

Registering with CVM's Electronic Submission System

Guidance for Industry

*This version of the guidance replaces the version made available in December 2015.
This document has been revised to update submission and registration information.*

Submit comments on this guidance at any time. Submit electronic comments to <https://www.regulations.gov/>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All written comments should be identified with the Docket No. FDA-1992-S-0039.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <https://www.fda.gov/AnimalVeterinary/default.htm> or <https://www.regulations.gov/>.

**U.S. Department of Health and Human Services
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Table of Contents

| | | |
|------|---|----|
| I. | INTRODUCTION | 3 |
| II. | COMMUNICATION BETWEEN CVM AND STAKEHOLDERS..... | 3 |
| III. | REGISTERING WITH THE CVM ELECTRONIC SUBMISSION SYSTEM..... | 4 |
| A. | Stakeholder Registration..... | 4 |
| B. | CVM ESS Registration Form (Manage form)..... | 4 |
| C. | Submitting a Digital Signature | 5 |
| D. | Adding, Deleting, or Changing Stakeholders | 5 |
| E. | Adding or Deleting a Coordinator or Changing an Email Address..... | 6 |
| IV. | PROCESSING PROCEDURES FOR ELECTRONIC SUBMISSIONS | 6 |
| A. | FDA Electronic Submissions Gateway Information and Communication..... | 6 |
| B. | Registering with the FDA ESG | 7 |
| C. | FDA ESG Email Address Policy..... | 7 |
| D. | Digital Signatures | 7 |
| E. | Configuring Adobe Acrobat for CVM ESS Digital Signatures | 7 |
| F. | Adding a Digital Certificate to Adobe Acrobat..... | 8 |
| G. | Applying a Digital Signature to the CVM ESS Manage form | 8 |
| H. | Sending Manage Forms to FDA CVM using the FDA ESG..... | 9 |
| I. | Electronic Response Messages from FDA | 10 |
| J. | Verifying FDA CVM's Digital Signature | 11 |
| V. | SECURITY MEASURES FOR ELECTRONIC SUBMISSIONS..... | 11 |
| A. | Disclosure/Non-Disclosure..... | 12 |
| B. | Confidentiality of the Information in Electronic Submissions..... | 12 |
| C. | Authentication Verification | 12 |
| D. | Digital Signature..... | 12 |
| E. | Verification of the Sender's Identity..... | 12 |
| F. | Verification of Date of Submission | 12 |
| G. | Submission Integrity..... | 13 |
| VI. | CHECKLIST FOR REGISTERING WITH CVM ESS..... | 13 |
| VII. | HELP..... | 14 |
| | APPENDIX 1 - Example of Registration Letter..... | 15 |
| | APPENDIX 2 - CVM ESS Registration Workflow | 16 |
| | APPENDIX 3 - FDA ESG Registration Workflow | 17 |

Registering with CVM's Electronic Submission System

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides general standards which should be used to register with the Center for Veterinary Medicine (CVM or the Center) Electronic Submission System (ESS).

The Center's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures regulation, 21 CFR part 11. The CVM ESS registration form and guidance is published in the Electronic Submissions Docket No. FDA-1992-S-0039 (<https://www.regulations.gov/>).

The Electronic Records; Electronic Signatures regulation (21 CFR part 11) requires that the Agency identify in the Electronic Submission Docket the types of documents or parts of documents acceptable for official electronic submission.

This guidance implements provisions of the Government Paperwork Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681 (1998), which requires that executive agencies, by October 21, 2003, provide: (1) for the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures when practicable.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. COMMUNICATION BETWEEN CVM AND STAKEHOLDERS

Successful electronic submission of information for review and evaluation using the FDA ESG requires a successful partnership between CVM and regulated industry. Information needs to be exchanged and errors need to be resolved. The Center has set up a hotline to resolve any problems and questions (240-402-7062). The stakeholder should identify at least one person to be the Coordinator who will be responsible for communication with the Center.

III. REGISTERING WITH THE CVM ELECTRONIC SUBMISSION SYSTEM

A. Stakeholder Registration

Stakeholders wishing to register with the CVM ESS should send an original, signed paper registration letter to CVM. The registration letter should identify:

- The name, mailing address, phone number, and email address of the Coordinator(s) [CVM recommends more than one coordinator];
- The name, mailing address, phone number, and email address for each stakeholder who will be submitting information electronically; and
- The subject of the letter should be **Registration Letter for Electronic Submission to CVM** to clearly identify the purpose of the letter.

