

February 7, 2020

## Introduction

The Center for Veterinary Medicine (CVM) is providing an update on the Office of Surveillance and Compliance (OSC) Drug Experience Reports (DER) eSubmitter program.

The OSC DER eSubmitter Program will soon require digital signatures on electronic submissions to be registered with the CVM Electronic Submission System (ESS). We expect this requirement to be implemented as early as mid-March 2020.

## Important message for OSC DER eSubmitter Program stakeholders

If you are using a digital signature already registered with the CVM ESS for the purposes of submission to ONADE or OMUMs, that registration will carry over to the OSC DER eSubmitter program and no changes are needed at this time.

If you already have a registered ESG production account and have successfully submitted DERs via eSubmitter in the past, please allow a minimum of two weeks to complete the ESS registration process.

If your firm already has an ESS account and you are adding a new stakeholder, you can use the CVM ESS Manage form (form FDA 3538) to update your account.

For information on registering with CVM's Electronic Submission System, see:

- Guidance for Industry (GFI) #108: Registering with CVM's Electronic Submission System: <https://www.fda.gov/media/70064/download>
- Electronic Submissions: <https://www.fda.gov/animal-veterinary/development-approval-process/electronic-submissions>
- CVM ESS Manage form (form FDA 3538) <https://www.fda.gov/media/70818/download>

Note that you may still submit DERs by paper if you experience delays in the registration process.

## Contacts

If you have any additional questions, please contact CVM at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov).