

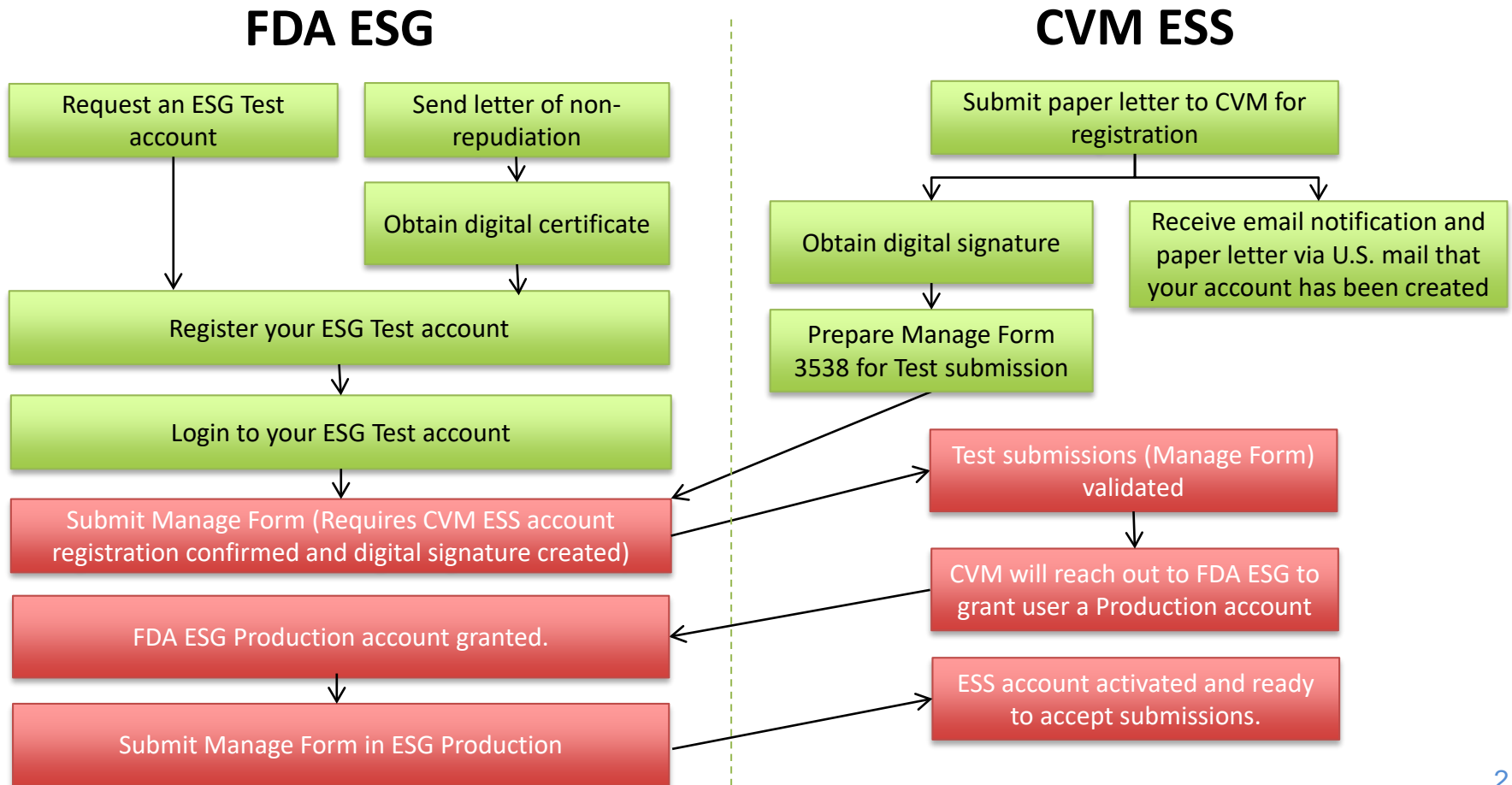
# CVM Electronic Submission System

- ▶ Steps for Submitting Electronically to CVM:
  1. [Register with the FDA ESG](#)
  2. [Submit a paper registration letter to CVM](#)
  3. [Download the CVM ESS Manage form \(FORM FDA 3538\)](#)
  4. [Submit a digital signature to CVM through FDA ESG using the CVM Manage Form](#)
  