The Center will send two acknowledgements to the stakeholder: (1) a paper acknowledgement of the registration letter stating that the stakeholder appears able to send compliant electronic submissions compatible with CVM's current technology, and (2) an email acknowledgement to each registered stakeholder with an email copy to their company Coordinator requesting stakeholders submit their digital signature. If the coordinator has not received both of the acknowledgements within 30 days, contact CVM by calling the CVM Electronic Submissions Hotline at 240-402-7062.

The Coordinator and all stakeholders must submit their digital signatures once they are registered. To submit a digital signature, complete Section II – Digital Signature Validation on the Manage form and submit it through the FDA ESG.

B. CVM ESS Registration Form (Manage form)

CVM has created an Agency- and OMB-approved electronic registration form (Manage form) for stakeholder use. The Manage form is the only registration form that the CVM ESS accepts for the Office of New Animal Drug Evaluation's (ONADE), the Office of Surveillance and Compliance's (OSC) Division of Animal Feeds (DAF) and Division of Surveillance (DS), and the Office of Minor Use and Minor Species Animal Drug Development's (OMUMS) submissions processing. The version of the Manage form must be Adobe Acrobat version 10.x or greater. Any version less than 10.x will be rejected and not processed. The Manage form can be found on the CVM Electronic Submissions Page at <https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm>.

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| FDA Form Number | Form Name | Guidance Document |
|------------------------|--|---|
| 3538 | Electronic Submission System Participant Management Form | Registering with CVM's Electronic Submission System |

C. Submitting a Digital Signature

After receiving the paper and electronic acknowledgements, each registered stakeholder must provide a digital signature (created by using Adobe[®] Acrobat[®]'s self-signing process) by submitting form FDA 3538 (Electronic Submission System Participant Management Form, also known as the Manage form). Each stakeholder must:

- fill out Section II of the Manage form (form FDA 3538).
- digitally sign the Manage form using Adobe Acrobat.
- submit the signed Manage form through the FDA ESG.

D. Adding, Deleting, or Changing Stakeholders

The Coordinator may **add** or **delete** stakeholders to the CVM ESS by using Manage form. The Coordinator should fill out all required fields in Section I of the Manage form for the changes requested. Only Coordinators are able to add or delete other stakeholders in their companies.

To add or delete stakeholder, Coordinators must complete Section I – Registration/Information on the Manage form by checking the radio buttons “*Add*” or “*Delete*.” Select the “*Validate*” button to confirm the require fields are completed. Select the “*Save*” button to save the form. Select the “*Signature*” button to add the Coordinator’s digital signature. Submit the form through the FDA ESG. Please be aware that the added Stakeholders must submit their own Manage forms signed with their digital signatures to activate their ESS accounts, as well as make sure they have registered for their own FDA ESG accounts.

Stakeholders also may **change** his/her own stakeholder information by using the Manage form. Please note that stakeholders may only change his/her own stakeholder information.

To change a stakeholder’s information (except for changing an email address), stakeholders must complete Section I – Registration/Information on the Manage form by checking the radio button “*Change*.” Complete the fields to be changed. Select the “*Validate*” button to confirm the require fields are completed. Select the “*Save*” button to save the form. Select the “*Signature*” button to add the Coordinator’s digital signature. Submit the form through the FDA ESG.

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E. Adding or Deleting a Coordinator or Changing an Email Address

To add or delete a Coordinator or to change an email address, send a single, original, signed change letter to CVM. The letter should list the changes to be made. The subject line of the letter should be **Change for ESS Stakeholders** to clearly identify the purpose of the letter.

IV. PROCESSING PROCEDURES FOR ELECTRONIC SUBMISSIONS

Information submitted to CVM through the FDA ESG should adhere to minimum standards to ensure confidentiality, integrity, security, and authenticity. CVM can process only submissions that comply with the Electronic Records; Electronic Signatures regulation. In addition, registration procedures described in this guidance take into consideration the current information technology capabilities of CVM. Adherence to these standards is verified by the CVM ESS processing, and generally only submissions in full compliance can be successfully processed as electronic submissions. If stakeholders wish to use a different approach, they should discuss it first with CVM.

Each transmission of an electronic submission will be acknowledged with a receipt issued within 2 Government business days from CVM confirming the submission was successfully processed, after the two standard responses from FDA ESG. If stakeholders do not receive an acknowledgement from CVM within 2 business days, please contact CVM.

