U.S. FOOD & DRUG ADMINISTRATION

CVM Public Webinar:

Reporting of Veterinary Drug Supply Chain Information Using the Animal Drug Manufacturing System (ADMS) eSubmitter Tool

June 22, 2022

Housekeeping

- All participants are muted on entry.
- You may enter questions into the Q&A pod at any time but we will wait to answer questions during the Live Q&A session at the end.
  - Q&A pod questions are not displayed publicly but should not contain promotional or proprietary information.
- This webinar is being recorded. The slides and recording will be posted to CVM websites.

Agenda

- **Introduction to ADMS** – *Andrea Kerrigan* *1:00-1:10 pm*
- **Using ADMS Books** – *Joe Faust* *1:10-1:50 pm*
  - Existing Establishment, Contact, and Product Description Books
  - Master File Book
  - ADMS Establishments Book
  - ADMS Supply Chains Book
- **Break** *1:50-2:00 pm*
- **Submission Templates** – *Kristen Anderson* *2:00-2:40 pm*
  - (J)INAD P
  - (A)NADA A/E
  - MCSRs
  - Supplements
  - VMFs
- **XML Import (Feedback Loop)** *2:40-2:45 pm*
- **Break** *2:45-3:00 pm*
- **Live Q&A** – *Laura Huffman and Trupti Dhami* *3:00-3:30 pm*

Why ADMS?

- Information related to animal drug products and their manufacturing sites is not easily searchable or is incomplete.
- CVM cannot readily retrieve information to address potential drug shortages in the event of a health event (e.g. Coronavirus outbreak) or natural disaster (e.g. hurricane or typhoon).
- ADMS will allow CVM to retrieve data from FDA and CVM systems that capture up-to-date information on drug substance or finished drug products and their manufacturing sites that can be used to address drug shortages, customs and border protection requests, and manufacturing changes.
- Drug sponsors/MF holders will routinely confirm the status of their manufacturing sites to provide the clearest picture of manufacturing capability in times of emergency.

FDA Announces eSubmitter Update to Enhance Monitoring of Animal Drug Supply Chain

December 20, 2021

Content current as of:
12/20/2021

Today, the FDA's Center for Veterinary Medicine is announcing an eSubmitter update that will enable animal drug manufacturers to provide more complete facility information, particularly about the establishments that are actively used in their manufacturing processes. The enhancement will enable animal drug manufacturers to provide supply chain data that will strengthen FDA's ability to monitor the animal drug supply chain and efficiently address any animal drug supply chain issues that may arise.

This enhancement is part of the Animal Drug and Manufacturing System (ADMS), a project funded by The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in response to the COVID-19 public health emergency. Collecting facility information will enable CVM to rapidly access information on animal drug products, active pharmaceutical ingredients, and the status of manufacturing sites, so that the agency can identify and address critical facilities and animal drugs impacted by emerging diseases or natural disasters and help to identify solutions to potential animal drug shortages.

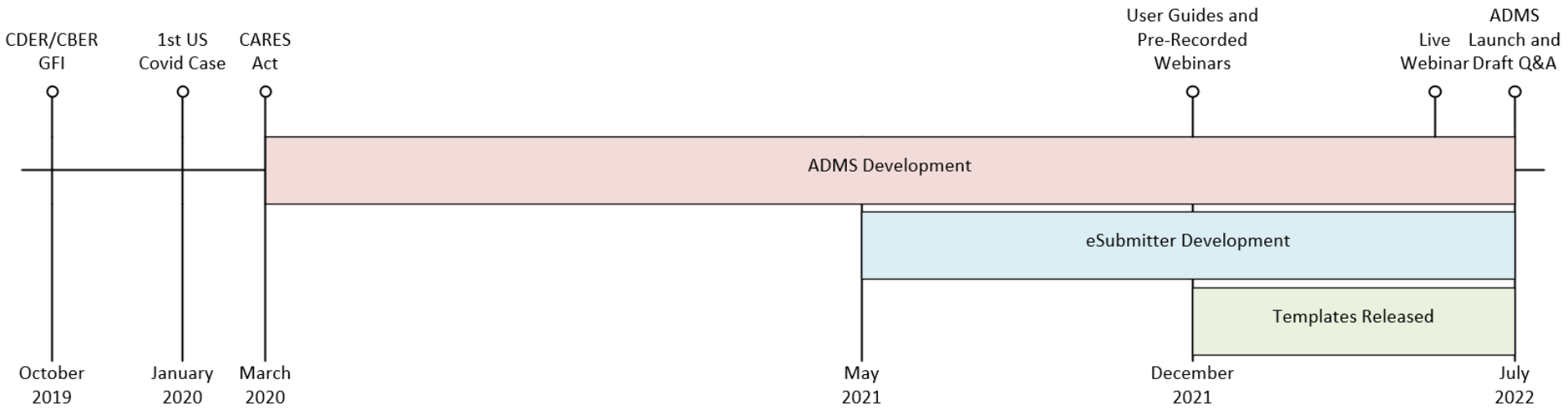
This step brings CVM in line with the FDA's other medical product centers that already require human drug and biologic manufacturers to provide facility information and operational status. CVM will phase in the new eSubmitter templates over the next six months; however, animal drug manufacturers may begin using the ADMS book (found within eSubmitter under the "Tools" menu) to provide facility information on a voluntary basis immediately. This information will be required when animal drug sponsors make new submissions to the eSubmitter program once updated versions of each template are released. Animal drug sponsors can view the CVM eSubmitter Programs webpage for more information, including the release schedule for the updated templates. The page also includes a new webinar outlining the eSubmitter update, including how sponsors can provide facility information and operational status through the program.