- ▶ [Submitting to CVM through FDA ESG WebTrader Gateway](#)

*\*See page 20 for definitions*

# Registration Workflow

Registrations for FDA ESG and CVM ESS can occur simultaneously. It is only further along in the registration process where the systems are dependent on each other for registration. We have highlighted the simultaneous portions in green and the dependency areas in red.





# Register with FDA WebTrader Gateway

Please follow the instruction here for registration with the FDA WebTrader Gateway: [Setting up a WebTrader Account Checklist](#)

Note: You may begin registration with FDA ESG and CVM ESS at the same time, but you will be unable to submit a test submission without an active FDA ESG Test account and CVM will be unable to accept your test submission without an ESS Account. Please keep that in mind.



# Submit a Paper Registration Letter to CVM

In order for CVM to process your registration and add you to our database you must send a single, original, signed registration letter to CVM. A template of the letter can be found in Appendix I of [Guidance for Industry \(GFI\) #108](#).

## **Mailing Address:**

CVM/Office of Management  
Attention: Kenneth Shane Burch  
MPN 2, Room N134  
12225 Wilkins Avenue  
Rockville, MD 20852

The letter should include:

- a. the name, mailing address, phone number, and Email address of the Coordinator
- b. the names, mailing addresses, phone numbers, and Email addresses for each stakeholder who will submit electronic submission
- c. the subject of the letter should be **Registration Letter for Electronic Submission to CVM** to clearly identify the purpose of the letter. The letter should be mailed to the address given in Appendix I of GFI #108

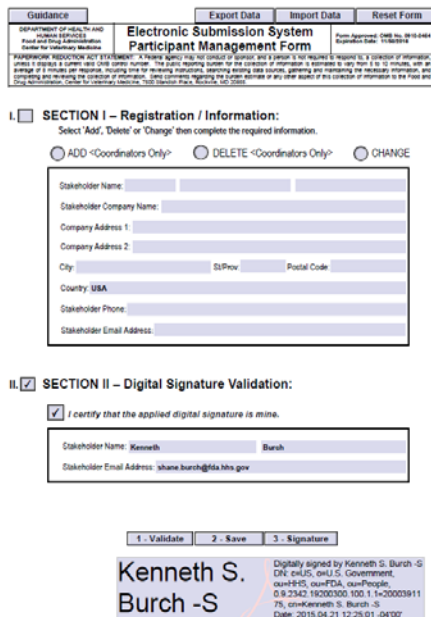
CVM will send a paper response letter once the registration process is complete. If the coordinator has not received the acknowledgements within 30 days, contact CVM by calling the CVM Electronic Submissions Hotline at 240-402-7062.

# Download CVM ESS Manage Form (FDA Form 3538)

Before submitting your CVM ESS Manage for you will need a valid digital signature. Please reference the Digital Signature Guide for completing this:

<https://www.fda.gov/industry/policiesguidance/important-information-about-digitalelectronic-signatures>

The Manage Form can be found here: <https://www.fda.gov/media/70818/download>



**Electronic Submission System Participant Management Form**

**SECTION I – Registration / Information:**  
Select 'Add', 'Delete' or 'Change' then complete the required information.

ADD <Coordinators Only>  DELETE <Coordinators Only>  CHANGE

Stakeholder Name: \_\_\_\_\_  
 Stakeholder Company Name: \_\_\_\_\_  
 Company Address 1: \_\_\_\_\_  
 Company Address 2: \_\_\_\_\_  
 City: \_\_\_\_\_ St/Prov: \_\_\_\_\_ Postal Code: \_\_\_\_\_  
 Country: USA  
 Stakeholder Phone: \_\_\_\_\_  
 Stakeholder Email Address: \_\_\_\_\_

**SECTION II – Digital Signature Validation:**

I certify that the applied digital signature is mine.