A. FDA Electronic Submissions Gateway Information and Communication

The Agency has established the FDA Electronic Submissions Gateway (FDA ESG) for accepting electronic regulatory submissions. The FDA ESG enables the submission of regulatory information for review. The overall purpose of the FDA ESG is to provide a centralized, Agency-wide communications point for securely receiving electronic regulatory submissions. The FDA ESG enables the FDA to process regulatory information through automated mechanisms while it enables:

- A single point of entry for the receipt and processing of all electronic submissions in a highly secure environment;
- Automation of the current electronic processes such as the electronic acknowledgments of submissions; and
- Support of the electronic standards of FDA regulated submissions.

The electronic submission process is defined as the receipt, acknowledgment, routing, and notification to a receiving Center of the receipt of an electronic submission by the FDA ESG. In this definition:

- “Receipt” means transfer of a submission from a sender’s system to a temporary storage area in the FDA ESG.
- “Acknowledgment” to the sender means that the submission was sent from the sender’s system and received by the FDA ESG.

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- “Routing” refers to delivering a submission to a Center-level storage area and initiating a load process to place a submission into a Center receiving system.
- “Notification” of a submission’s arrival is made to those individuals responsible for the Center’s receiving system.

Each of these terms denotes a step in the process of electronic submission delivery, and together, these steps comprise the whole scope of electronic submission delivery.

The FDA ESG is a conduit, or “highway,” along which submissions travel to reach their final destination. It does not open or review submissions; it merely routes them to the proper destination.

The FDA ESG uses a software application certified to comply with secure messaging standards.

B. Registering with the FDA ESG

The registration processes and procedures to use the FDA ESG are separate and distinct from the CVM ESS registration processes. Stakeholders must register with the FDA ESG using the FDA ESG registration process. Access to the FDA ESG documentation can be found at: <https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

C. FDA ESG Email Address Policy

Please refer to the FDA ESG e-mail address requirements found here: <https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm176341.htm>

D. Digital Signatures

The Manage form has a location for stakeholders’ digital signatures that becomes activated when the ‘Signature’ command button is pressed on the form. When the Adobe digital signature process is invoked by applying your digital signature, you are certifying that you attest to the contents of the form.

A critical piece of the digital signature is your registered email address, which is contained in the ‘Contact Information’ field. This email address must match the email address that was registered with the CVM ESS. **If the email addresses do not match, your submission will be rejected and it will not be processed.**

E. Configuring Adobe Acrobat for CVM ESS Digital Signatures

This section documents the configuration procedures that each CVM ESS stakeholder must accomplish before sending submissions to FDA CVM for those stakeholders required to register with the CVM ESS.

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1. Configuration of Identify Information – In Adobe Acrobat you must fill out the required information regarding your identity. You must pay strict attention to the email address that you enter. Please make sure that the entered email address matches the email address that the CVM ESS has registered for you. For more information regarding identity configuration please visit Adobe’s website here: <https://helpx.adobe.com/support.html>
2. Configuration of Digital Signatures -- In Adobe Acrobat you will need to add a new Digital Signature configuration. You must supply a title to the signature configuration. Make sure that in the ‘*Configure Text*’ area that all options are checked. For more information regarding digital signatures please visit Adobe’s website here: <https://helpx.adobe.com/support.html>

F. Adding a Digital Certificate to Adobe Acrobat

In order to apply a digital signature to any CVM ESS Form, you must have added a valid digital certificate to the Adobe Digital ID library. Information regarding digital certificates can be found on Adobe’s website here: <https://helpx.adobe.com/support.html>.

G. Applying a Digital Signature to the CVM ESS Manage form

The CVM ESS registration procedure requires that you digitally sign your Manage form. The following text documents how you apply a digital signature to the CVM ESS Manage form.

When you press the ‘*Signature*’ command button a signature box will be presented and to sign the form you need to click inside the magenta signature box. After clicking inside the signature box the ‘*Apply Signature to Document*’ dialogue box is presented. The information within the dialogue box needs to be verified before applying the digital signature to the form. The following needs to be verified in the signature details box:

1. The ID being shown is the correct Digital ID.
2. The certificate password has been entered in the ‘*Confirm Password*’ field.
3. A reason for signing has been selected in the ‘*Reason for Signing*’ field.
4. The ‘*Option*’ section is visible
5. The Digital Signature the user created within ‘Section G - Digital Signatures’ is visible in the ‘*Signature Appearance*’ field within the ‘*Option*’ section.
6. The correct email address that you registered with CVM is displayed in ‘*Your Contact Information.*’

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If all of the above information is correct and all of the steps have been completed you should now press the ‘Sign’ button. Note, once you sign the document and save it you will no longer be able to modify the Manage form nor will you be able to export data from the form.

