

Guidance for Industry

How to Submit Information in Electronic Format to CVM using the FDA Electronic Submission Gateway

(THIS VERSION OF THE GUIDANCE REPLACES THE VERSION MADE AVAILABLE IN JUNE 2007)

This guidance document is intended to provide instructions on how to submit information in electronic format to the Center for Veterinary Medicine (CVM or the Center) using the FDA Electronic Submission Gateway (ESG). The guidance was revised to update the phone number for the Electronic Document Control Unit and to replace the web site to submit electronic comments.

Comments and suggestions regarding this document should be sent to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the exact title of the document. Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Electronic submissions that follow this guidance will be compatible with CVM's current information technology capabilities. This will help ensure the confidentiality, integrity, security, and authenticity of data submitted to the Center. If a stakeholder wishes to use an electronic approach other than that set forth in this guidance document, the Center will, on request, discuss alternative methods of submitting information.

For questions regarding this document, contact Margaret Zabriski, Center for Veterinary Medicine (HFV-010), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9143, e-mail: margaret.zabriski@fda.hhs.gov.

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910-0454. The time required to complete this information collection is estimated to vary between 5 and 10 minutes per response, including the time to review instructions, search existing data resources, gather the necessary data, and complete and review the information collection.

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GUIDANCE FOR INDUSTRY¹

HOW TO SUBMIT INFORMATION IN ELECTRONIC FORMAT TO CVM USING THE FDA ELECTRONIC SUBMISSION GATEWAY (ESG)

This guidance represents the Agency's current thinking on how to submit information in electronic format to the CVM using the FDA ESG. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statute and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides general standards which should be used for the submission of any information in electronic format to the Center for Veterinary Medicine (CVM) using the FDA Electronic Submission Gateway (ESG).

FDA's guidance documents, including this guidance, does not establish legally enforceable responsibilities. Instead, guidance describing 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 guidance's means that something is suggested or recommended, but not required.

CVM'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 11. The Center will accept certain types of submissions through the FDA ESG with no requirement for a paper copy. The list of these submissions is published in the Electronic Submissions Docket No. 92S-0251 (available on the FDA Home Page, <http://www.fda.gov>).

The Electronic Records; Electronic Signatures regulation (21 CFR 11) requires that the Agency identify in the Electronic Submissions 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

¹ This guidance has been prepared by CVM at FDA. For additional copies, access the document on the Internet at the CVM Home Page (<http://www.fda.gov/cvm/default.html>) or send a request to the Communications Staff, HFV-12, 7519 Standish Place, Rockville, MD 20855.

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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.

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 (240-276-8584). The stakeholder should identify one person to be the Coordinator who will be responsible for communication with the Center.

III. REGISTRATION TO SEND ELECTRONIC SUBMISSIONS LISTED IN ELECTRONIC SUBMISSIONS DOCKET

A. Stakeholder Registration

Stakeholders wishing to submit information electronically should send a single, original, signed paper registration letter to CVM. In an enclosure with this letter, the stakeholder should identify:

- The name, mailing address, phone number, and e-mail address of the Coordinator;
- The name, mailing address, phone number, and e-mail address for each person 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.

An electronic copy of the registration letter should be sent by e-mail to cvmdcu@fda.hhs.gov with the subject line of the e-mail reading **REGISTER**. (See Section II - Communication between CVM and STAKEHOLDERS)

The Center will send acknowledgements to the stakeholder: (1) a paper letter acknowledging receipt of the registration and stating that the stakeholder appears to be able to make electronic submissions that are compatible with CVM's current technology, (2) after CVM successfully accesses and processes the electronic registration letter, an electronic receipt for the registration letter, by e-mail, to the Coordinator.

B. Using the Electronic Submission System (ESS)

After receiving the paper and electronic acknowledgements, the Coordinator and each person submitting electronic submissions must provide a digital

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signature by submitting FORM FDA 3538 (Electronic Submission System Participant Management Form)

- Each person must fill out section II of FORM FDA 3538.
- Each person must digitally sign the FORM FDA 3538.
- Each person must submit the signed FORM FDA 3538 via the FDA ESG.

C. Adding, Deleting, or Changing Stakeholders

The Coordinator may add or delete stakeholders to the ESS by using FORM FDA 3538

- The Coordinator should fill out all required fields in Section I of FORM FDA 3538 for the change requested

The Coordinator may change his/her own stakeholder information by using FORM FDA 3538. Please note that stakeholders may only change his/her own stakeholder information.