Stakeholder Name: Kenneth Burch  
 Stakeholder Email Address: skhane.burch@fda.hhs.gov

1 - Validate 2 - Save 3 - Signature

**Kenneth S. Burch -S**  
 Digitally signed by Kenneth S. Burch -S  
 DN: cn=US, ou=U.S. Government,  
 ou=HHS, ou=FDA, ou=People,  
 o=62345 18200000 100 1 1-20003911  
 75, cn=Kenneth S. Burch -S  
 Date: 2015.04.21 12:25:01 -0400

The FDA Manage Form is used to:

1. Register, Delete, and Change Stakeholder information for CVM’s Electronic Submission System
- OR
2. Validate a User’s Digital Signature for submitting electronically

\*Your manage form will be submitted via ESG Test in order to grant you a ESG Production account. It must then be submitted again in Production in order to activate your ESS Account for electronic submission.

\*Manage form must be resubmitted whenever a digital signature is renewed. This will allow validation of the renewed signature.

# Submitting Your Digital Signature Using CVM ESS Manage Form (FDA Form 3538)

Guidance	Export Data	Import Data	Reset Form
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine		<b>Electronic Submission System Participant Management Form</b> Form Approved: OMB No. 0910-0464 Expiration Date: 11/30/2018	
<small>PAPERWORK REDUCTION ACT STATEMENT: A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. The public reporting burden for the collection of information is estimated to vary from 5 to 10 minutes, with an average of 8 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, 7610 Standish Place, Rockville, MD 20855.</small>			

I.  SECTION I – Registration / Information:

Select 'Add', 'Delete' or 'Change' then complete the required information.

ADD <Coordinators Only>
  DELETE <Coordinators Only>
  CHANGE

Stakeholder Name:	
Stakeholder Company Name:	
Company Address 1:	
Company Address 2:	
City:	St/Prov: Postal Code:
Country:	USA
Stakeholder Phone:	
Stakeholder Email Address:	

II.  SECTION II – Digital Signature Validation:

I certify that the applied digital signature is mine.

Stakeholder Name:	Kenneth	Burch
Stakeholder Email Address:	shane.burch@fda.hhs.gov	

1 - Validate    2 - Save    3 - Signature

Kenneth S. Burch -S  
 Digitally signed by Kenneth S. Burch -S  
 DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000391175, cn=Kenneth S. Burch -S  
 Date: 2015.04.21 12:25:01 -04'00'

## Prerequisites:

- Active ESG Test Account
- Email/letter from CVM ESS regarding your coordinator and stakeholder registration

## Steps:

1. Submit your Manage Form in ESG Test (Making sure to choose **CVM** as the center and **Manage Form** as the submission type (Screenshot example of page 10)
2. CVM will verify that your test submission was valid
3. CVM will reach out to FDA ESG to have a ESG Production account granted for you.
4. You will receive an email from FDA ESG regarding your Production account creation
5. Submit your manage form again in ESG Production in order to activate your CVM ESS account. This is the final step that validates your digital signature  
 \*This must be done for all coordinators and stakeholders in order to activate their accounts.

# FDA WebTrader Gateway - Test

Logging into the FDA Electronic Submissions Gateway (ESG) – Test Submissions Only

The URL to get to this screen is <https://esgtest.fda.gov>

**Both User ID and Password are case sensitive**

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA ELECTRONIC SUBMISSIONS GATEWAY - TEST SYSTEM

|

Password

I agree to the terms set forth in the Rules of Behavior. [View Rules of Behavior](#)

Log in

[ESG Web Help](#) [FAQs](#) [System Status](#)

# FDA WebTrader Gateway - Production

Logging into the FDA Electronic Submissions Gateway (ESG)

