFA and AGDUFA legislation will require the most recent version of the templates.
- CVM will be releasing an update to the CVM eSubmitter program on **Sunday September 30th**.
- This is a **critical update** that must be installed to utilize the new processes and timelines agreed upon in both user fee acts.

Questions