Additional Information

- CVM eSubmitter Programs
- CVM eSubmitter Resource Center

Issued by FDA Center for Veterinary Medicine.
For questions, Contact CVM.

The Project Timeline



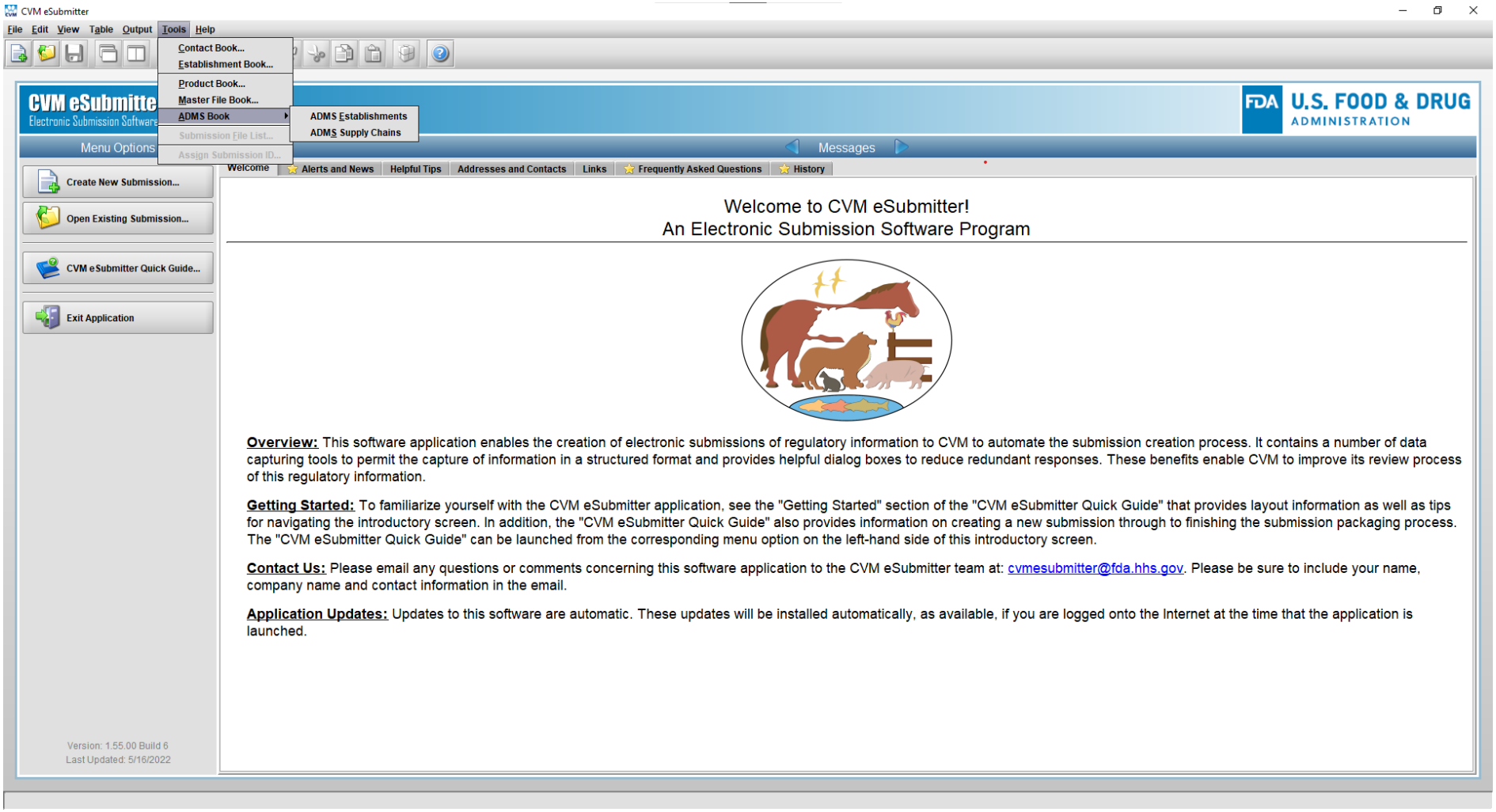
CDER/CBER GFI: Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers

CARES Act: Coronavirus Aid, Relief, and Economic Security Act

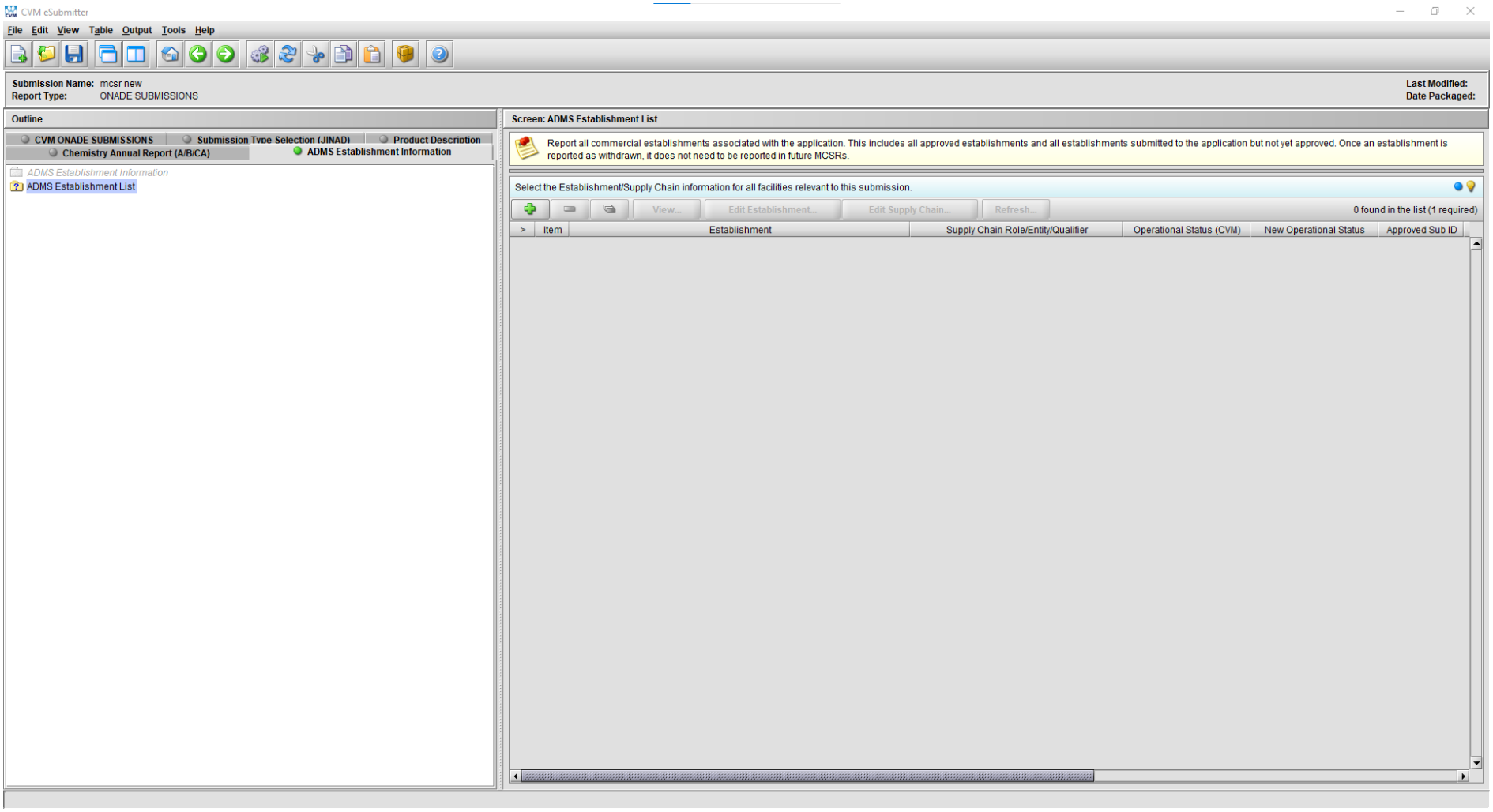
eSubmitter Template Release

1. (J)INAD P – December 2021
2. (A)NADA CMC supplements – February 2022
3. (A)NADA MCSRs – March 2022
4. (A)NADA A/E – April 2022
5. (A)NADA NF/B1 supplements – May 2022
6. VMF A (Opening a VMF)– June 2022
7. VMF originals, supplements and annual updates – July 2022

ADMS Books


CVM eSubmitter
File Edit View Table Output Tools Help
Contact Book...
Establishment Book...
Product Book...
Master File Book...
ADMS Book
Submission File List...
Assign Submission ID...
ADMS Establishments
ADMS Supply Chains
CVM eSubmitte
Electronic Submission Softwar
FDA U.S. FOOD & DRUG ADMINISTRATION
Menu Options
Messages
Create New Submission...
Open Existing Submission...
CVM eSubmitter Quick Guide...
Exit Application
Welcome
Alerts and News
Helpful Tips
Addresses and Contacts
Links
Frequently Asked Questions
History
Welcome to CVM eSubmitter!
An Electronic Submission Software Program
Overview: This software application enables the creation of electronic submissions of regulatory information to CVM to automate the submission creation process. 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.
Getting Started: To familiarize yourself with the CVM eSubmitter application, see the "Getting Started" section of the "CVM eSubmitter Quick Guide" that provides layout information as well as tips for navigating the introductory screen. In addition, the "CVM eSubmitter Quick Guide" also provides information on creating a new submission through to finishing the submission packaging process. The "CVM eSubmitter Quick Guide" can be launched from the corresponding menu option on the left-hand side of this introductory screen.
Contact Us: Please email any questions or comments concerning this software application to the CVM eSubmitter team at: cvmesubmitter@fda.hhs.gov. Please be sure to include your name, company name and contact information in the email.