IV. PROCESSING PROCEDURES FOR ELECTRONIC SUBMISSIONS

Information transmitted 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, procedures described in this guidance take into consideration the current information technology capabilities of CVM. Adherence to these standards is verified by the Center's 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.

Sponsors should send each electronic submission as a PDF file (compatible with Adobe[®] Acrobat[®] version 6.0 or greater) via an FDA ESG transmission. Each transmission of a submission will be acknowledged with a number of receipts issued within two working days from CVM confirming the submission was successfully processed.

A. Gateway Information and Communication

The Agency has established a solution [referred to as 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 receiving electronic regulatory submissions, securely. The new Agency Gateway will enable 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.
- Automating current electronic processes such as the electronic acknowledgment of submissions.

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- Supporting 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. 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 that the submission was sent from the sender’s system and received by the Gateway.
 - “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 the central transmission point for sending information electronically to the FDA. Within that context, 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. Registration Procedures for Gateway Operations

The registration processes and procedures to use the Gateway are separate and distinct from CVM’s ESS registration processes. Stakeholders must register with the Gateway using the Gateway registration process. Access to the Gateway documentation can be found at the following URL: <http://www.fda.gov/esg>

C. Email Communication with CVM

While the ESS II system has migrated away from using Email as the vehicle to accept submissions there are cases where stakeholders can send an Email message to CVM. These Email messages must be addressed to the following address:

CVMDUCU@FDA.HHS.GOV

D. Subject Line of Email Message

The format of the Email must be formatted in the following manner.

1. The Email message must have a single word as the subject. The next table shows the allowable subject line words.

Subject Line	Type of Electronic Information
REGISTER	Electronic copy of registration letter specifying stakeholder's intent to submit

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	information electronically
CHANGE	Electronic notification of changes in conditions of registration

- Each submitted Email must have a single PDF file attached that details the instructions to CVM as to either a new stakeholder company registration or a change to an existing stakeholder registration.

E. CVM Created Adobe Forms (SmartForms)

CVM has created for stakeholder use a set of Agency and OMB approved electronic forms. These are the only forms that CVM's ESS accepts for submission processing. The version of the electronic forms must be version 5.x or greater. Any form version less than 5.0 will be rejected and not processed. The following table documents the forms for use with ESS. Each form has its own guidance document which can be found via the Guidance Document Link URL.

FDA Form Number	Form Name	Guidance Document Link
3458	Notice of Claimed Exemption	http://www.fda.gov/cvm/Guidance/guidance59.pdf
3487	Notice of Final Disposition of Animal Not Intended for Slaughter	http://www.fda.gov/cvm/Guidance/Guidance86.pdf
3488	Notice of Intent to Slaughter for Human Food Purposes	http://www.fda.gov/cvm/Guidance/fguide87.pdf
3489	Request for Meeting or Teleconference	http://www.fda.gov/cvm/Guidance/fguide88.pdf
3536	Protocol for Non-Clinical Laboratory and Effectiveness Studies	http://www.fda.gov/cvm/Guidance/fguide107.pdf
3538	Electronic Submission System Participant Management Form	http://www.fda.gov/cvm/Guidance/fguide108.pdf

The rest of this section documents common elements for all forms.

F. Digital Signatures

Each electronic SmartForm has a location for a stakeholder digital signature that becomes activated when the 'Signature' command button is pressed on the form. When the Adobe digital signature process is invoked by applying your electronic signature you are certifying that you attest to the contents of the form and attached documents.

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 you registered with CVM. If the Email addresses do not match your submission will be rejected and it will not be processed.

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G. Configuring Adobe Acrobat® for ESS II Digital Signatures

This section documents the configuration procedures that each ESS stakeholder must accomplish before sending submissions to FDA CVM. Please refer to the following URL to view actual screenshots to aid in your Adobe configuration:

<http://www.fda.gov/cvm/Documents/ESSAdobeConfiguration.pdf>

1. Configuration of Identify Information – In Adobe Acrobat under the ‘Edit’ command selection, navigate to the ‘Preferences’ screen and then navigate to the ‘Identify’ screen and then fill out the required information on that screen. 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 FDA CVM has registered for you.
2. Configuration of Digital Signatures -- In Adobe Acrobat under the ‘Edit’ command selection, navigate to the ‘Preferences’ screen and then navigate to the ‘Security’ screen. Select ‘New’ 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.