H. Sending Manage Forms to FDA CVM using the FDA ESG

After you have completed filling out and applied your digital signature to the Manage form, you must submit your form to CVM to activate your CVM ESS account to complete your registration. Once you receive notification from CVM that your account has been activated, you can begin sending in electronic submissions to CVM using the FDA ESG.

CVM ESS allows Coordinators to group multiple Manage form submissions into a single FDA ESG transmission. Coordinators also have the option of sending an individual Manage form per transmission or sending a group of Manage forms with a single transmission. Note: Because of FDA ESG technical reasons, CVM recommends stakeholders always send in Manage forms using the ‘Send directory’ method of transmission. Use this method even if you are sending a single Manage form submission.

The following are the steps that you are required to accomplish to use the WebTrader[©] component of the FDA ESG. Please refer to the following URL to view actual screenshots to aid in sending your Manage form to FDA: FDA Gateway Submission and Receipts – <https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/Electron%20icSubmissions/UCM448692.pdf>.

1. Open your web browser and enter in the following URL: <https://esg.fda.gov/>
2. Enter in your assigned FDA ESG User ID.
3. Enter in your assigned FDA ESG Password.

Note: The FDA ESG User ID and Password are both case sensitive.
4. Click the terms agreement button.
5. Click the ‘Login’ button
6. After logging in you will be presented with your ‘Inbox.’ You can check for past submissions and move/copy or delete messages from the ‘Inbox.’
7. To send a transmission to FDA navigate the cursor to the WebTrader menu tab and select ‘Send Document.’
8. After you are presented with the ‘Send Document’ screen proceed with the next steps.

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9. On the 'Center:' pull down select 'CVM.'
10. On the Submission 'Type:' pull down list and select 'Electronic Submissions' to submit your Manage form(s).
11. On the 'Path:' textbox user may click on the 'Browse' button then navigate to the submission file or a directory where the submission exists, or type in the full path to file or directory of the submission in that text box.

Note: for Manage Form submission, we recommend that you use the directory submission method even if you are sending a single submission.

12. If this is the first time you have made a transmission to FDA ESG, you must browse for your digital certificate that is stored on your system. This certificate must be verifiable by the FDA ESG. Select the certificate that you want to apply to this transmission. If you have already sent a successful transmission to FDA ESG, you do not need to select a certificate again as the WebTrader software will remember your last selected certificate. You must enter your certificate password at this time.
13. Review all of the 'Send Document' screen information for correctness.
14. If all items have been verified and are correct then press the 'Send' button.
15. The WebTrader software will now package up your submission(s) for transmission.

Note: Do not close the browser window or attempt any other operation until the WebTrader software has completed. If you do interrupt the sending process your submission will not be received.

16. When the 'Upload Progress' screen indicates that the transmission is completed you may close the 'Upload Progress' window. You have completed the transmission process and you now can close the WebTrader browser and/or go on to other tasks.
17. The next section documents the messages that you will receive from the FDA ESG and the CVM ESS.

I. Electronic Response Messages from FDA

The FDA ESG will return at least two acknowledgements to you for each transmission you send to FDA. In addition to the Gateway acknowledgements you will receive a notification from the CVM ESS. Please refer to the following URL to view actual screenshots of returned acknowledgements: FDA Gateway Submissions and Receipts (<https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/UCM448692.pdf>). The messages will vary depending on what method you used to transmit the submission(s). In all cases you will receive three acknowledgements:

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1. The first acknowledgement will be a FDA Gateway Receipt Message Digest Notification (MDN). This acknowledgement message can be ignored as it has information that is unreadable using the WebTrader software. It is used for the Gateway-to-Gateway transmission method and not the WebTrader transmission method.
2. The second acknowledgement that you will receive occurs when the FDA ESG transfers the incoming transmission to the CVM ESS. This is the official receipt that the FDA has received your transmission. This receipt does not signify that your submission has been validated, accepted or reviewed by CVM.
3. The third acknowledgement you will receive will come in one of two formats. The acknowledgement format will depend on whether you sent in a single submission transmission or you sent in a multiple submission transmission.
 - a. If you sent in a single Manage form transmission, you will receive a single Adobe PDF file that details the processing of your submission. This receipt will indicate that your Manage form was either accepted or rejected with a processing error.
 - b. If you sent in multiple Manage forms transmissions, you will receive a Zip file that contains a number of PDF files. The number of files within the Zip file will directly relate to the number of Manage forms that you sent in your transmission. These individual receipts will indicate that your submission(s) were either accepted or rejected with a processing error.