Application Updates: Updates to this software are automatic. These updates will be installed automatically, as available, if you are logged onto the Internet at the time that the application is launched.
Version: 1.55.00 Build 6
Last Updated: 5/16/2022

ADMS and Submissions



ADMS Resources

CBER/CDER GFI Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers Guidance for Industry
https://www.fda.gov/media/131911/download

CVM eSubmitter Resource Center
https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center

- CVM eSubmitter New Product Description and Product Book Quick Guide
- CVM eSubmitter Data Book Quick Guide
- CVM eSubmitter ADMS Book Quick Guide
- CVM eSubmitter Master File Quick Guide

Pre-recorded Webinars
https://youtube.com/playlist?list=PLey4Qe-UxcxYpFaXMzdX3SfNdp38YxXV

- ADMS Establishment Databook Walk Through
- ADMS Supply Chain Databook Walk Through
- (J)INAD-P-MC, (A)NADA-C/R, (A)NADA-B/F, (A)NADA-A/E Walk Throughs

CVM Public Webinar
https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/cvm-public-webinar-reporting-veterinary-drug-supply-chain-information-using-animal-drug

ADMS Benefits

CVM

- Automation
- Data Standardization
- Improve data quality
- Consistency with CDER/CBER
- Anticipate/Respond to shortages

- Data connectivity
- Up-to-date information
- Annual verification
- Supply chain data
- Improved search capability

Sponsors

- Automation
- Data Standardization
- Improve data quality
- Consistency with CDER/CBER
- Enhance Collaboration with FDA to Anticipate/Respond to shortages

- Transparency
- Receive feedback from CVM
- ADMS and MF Books
- Ease of updating information

Next Steps

- Continue template release
- Final launch, including feedback loop July 2022
- Continue stakeholder outreach
- Make changes/improvements based on user feedback/defect identification (Industry and CVM)
- Incorporate enhancements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