H. Adding a Digital Certificate to Adobe Acrobat

In order to apply a digital signature to FDA CVM ESS II SmartForm you must have added a valid digital certificate to the Adobe Digital ID library. The following steps will assist you in adding a digital certificate. Please refer to the following URL to view actual screenshots to aid in your Adobe configuration:

<http://www.fda.gov/cvm/Documents/ESSAdobeConfiguration.pdf>

In Adobe Acrobat select the ‘Advanced’ command menu option and then select ‘Security Settings ...’. You should see the screen ‘Manage My Digital IDs’. Press the ‘Add ID’ icon to either add a digital certificate or to generate an Adobe Self-Sign© certificate. Select the option that you want and proceed to either add an external certificate or to generate a self-sign digital certificate. After completing the Digital ID creation process you must select the certificate you just created and then select the ‘Set Default’ icon and then select the ‘For Signing’ default option. This will insure that this certificate will be the certificate used to apply your digital signature to FDA CVM’s SmartForms.

I. Applying a Digital Signature to an ESS SmartForm

ESS II procedure requires that you digitally sign your electronic submission. The following text documents how you apply a digital signature to an ESS II SmartForm. Please refer to the following URL to view actual screenshots to aid in applying your Adobe Digital signature using your version of Adobe Acrobat:

<http://www.fda.gov/cvm/Documents/ESSAdobeDigitalSignatures.pdf>.

Regardless of the version of Adobe Acrobat that you are using all of FDA CVM’s SmartForms act exactly the same 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

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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 - Configuring Adobe Acrobat® for ESS II 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*'.

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

J. Sending a Submission to FDA CVM using the FDA ESG

After you have completed filling out the FDA CVM SmartForm and applying your digital signature to the form you are now ready to send the submission using the FDA ESG.

ESS II allows you to group multiple submissions into a single ESG transmission. You also have the option of sending an individual submission per transmission or sending a group of submissions with a single transmission. Note: Because of FDA ESG technical reasons, it would be beneficial to both stakeholders and the FDA CVM ESS to always use the send directory method of transmission. Use this method even if you are sending a single 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 SmartForm submission(s) to FDA:

<http://www.fda.gov/cvm/Documents/ESSGatewaySubs&Receipts.pdf>

1. Open your web browser and enter in the following URL: <http://esg.fda.gov>
2. Enter in your assigned ESG User ID
3. Enter in your assigned ESG Password
Note: The 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*'.

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8. After you are presented with the '*Send Document*' screen proceed with the next steps.
9. On the '*Center:**' pull down select '*CVM*'.
10. On the '*Path: **' text area users may type in the location of the submission within the block or click on the '*Browse*' button and select the submission directory.
11. If you pressed the '*Browse*' button, then navigate to the submission file or a directory where the submission exists.
12. Make sure you have either selected a directory of submissions or a specific submission file. Note: we recommend that you always use the directory submission method even if you are sending a single submission.
13. After selecting what to transmit to FDA move to the Submission '*Type: **' pull down list and select '*Electronic Submissions*'.
14. If this is the 1st 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 you're last selected certificate.

15. Review all of the '*Send Document*' screen information for correctness.
16. If all items have been verified and are correct then press the '*Send*' button.
17. The WebTrader software will now package up your submission(s) for transmission. It will ask you for a certificate password which you must enter at this time. After entering in the password click the '*Ok*' button.
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.
18. 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.
19. The next section documents the messages that you will receive from the FDA ESG and FDA CVM's ESS.

K. Electronic Response Messages from FDA

The FDA ESG will return a number of messages to you for each transmission you send to FDA. In addition to the Gateway messages you will receive a message from FDA CVM's Electronic Submission System. Please refer to the following URL to view actual screenshots of returned messages: <http://www.fda.gov/cvm/Documents/ESSGatewaySubs&Receipts.pdf>. The messages will vary depending on what method you used to transmit the submission(s). In all cases you will receive the following messages:

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1. The first message will be a FDA Gateway Receipt Message Digest Notification (MDN). This message can be ignored as it has information that is unreadable via the WebTrader software. It is used for the Gateway-to-Gateway transmission method and not the WebTrader transmission method.
2. The 2nd message that you will receive is when the Gateway transfers the incoming transmission to the FDA CVM ESS. This is the official receipt that the FDA has received your transmission. This receipt does not signify that your submission(s) has been validated, accepted or reviewed.
3. The 3rd message you will receive will come in one of two varieties. The message format will depend on if you sent in a single submission transmission or you sent in a multiple submission transmission.
 - a. If you sent in a single submission transmission you will receive a single Adobe PDF file that details the processing of your submission. This receipt will indicate that your submission was either accepted for review or rejected with a processing error.
 - b. If you sent in a multiple submission transmission then 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 submissions that you sent in your transmission. These individual receipts will indicate that your submission(s) were either accepted for review or rejected with a processing error.