The URL to get to this screen is <https://esg.fda.gov>

**Both User ID and Password are case sensitive**

FDA ELECTRONIC SUBMISSIONS GATEWAY

Password



I agree to the terms set forth in the Rules of Behavior. [View Rules of Behavior](#)

**Log in**

[ESG Web Help](#) [FAQs](#) [System Status](#)




# Main WebTrader Software Screen




WebTrader


C


Welcome


  


Send Document



Alerts


In Progress


Inbox
3126


Sent Items

**Inbox** 3217 results


<

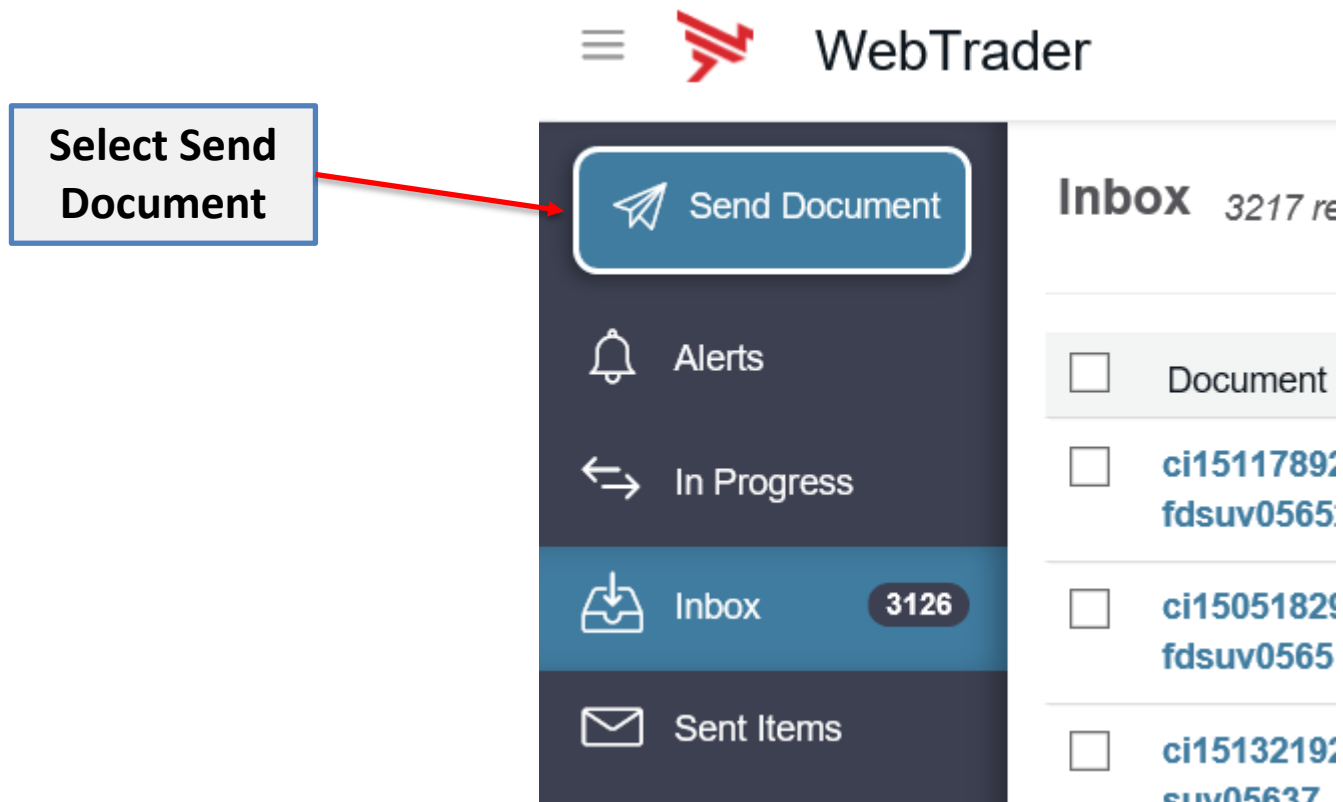
1

of 215
>

<input type="checkbox"/>	Document Name	Sender	Recipient	Date <span style="font-size: small;">▼</span>	File Size	Type
<input type="checkbox"/>	<a href="#">ci1511789233083.576103@fdsuv05652_te1.zip</a>	FDATST	FDA CVM - WC	Mar 28th 2018, 10:29:34 am	2 MB	Acknowledgement
<input type="checkbox"/>	<a href="#">ci1505182977857.166149@fdsuv05651_te1.zip</a>	FDATST	FDA CVM - WC	Feb 5th 2018, 12:56:56 pm	10 MB	Acknowledgement
<input type="checkbox"/>	<a href="#">ci1513219282610.3985@fdsuv05637_te1.zip</a>	FDATST	FDA CVM - WC	Jan 26th 2018, 4:47:37 pm	102 KB	Acknowledgement
<input type="checkbox"/>	<a href="#">ci1513219282610.3985@fdsuv05637_te1.zip</a>	FDATST	FDA CVM - WC	Jan 26th 2018, 4:42:06 pm	101 KB	Acknowledgement
<input type="checkbox"/>	<a href="#">ci1513219282610.3985@fdsuv05637_te1.zip</a>	FDATST	FDA CVM - WC	Jan 26th 2018, 4:30:13 pm	102 KB	Acknowledgement
<input type="checkbox"/>	<a href="#">ci1513204715170.364935@fdsuv05649_te1.zip</a>	FDATST	FDA CVM - WC	Jan 23rd 2018, 4:35:29 pm	2 MB	Acknowledgement

