

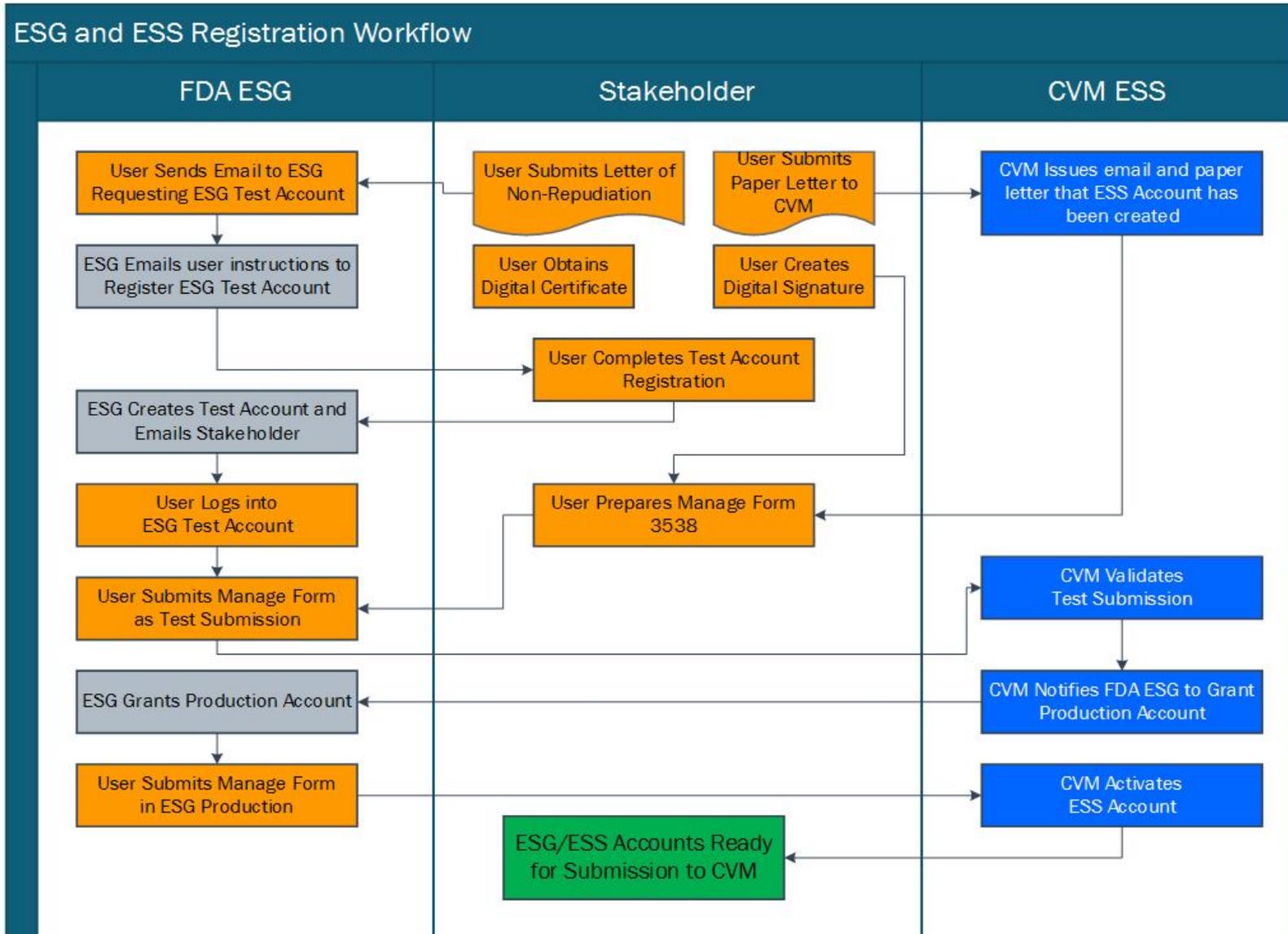
CVM Electronic Submission System (ESS)

- ▶ Steps for Submitting Electronically to CVM:
 1. [Registration Workflow](#)
 2. [How to Register with the CVM ESS](#)
 3. [CVM ESS Manage Form](#)
 4. [Submitting Your Digital Signature Using the CVM ESS Manage Form](#)

- ▶ [Using FDA ESG WebTrader](#)

**See page 20 for definitions*

Registration Workflow





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.



How to Register with the CVM ESS

- Mail 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

- Registration Letter must include:
 - a. names, mailing addresses, phone numbers, and emails of Coordinators & Stakeholders
 - b. subject line should be **Registration Letter for Electronic Submission to CVM**
- CVM will respond once the registration process is complete.
- Please contact CVM if you haven't received a response within 30 days
 - CVM ESS Hotline: 240-402-7062.

