

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine

## Electronic Submissions System Broadcast Message

September 17, 2018

### Introduction

This is an update on the latest news concerning CVM's Electronic Submission System (ESS) Program to industry stakeholders. This broadcast contains very important information on the following subject(s):

- eSubmitter Update to Support ADUFA IV and AGDUFA III

### Background

Due to the reauthorization of the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA), beginning October 1, 2018, all applications and submissions made to ONADE under the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 512(b) and 571 must be submitted to CVM electronically using the CVM eSubmitter tool.

### Message

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 30<sup>th</sup>. This is a critical update that must be installed to utilize the new processes and timelines agreed upon in both user fee acts. Following this update, users will still have the usual 6-month window to make any submission that was started prior to the update using the previous template versions. However, it is important to note that if you are using an outdated template version, you will not be able to enable all functionality related to the new updates. Users can update the template version of submissions currently being worked on by selecting "Save As" from the file menu. (Note: in some cases, previously entered data may be lost due to significant changes in the template).

### Contacts

Please contact [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov) with any questions.