**This is the WebTrader main screen that you do everything from.**

# Sending a Submission or Submissions to FDA



The screenshot shows the 'WebTrader' interface. At the top, there is a hamburger menu icon, a red stylized logo, and the text 'WebTrader'. A dark sidebar menu is open, listing several options: 'Send Document' (highlighted with a blue rounded rectangle and a red arrow pointing from a callout box), 'Alerts', 'In Progress', 'Inbox' (with a '3126' badge), and 'Sent Items'. To the right of the sidebar, the main content area shows an 'Inbox' with '3217 re' items. Below this, there is a list of document entries, each with a checkbox and a document ID: 'Document', 'ci1511789% fdsuv0565', 'ci1505182% fdsuv0565', and 'ci1513219% siv05637'.

# WebTrader – Send Document Screen

**System you are logged into. FDA ESG Test or Production**

**Select CVM Center**

**Select Manage Form**

**Click Add documents to attach submission documents**

**Click Select a certificate to attach your digital certificate. Enter the Certificate password after attaching your certificate**

**Click Send when completed**

The screenshot shows the 'Send Document' interface with the following elements and callouts:

- System you are logged into. FDA ESG Test or Production:** Points to the top header area.
- Select CVM Center:** Points to the '\*Center:' dropdown menu showing 'CVM'.
- Select Manage Form:** Points to the '\*Submission Type:' dropdown menu showing 'Manage Form'.
- Click Add documents to attach submission documents:** Points to the '+ Add documents' button in the 'Document Selection' section.
- Click Select a certificate to attach your digital certificate. Enter the Certificate password after attaching your certificate:** Points to the 'Select a certificate' button in the 'Document Signing' section.
- Click Send when completed:** Points to the 'Send' button at the bottom of the form.