CVM ESS Manage Form (Form FDA 3538)

- Before submitting your Manage Form, you will need a valid digital signature.
 - Digital Signature Guide: <https://www.fda.gov/downloads/forindustry/fdaesubmitter/ucm403780.pdf>
- Manage Form: <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM061970.pdf>



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:	skenneth@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=Program,
o=62342-18200000-100-1-1-00003911
75, cn=Kenneth S. Burch -S
Date: 2015.04.21 12:25:01 -0400

The Manage Form is used to:

1. Register, Delete, and Change Stakeholder information in CVM’s ESS, or
2. Validate a stakeholder’s Digital Signature

*Submit your Manage Form as your guidance-compliant, test submission. CVM will validate your form as compliant and request that FDA ESG grant you a FDA ESG Production account. Resubmit your Manage Form using your ESG Production account to activate your CVM ESS Account.

*NOTE: 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

Guidance	Export Data	Import Data	Reset Form
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine		Electronic Submission System Participant Management Form Form Approved: OMB No. 0810-0464 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 8 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
- Acknowledgement from CVM ESS regarding your coordinator and stakeholder registration

Steps:

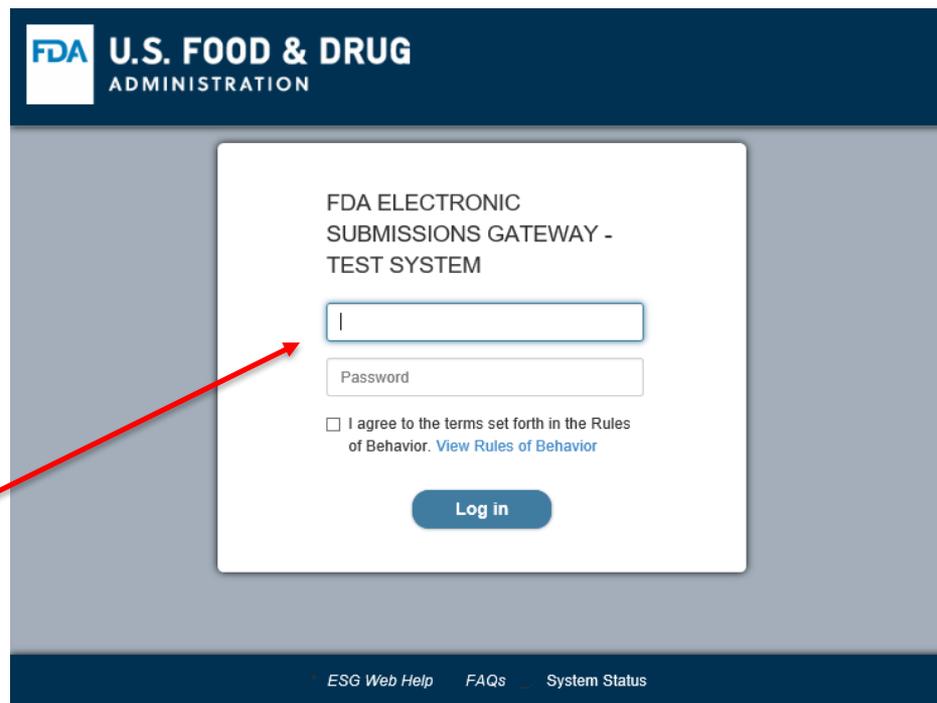
1. Complete Section II of the Manage Form and Sign using your Digital Signature
2. Submit your signed Form using your ESG Test (Choose **CVM** as the Center and **Electronic_Submissions** as the Submissions Type)
3. CVM will verify your test submission is compliant
4. CVM will notify FDA ESG to have an ESG Production account granted for you.
5. FDA ESG will notify you regarding your Production account creation
6. Submit your signed form using your ESG Production to activate your CVM ESS account.
*This must be done for all coordinators and stakeholders to activate their accounts.

