FDA CVM ESS II

Screen Shot
Demo
I. SECTION I – Registration / Information:

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

- ADD <Coordinators Only>
- DELETE <Coordinators Only>
- CHANGE

<table>
<thead>
<tr>
<th>Stakeholder Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholder Company Name:</td>
<td></td>
</tr>
<tr>
<td>Company Address 1:</td>
<td></td>
</tr>
<tr>
<td>Company Address 2:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>StProv:</td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
<tr>
<td>Stakeholder Phone:</td>
<td></td>
</tr>
<tr>
<td>Stakeholder Email Address:</td>
<td></td>
</tr>
</tbody>
</table>

II. SECTION II – Digital Signature Validation:

I certify that the applied digital signature is mine.

<table>
<thead>
<tr>
<th>Stakeholder Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholder Email Address:</td>
<td></td>
</tr>
</tbody>
</table>

1 - Validate  2 - Save  3 - Signature

Digitally signed by Howard Conrad
DN: cn=Howard Conrad, o=US, o=Booz Allen Hamilton, email=howard.conrad@fda.hhs.gov
Reason: I am the author of this document
Location: Rockville, MD
Date: 2007.05.15 09:34:38 -04'00'
Both User ID and Password are case sensitive.
This is the WebTrader main screen that you do everything from.
Select Send Document
Select CVM Center
Send document

Select who will receive the document
Gateway: FDATST
Center: *

Select the contents of the submission
Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: *
Root directory: *
Submission type: *

Select a signing certificate
Current file: Q:\Software\ESS_II\Certs\FDA-CVM-Test-1.p12
New file: MyCertificate.p12 or MyPrivateKey.pfx

Send
Send document

Select who will receive the document
Gateway: FDATST
Center:* CVM

Select the contents of the submission
Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.
Path:*
C:\Documents and Settings\hconrad\Desktop\Submission Dire

Root directory:
C:\Documents and Settings\hconrad\Desktop\Submission Dire

Submission type:* Electronic Submissions

Select a signing certificate
Current file: Q:\Software\ESS_II\Certs\FDA-CVM-Test-1.p12
New file:
Browse...

MyCertificate.p12 or MyPrivateKey.pfx

Press Send When Filled In
Enter Certificate Password and Select OK
This can take a long time based on the size of submission or how busy the Gateway is. Please be patient.
SUCCESS
Initial Receipt from the Gateway – Not usable until you rename the file

Click on Details
The Next Screen appears
Click on Rename
Add ".txt" to the end of the Receipt file name – Press the Green check box
You can open the text file or save it to your local system
This is a Message Digest Notification – Has little useful information
Opening the Second Gateway Receipt – Just Click on the File name
This second Gateway notification informs the submitter that the submission has been transferred to CVM’s ESS.

CoreId: 1178826071339.1587@llntap02
DateTime Receipt Generated: 05-10-2007, 14:44:48

The date and time stamp contained in this message conveys when CVM received your submission from the Electronic Submission Gateway. If your submission was received at CVM after 4:30 PM EST, the official receipt date for the submission is the next government business day.

This is the Unique Identifier assigned to your transmission.
Viewing the CVM ESS response requires you to open a ZIP file.
Clicking on the filename opens the Zip program on your PC. You can save the zip file or open it.
This is the ESS Sponsor Notification form – Notice that the filename matches the file name you submitted. Clicking the filename will open the Sponsor Notification PDF. If you submitted multiple submissions within one transmission they will be bundled up within the zip file.
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.
Document Certification is valid, signed by CVM ESS II Signee.

Signed by: CVM ESS II Signee
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.
This is the ESS II Sponsor Notification form. Notice that the form will be used for both submission rejections and acceptances.

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Food and Drug Administration**

**Date:** Tue May 15 12:50:17 EDT 2007

**To:** Submitter

**Subject:** FDA CVM ESS – Stakeholder Submission Notification

The Center for Veterinary Medicine, Food and Drug Administration acknowledges the receipt of your submission to the FDA CVM Electronic Submission System. The following information documents the state of your submission. If you have any questions, please contact either the review division or the Electronic Submission Coordinator at 301-827-8277.

**Memo:**

Your submission has been rejected. The submitted form must be version 5.0 or later.

<table>
<thead>
<tr>
<th>Date/Time Received:</th>
<th>05-15-2007, 09:39:52</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission Identifier:</td>
<td>1179236200500.2448@ftntap02-1-1</td>
</tr>
<tr>
<td>Submission Identifier:</td>
<td>N/A</td>
</tr>
<tr>
<td>Applicant Name:</td>
<td></td>
</tr>
<tr>
<td>Chemical Name:</td>
<td></td>
</tr>
<tr>
<td>Submitted Document Type:</td>
<td></td>
</tr>
<tr>
<td>Submission Type:</td>
<td></td>
</tr>
<tr>
<td>Correspondence Date:</td>
<td></td>
</tr>
<tr>
<td>CVM Due Date:</td>
<td></td>
</tr>
<tr>
<td>Parent Submission:</td>
<td></td>
</tr>
<tr>
<td>Reference Submission:</td>
<td></td>
</tr>
<tr>
<td>Stakeholder File Name:</td>
<td>Signature Validation.pdf</td>
</tr>
<tr>
<td>Multi-Document Index:</td>
<td></td>
</tr>
</tbody>
</table>
This is the bottom of the Stakeholder Notification Receipt. Notice that it is Digitally Signed.