# Receipt and Acknowledgements

- Send Document
- Alerts
- In Progress
- Inbox **3126**
- Sent Items**

Sent Items 1038 results

1 of 70

<input type="checkbox"/>	Status	Document Name		Center	Type	File Size	Date
<input type="checkbox"/>	Delivered	<a href="#">FDA Manage Form 3538.pdf</a>	Receipt 2 Acknowledgements	CVM	Electronic_Submissions	174 KB	Apr 3rd 2018, 6:20:29 pm
<input type="checkbox"/>	Delivered	<a href="#">DM PP ZAOT OMUMS eSub011118 sub13.zip</a>	Receipt 2 Acknowledgements	CVM	eSubmitter	1 MB	Jan 11th 2018, 8:07:15 am
<input type="checkbox"/>	Delivered	<a href="#">DM PP ZAOT OMUMS eSub011118 sub12.zip</a>	Receipt 2 Acknowledgements	CVM	eSubmitter	1 MB	Jan 11th 2018, 8:07:15 am
<input type="checkbox"/>	Delivered	<a href="#">DM PP ZAOT OMUMS eSub011118 sub11.zip</a>	Receipt 2 Acknowledgements	CVM	eSubmitter	1 MB	Jan 11th 2018, 8:07:14 am
<input type="checkbox"/>	Delivered	<a href="#">DM PP ZAOT OMUMS eSub011118 sub10.zip</a>	Receipt 2 Acknowledgements	CVM	eSubmitter	1 MB	Jan 11th 2018, 8:07:05 am
<input type="checkbox"/>	Delivered	<a href="#">DM_MIFS_T_ZH-EL_Accept_M.zip</a>	Receipt 2 Acknowledgements	CVM	eSubmitter	2 MB	Jan 11th 2018, 7:42:46 am

Click on the document name in the sent items to view the document's receipt, acknowledgements, and details.

# ESG Gateway Receipt

Document Details ×

[> Acknowledgement](#)

[∨ Receipt](#)

---

**File Name:** Receipt for FDA Manage Form 3538.pdf.txt

**Status:** Delivered

**Date:** Apr 3rd 2018, 6:20:30 pm

**File Size:** 2 KB

**Submission Message Id:** <2129682351.4.1522794029777@CVL0181901>

**Sender:** [FDATST](#)

**Recipient:** [FDA CVM - WC](#)

[> Sent Details](#)



**Initial Receipt from the Gateway - Click to see details**

**Click Download icon to download a copy of the receipt**

**Click View document icon to view receipt**

Close

Document Content ×

[← Go back to details](#)

---

Date: Tue, 03 Apr 2018 22:20:31 GMT  
From: esghelpdesk@fda.hhs.gov  
Message-Id: <1522794030974.296326@nUITjJo1LmuePPIb4kY=>  
Subject: WenminChenWebTrader;ZZFDATST  
MIME-Version: 1.0  
Content-Type: multipart/signed; boundary="====\_Part\_1521\_790348646.1522794030975"; protocol="application/pkcs7-signature"; micalg=sha1  
EDIINT-Features: CEM  
X-Cyclone-From: ZZFDATST  
X-Cyclone-To: WenminChenWebTrader  
Content-Length: 2543

# ESG Acknowledgement #1

Document Details ✕

---

▼ Acknowledgement

---

**File Name:** ci1522794030466.296298@fdsuv05650\_te1.pdf  
**Status:** Delivered ↓  
**Date:** Apr 3rd 2018, 6:24:54 pm  
**File Size:** 217 KB  
**Submission Message Id:** <2129682351.4.1522794029777@CVL0181901>  
**Sender:** [FDATST](#)  
**Recipient:** [FDA CVM - WC](#)

---

**File Name:** ci1522794030466.296298@fdsuv05650\_te1.txt  
**Status:** Delivered 📄 ↓ 🖨️  
**Date:** Apr 3rd 2018, 6:24:26 pm  
**File Size:** 267 bytes  
**Submission Message Id:** <2129682351.4.1522794029777@CVL0181901>  
**Sender:** [FDATST](#)  
**Recipient:** [FDA CVM - WC](#)

> Receipt

---

> Sent Details

**Opening the first submission acknowledgment – click on the first Acknowledgment link**

**Click View document icon to view acknowledgment**

**This is the Unique Identifier assigned to your transmission**

Document Content ✕

---

← [Go back to details](#)

---

MessageId: <2129682351.4.1522794029777@CVL0181901>  
 CoreId: ci1522794030466.296298@fdsuv05650\_te1  
 DateTime Receipt Generated: 04-03-2018, 18:23:34

"The date and time stamp contained in this message conveys when Electronic Submission Gateway received your submission."