Note: The Zip file that contains the stakeholder notifications will contain both accepted submissions and rejected submission notifications.

J. Verifying FDA CVM's Digital Signature

The CVM ESS applies a digital signature to each notification acknowledgement it transmits. This digital signature can be validated and trusted. Please refer to the following URL to view actual screenshots of FDA CVM's digital signature: FDA Gateway Submissions and Receipts (<https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/UCM448692.pdf>)

V. SECURITY MEASURES FOR ELECTRONIC SUBMISSIONS

Corporations have used the Internet as an expeditious vehicle for the exchange of information for several years. However, many corporations and government agencies have avoided using the Internet for the exchange of sensitive and/or confidential information because of concerns about security. In developing an electronic submission project using the Internet as the message-carrying vehicle, four areas of security should be addressed adequately by all participants prior to its adoption.

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A. Disclosure/Non-Disclosure

Information submitted to CVM is subject to the Freedom of Information Act and FDA's regulations on public information at 21 CFR parts 20 and 514. Some information, such as trade secrets, certain commercial and financial information is confidential in nature and is not to be disclosed. Therefore, using the Internet to submit confidential information can be done only with adequate encryption.

B. Confidentiality of the Information in Electronic Submissions

The CVM ESS will only accept digitally signed PDF files to protect the confidentiality of submitted information. The person submitting the electronic information should digitally sign the document.

C. Authentication Verification

Currently, CVM receives paper submissions from stakeholders by US Postal Service, Federal Express, United Parcel Service, etc. With these submissions, there is a cover letter on letterhead signed by an authorized stakeholder official. This information allows CVM to authenticate that the submission is from the stated stakeholder. Any electronic submission should also provide a means by which CVM can authenticate the origin of the electronic document, such as the digital signature.

D. Digital Signature

The registration letter should contain the name and email address for each authorized stakeholder. After the receipt of CVM's acknowledgment letter for the registration, each stakeholder should submit to CVM ESS a digital signature using the Manage form (form FDA 3538) as described in Section IV.I of this guidance. The digital signature will serve as the electronic signature under 21 CFR 11.200(a)(1) and will authenticate the identity of the sender. CVM will maintain a database of digital signatures and will automatically reject any electronic submission received that does not match the digital signature on file.

E. Verification of the Sender's Identity

An additional precaution will be taken to ensure that the submission received at CVM did indeed come from the stakeholder designated. CVM will acknowledge receipt of the electronic submission as described in Section IV.I. If a sender receives an acknowledgment but has not sent an electronic submission to CVM, he/she should immediately report this to CVM by telephone to 240-402-7062.

F. Verification of Date of Submission

Currently, time-sensitive information is submitted by certified mail so that the stakeholder has a record verifying the date and name of an individual who received the information at

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CVM. This also provides a legal basis by which stakeholders can assert their compliance with laws and regulations.

Currently, CVM uses the date of FDA ESG receipt (following successful CVM ESS validation) to determine whether information was submitted within the time required by statute or regulation.

G. Submission Integrity

The integrity of the content of a submission to CVM is the responsibility of the stakeholder. If sections of a paper submission are missing or illegible, CVM requires the stakeholder to provide copies of the missing or illegible information. A remote possibility exists that intentional or unintentional changes could be made to an electronic submission that could not be made to a paper submission. For example, unintentional "scrambling" of the submission may occur during transmission so that CVM receives a corrupted, unusable file.

CVM will rely on the digital signature of the PDF file to ensure the integrity of the electronic transmission. If the transmission is received by CVM intact and can be processed and opened by Adobe Acrobat, and CVM can verify via the digital signature that no changes occurred to the submission once it was submitted to the FDA ESG, then CVM will accept the transmission. If CVM receives a corrupted file and can identify who the sender is, CVM will notify the sender that its file was corrupted and the sender will be required to resubmit the file.

VI. CHECKLIST FOR REGISTERING WITH CVM ESS

To register for the CVM ESS, stakeholders should:

- Register with the FDA ESG
(<https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>)

Note: Please use the CVM Manage form as your ESG Test Submission.
(See Section IV for details.)

- Submit a registration letter to CVM (See Section III for details.)
- Download the CVM ESS Manage form (form FDA 3538) from the CVM Electronic Submissions page
(<https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm>) (See Section III for details.)
- Submit a digital signature to CVM using form FDA 3538 (See Section III for details.)