FDA ESG WebTrader - 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 ESG WebTrader - 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 U.S. FOOD & DRUG ADMINISTRATION

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


<

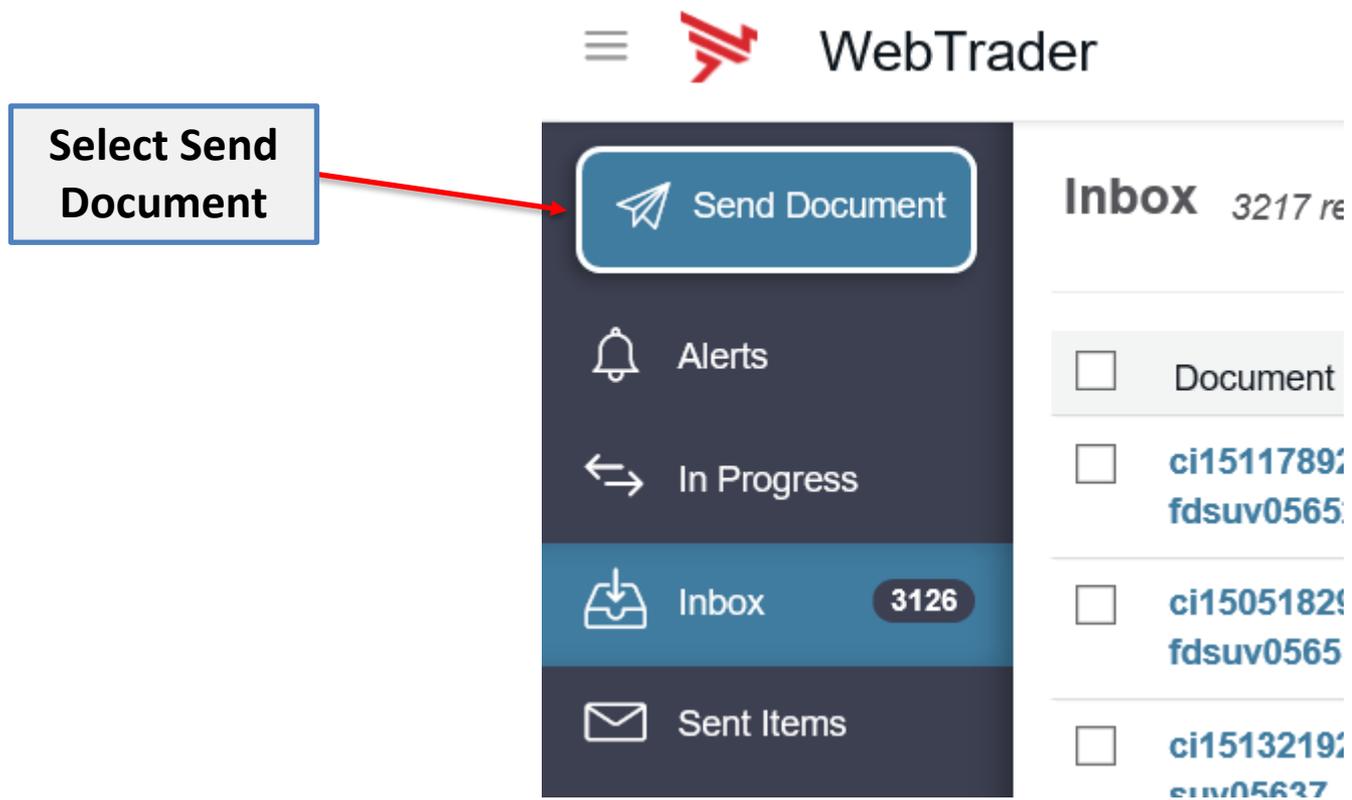
1

of 215
>

<input type="checkbox"/>	Document Name	Sender	Recipient	Date ▼	File Size	Type
<input type="checkbox"/>	ci1511789233083.576103@fdsuv05652_te1.zip	FDATST	FDA CVM - WC	Mar 28th 2018, 10:29:34 am	2 MB	Acknowledgement
<input type="checkbox"/>	ci1505182977857.166149@fdsuv05651_te1.zip	FDATST	FDA CVM - WC	Feb 5th 2018, 12:56:56 pm	10 MB	Acknowledgement
<input type="checkbox"/>	ci1513219282610.3985@fdsuv05637_te1.zip	FDATST	FDA CVM - WC	Jan 26th 2018, 4:47:37 pm	102 KB	Acknowledgement
<input type="checkbox"/>	ci1513219282610.3985@fdsuv05637_te1.zip	FDATST	FDA CVM - WC	Jan 26th 2018, 4:42:06 pm	101 KB	Acknowledgement
<input type="checkbox"/>	ci1513219282610.3985@fdsuv05637_te1.zip	FDATST	FDA CVM - WC	Jan 26th 2018, 4:30:13 pm	102 KB	Acknowledgement
<input type="checkbox"/>	ci1513204715170.364935@fdsuv05649_te1.zip	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 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, containing the following items: 'Send Document' (highlighted with a blue rounded rectangle and a red arrow pointing from a callout box), 'Alerts' (with a bell icon), 'In Progress' (with a double-headed arrow icon), 'Inbox' (with a folder icon and a badge showing '3126'), and 'Sent Items' (with an envelope icon). To the right of the sidebar, the main content area shows an 'Inbox' with '3217 re' (likely records). Below this, there is a list of document entries, each with a checkbox and text: 'Document', 'ci1511789% fdsuv0565', 'ci1505182% fdsuv0565', and 'ci1513219% suv05637'.