Close

This first acknowledgment informs the submitter that the submission has been transferred to CVM's ESS

# ESG Acknowledgement #2

Document Details ×

---

▼ Acknowledgement

---

**File Name:** ci1522794030466.296298@fdsuv05650\_te1.pdf

**Status:** Delivered ↓

**Date:** Apr 3rd 2018, 6:24:54 pm

**File Size:** 217 KB

**Submission Message Id:** <2129682351.4.1522794029777@CVL0181901>

**Sender:** [FDATST](#)

**Recipient:** [FDA CVM - WC](#)

---

**File Name:** ci1522794030466.296298@fdsuv05650\_te1.txt

**Status:** Delivered 📄 ↓ 🖨

**Date:** Apr 3rd 2018, 6:24:26 pm

**File Size:** 267 bytes

**Submission Message Id:** <2129682351.4.1522794029777@CVL0181901>

**Sender:** [FDATST](#)

**Recipient:** [FDA CVM - WC](#)

---

> Receipt

---

> Sent Details

**Click Download icon to view second acknowledgement**

Viewing the second acknowledgement (CVM ESS response) depends on the type of submission

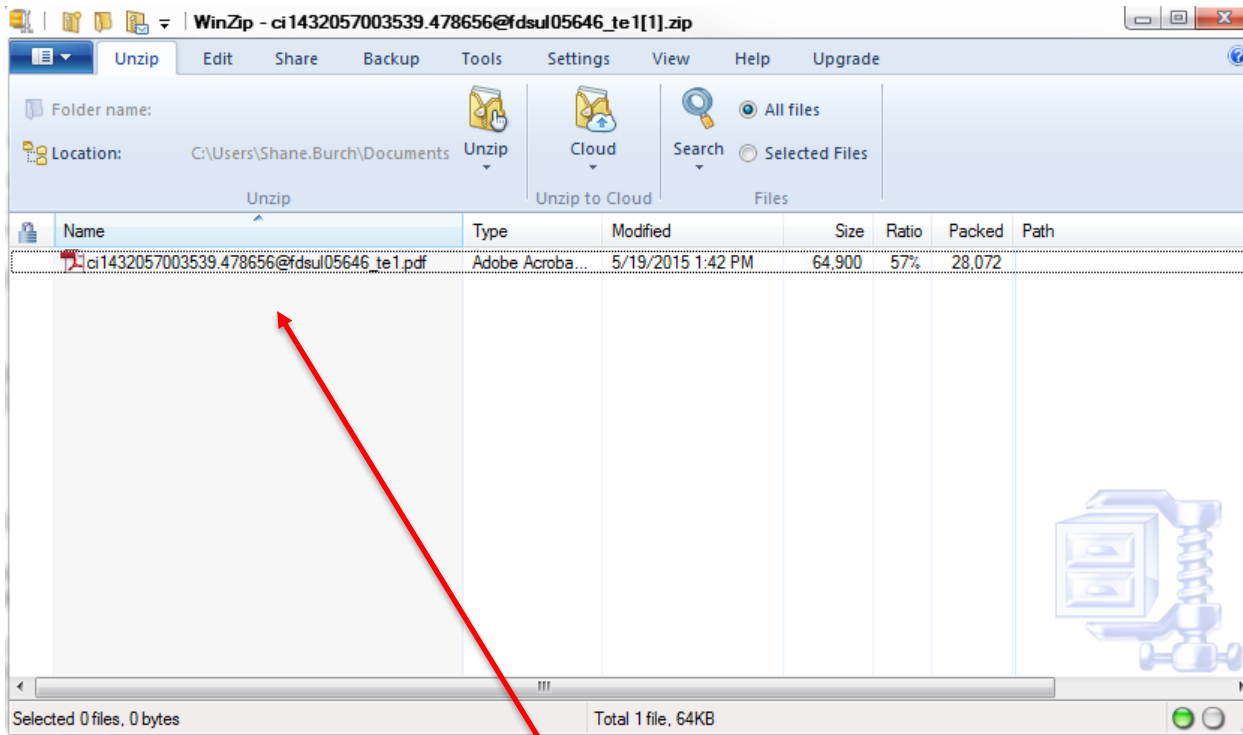
**Manage Form:** PDF document

**Adverse\_Events\_Reports :** Text document (Can be viewed in browser or downloaded and opened with standard text editor such as notepad)