VII. HELP

While the CVM ESS system does not use email as the vehicle to accept submissions, email messages related to stakeholder registration or the CVM ESS can be sent to the following address:

CVMDUCU@FDA.HHS.GOV

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APPENDIX 1 - Example of Registration Letter

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

Subject: Registration Letter for Electronic Submission to CVM

Dear CVM ESS Administrator:

This letter notifies the Center for Veterinary Medicine (CVM) of our intent to electronically submit documents listed in the Electronic Submissions Docket No. FDA-1992-S-0039 using the FDA Electronic Submissions Gateway (ESG). An enclosure to this registration letter contains the name of the person who will serve as our Coordinator and the names of the persons who will be submitting electronic information, along with their mailing addresses, phone numbers, and email addresses for initializing the Electronic Submission System.

We have certified to the Food and Drug Administration, Office of Regional Operations (HFC-100), that the electronic signatures used to submit information on our behalf are intended to be the legally binding equivalent of traditional handwritten signatures.

We look forward to receipt of CVM's letter acknowledging our intent to submit information using the FDA ESG and stating that we appear to be able to make electronic submission that are compatible with CVM's current technology.

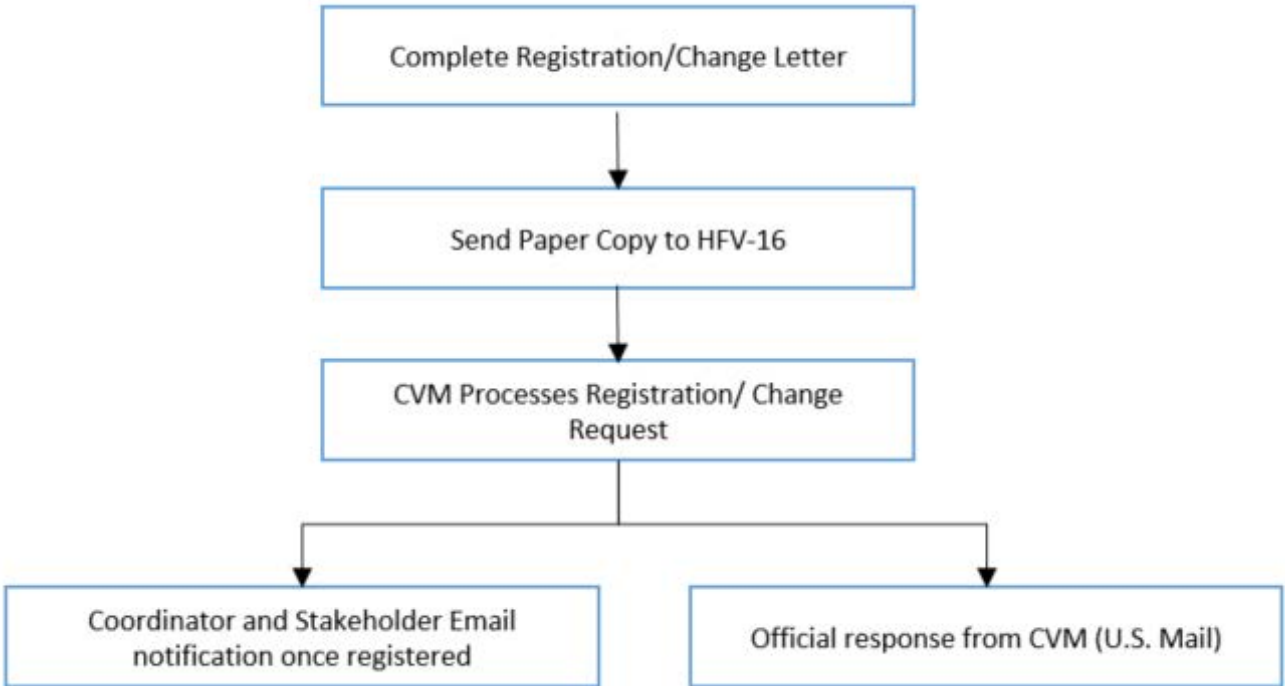
Sincerely yours,

/s/

Enclosure

APPENDIX 2 - CVM ESS Registration Workflow

**How to Register or Make a Change request for the CVM ESS
(Electronic Submission System)**



APPENDIX 3 - FDA ESG Registration Workflow

How to Register for the FDA ESG
(Electronic Submission Gateway)