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

L. Verifying FDA CVM's Digital Signature

The FDA CVM ESS applies a digital signature to each notification message it transmits. This signature can be validated and trusted if you accomplish the following steps. Please refer to the following URL to view actual screenshots of FDA CVM's digital signature and the steps to validate the signature:

<http://www.fda.gov/cvm/Documents/ESSGatewaySubs&Receipts.pdf>

1. Using Adobe Acrobat open ESS notifications receipt PDF.
2. You will receive a 'Document Status' information window announcing the status of the PDF file.
3. You can check to properties of CVM's digital signature by clicking 'Signature Properties'.
4. You can check the legal notice and the certificate used to generate the signature by clicking 'Legal Notice'.
5. Selecting the 'Signatures' tab on the left side of the PDF document exposes all the information about the document and its status and digital signature information.

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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.

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. Protecting the Confidentiality of the Information in Electronic Submissions

The 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.

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.

Digital Signature

The registration letter should contain the name and e-mail address for each authorized stakeholder. Subsequent to the receipt of CVM's acknowledgment letter for the registration, each stakeholder should submit to CVM ESS a digital signature using 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.

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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.K. 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 240-276-8584.

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

Currently, CVM uses the date on the cover letter to determine whether information was submitted within the time required by statute or regulation. If CVM is able to open and read the file, the date within the file will serve as the date of submission.

D. 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 that 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 ELECTRONIC SUBMISSIONS

To make electronic submissions, stakeholders should:

- Register with the FDA ESG (<http://www.fda.gov/esg/default.htm>)
- Submit a registration letter to CVM

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- Download the CVM PDF SmartForms from the CVM Electronic Submissions page (<http://www.fda.gov/cvm/esubstoc.html>)
- Submit a digital signature to CVM using FORM FDA 3538

A. REGISTRATION PROCESS (see Section III for details):

1. Send a single, original, signed registration letter to CVM. See Appendix I for an example of the registration letter. The letter should include:
 - a. the name, mailing address, phone number, and e-mail address of the Coordinator;
 - b. the names, mailing addresses, phone numbers, and e-mail addresses for each stakeholder who will submit electronic submissions;
 - c. the subject of the letter should be **Registration Letter for Electronic Submissions to CVM** to clearly identify the purpose of the letter. A paper copy of the letter should be mailed to the address given in Appendix I.
2. Create a PDF copy of the registration letter. Attach it to an e-mail message and send it to CVMDCU@FDA.HHS.GOV. The subject line of the e-mail message should be **REGISTER**.
3. CVM will send an e-mail to the Coordinator named in the registration letter. A paper response will also be sent once the registration process is complete. If the coordinator has not received both of the acknowledgements within 30 days, contact CVM by calling the Electronic Document Control Unit at 240-276-8584.
4. 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 FORM FDA 3538 and submit it through the FDA ESG.

B. ADDING, DELETING or CHANGING STAKEHOLDER INFORMATION

1. 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 FORM FDA 3538 by checking the radio buttons “Add” or “Delete”. Only Coordinators can add or delete stakeholders for their company. 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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2. To change a stakeholder's information (except for changing an e-mail address), stakeholders must complete Section I – Registration/Information on FORM FDA 3538 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.

C. ADDING OR DELETING A COORDINATOR OR CHANGING AN E-MAIL ADDRESS

1. To add or delete a Coordinator or to change an e-mail 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.
4. Create a PDF copy of the change letter. Attach it to an e-mail message and send it to CVMDUCU@FDA.HHS.GOV. The subject line of the e-mail message should be **CHANGE**.

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APPENDIX I

Example of Registration Letter

HFV-199

Attention: Lesley Groves

Office of New Animal Drug Evaluation
Center for Veterinary Medicine
7500 Standish Place
Rockville, Maryland 20855

Subject: Registration Letter for Electronic Submission to CVM

Dear 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. 92S-0251 using the FDA Electronic Submissions Gateway (ESG). An attachment 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 e-mail 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 are submitting an electronic copy of this request to cvmdcu@fda.hhs.gov.

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 submissions that are compatible with CVM's current technology.

Sincerely yours,

Enclosure