**eSubmitter :** requires you to open a ZIP file to view PDF

**Please note:** You may need a third party compression tool such as WinZip or 7-Zip to open the file.

# ESG Acknowledgement #2 Continued...



**If your acknowledgement is a zip file, you will need a third party compression tool such as WinZip or 7-Zip to open the file. Once open, you will find the ESS Sponsor Notification form – Clicking the filename will open the Sponsor Notification PDF.**



# CVM Digital Signature on Sponsor Notification

The screenshot shows the Adobe Acrobat Professional interface. The main window displays a document titled "[Signature Validation.pdf]". On the left sidebar, the "Signatures" tab is active. The document content includes the Department of Health & Human Services logo, a date, recipient information, and a memo. A "Document Status" dialog box is open, displaying the following information:

**Document Status**

This document has special status or special features.

**Document Status**

Certification VALID.

This document was Certified with the Digital Signature of:

- Name: CVM ESS II Signee
- Organization: Center for Veterinary Medicine
- Issued by: CVM ESS II Signee

The Digital Signature is valid and the document has not been subsequently tampered with.

Click 'Signature Properties' to view more information about the signature and its validity. Reliance upon this Certified document requires your acceptance of the terms described when you click 'Legal Notice'.

To access signature information later, open the Signatures Tab on the left, select the Certifying Signature and choose 'Properties' from the Options menu.

Do not show this dialog next time this document is opened.

Document Status icons are always located at the bottom-left corner of the document window. Click a Document Status icon to view this dialog again.

Buttons: Legal Notice..., Signature Properties..., Close

Opening the PDF file you will be shown the following screen stating that CVM has digitally signed the Sponsor Notification Document

Clicking the Signature Properties will show you the next Screen

# CVM Digital Signature on Sponsor Notification Continued...



# CVM ESS Sponsor Notification Form

**This is the ESS Sponsor Notification form. Notice that the form will be used for both submission rejections and acceptances.**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Date: 05/19/2015  
To: Submitter  
Subject: FDA CVM EDSR – User Submission Notification

The Center for Veterinary Medicine, Food and Drug Administration acknowledges the receipt of your eSubmitter submission to the FDA CVM Electronic Submission System. The following information documents the state of your submission. If you have any questions, please submit an email detailing your questions to [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov).

**Memo:**

Your submission has been rejected. The manifest.xml can't be read.

CVM Received Date:	05/19/2015		
Transmission Identifier:	ci1432057003539.478656@fdsul05646_te1		
Submission Identifier:		Review Division:	
Firm Name:			
Established Drug Name(s):			
Submitted Document Type:			
Submission Type:			
Correspondence Date:		CVM Due Date:	
Parent Submission:		Reference Submission:	


# CVM ESS Sponsor Notification Form Continued...

Notes:

Stakeholder Receipt (EDSR) 5.1

Digital Signature:

Document Certified by CVM ESS II Signee.  
Digitally signed by CVM ESS II Signee  
Date: 2007.05.15 12:50:17 EDT  
Reason: I am the author of this document





**This is the bottom of the Stakeholder Notification Receipt.  
Notice that it is Digitally Signed.**

# Definitions

## **FDA ESG**

The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review.

The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office.

## **CVM ESS**

The Center for Veterinary Medicine (CVM) Electronic Submissions System (ESS) is a center-wide solution for accepting electronic regulatory submissions. This system is used to accept electronic submissions for animal and veterinary products.