WebTrader – Send Document Screen

WebTrader

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

Send Document

Routing Information

Recipient: FDATST

*Center:

*Submission Type:

Document Selection

*Documents: [+ Add documents](#)

Document Signing

*Signing Certificate: [Select a certificate](#)

Certificate Password:

[Send](#)

[Reset](#)

System you are logged into. FDA ESG Test or Production

Select CVM Center

Select Electronic_Submissions

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

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

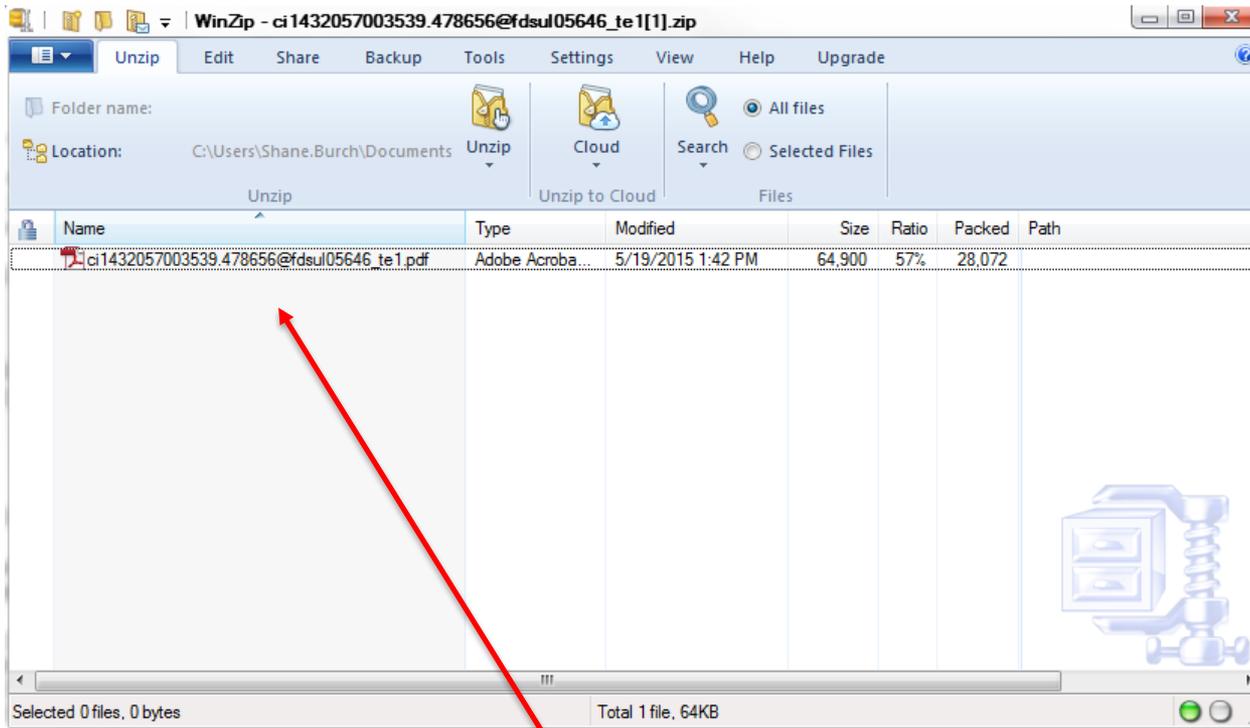
Electronic_Submissions : PDF document

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 header. A 'Document Status' dialog box is open, providing details about the digital signature. The dialog box contains the following text:

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...

Signature Properties

Document Certification is valid, signed by CVM ESS II Signee.

Summary Document Signer Date/Time Legal

Signed by: CVM ESS II Signee [Show Certificate...](#)

Reason: I am the author of this document

Date: 2007/05/15 12:50:17 -04'00' Location: Not available

Validity Summary

-  The document has not been modified since it was certified.
-  The Signer's Identity was valid when it was issued, but no revocation checks could be made to validate the identity at this time.
-  Signature date/time are from the clock on the Signer's computer.

Signature was created using Adobe Acrobat.

[Verify Signature](#) [Close](#)

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.

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 Submission 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.

