

| AHI Meeting

- ▶ CVM Electronic Submissions
- ▶ (ESS II)
- ▶ May 16, 2007



Agenda

- ▶ Introduction
- ▶ What Got Us Here?
- ▶ Where We are in the Modernization Process!
- ▶ Current Schedule
- ▶ Electronic Submissions Gateway
- ▶ Digital Certificates
- ▶ Digital Signatures
- ▶ Other Important Information
- ▶ Stakeholder Registration
- ▶ Registration Process
- ▶ Questions
- ▶ Today's Demo



What Got Us Here?

- ▶ Agency shifting away from Email for Electronic Submissions
 - Submission Size Restrictions
 - Upgrading Agency Email System
- ▶ Introduction of the FDA Electronic Submission Gateway
 - Digital Certificates
 - Better Encryption
 - Single Standard for all Electronic Submissions
 - Almost unlimited Submission Sizes
- ▶ Digital Signatures
 - Upping the Requirements for Electronic Submissions
- ▶ ESS I – Aging Code
 - Not an FDA Standard
 - Cranky Adobe Password Protection Capability
 - Could not Fold in New Technologies
 - Very hard to make new changes
- ▶ Setting the Stage for Future Developments
 - Additional Functionality is Being Planned



Where We are in the Modernization Process!

- ▶ All submission forms have been updated
 - Removed Adobe password capability
 - Enabled digital signature functionality
- ▶ Gateway Interface for receipt & transmission functional
- ▶ Guidance documents are being updated
- ▶ Communication outreach initiated and several broadcasts sent



Where are we in the Modernization Process! (cont'd)

- ▶ Phase I is complete
 - Form and unit testing completed
 - Stakeholder registration process finalized
 - Digital signature processes completed
- ▶ Starting Phase II
 - End-to-End internal testing
 - External stakeholder testing



Current Schedule

- ▶ Begin stakeholder testing – May 21, 2007
- ▶ Additional broadcasts
- ▶ Purging of inactive stakeholders – May 21, 2007
- ▶ Begin final testing – June 15, 2007
- ▶ Go Live by the end of June – early July



FDA Electronic Submissions Gateway (ESG)

- ▶ FDA ESG has been operational since October 2006
 - It has been receiving submissions
- ▶ Test and Production instances available
 - You can try out Gateway functionality without impacting live systems
- ▶ Gateway is digital certificate-based
 - Certificates must be valid and checkable by the Gateway
 - You can use the same certificate in the test and production systems



FDA Electronic Submissions Gateway (ESG) (cont'd)

- ▶ Two transmission methods available
 - Method 1 – WebTrader
 - Browser-based
 - Relatively easy to use
 - No software installation required other than Java library
 - Offers complete inbox services
 - Method 2 – Gateway to Gateway
 - Requires the purchase and installation of a gateway product
 - Your Gateway must support the AS2 protocols
- ▶ Procedures and instructions available on the Gateway's Web Site
 - <http://www.fda.gov/ESG>



Gateway Registration Process

- ▶ Follow exactly the WebSite instructions
 - Send a non-repudiation letter to FDA
 - Register for a test account
 - Send a test submission
 - If Ok continue else go back
 - Register for a production account
- ▶ After Gateway Registration the 1st Submission to CVM should be the coordinator verifying their Digital Signature – Manage Form -- Section II
- ▶ All stakeholders even if migrated from ESS I will need to send in a Digital Signature verification – Manage Form – Section II before FDA CVM will accept submissions



Digital Certificates

- ▶ Used to electronically establish trust between two parties
- ▶ Certificates can either be generated by your IT Department or can be externally purchased.
- ▶ Certificates **MUST** be verifiable before the Gateway can be engaged
- ▶ The certificate is validated and checked each time you invoke the Gateway
 - If your certificate has become invalid you will not be able to use the Gateway
 - Example: Generally certificates have a time period that they are valid for. After they expire you must either renew or obtain a new certificate. In either case you must renew your Gateway Registration



Digital Signatures

- ▶ All submission forms will require an Adobe digital signature on each Form submitted
- ▶ You must configure Adobe Acrobat to apply and to validate digital signatures
 - The key field in the Signature is the “Contact” information field. This field MUST contain your valid Email address that was supplied when you were registered
 - A Broadcast will be forth coming in the configuration of Adobe Digital Signatures
- ▶ FDA CVM will apply a digital signature to all outgoing electronic correspondence



Other Important Information

- ▶ Applicant name validation
 - Applicant names on submitted forms must match the stored CVM applicant name exactly. This includes punctuation; case does not matter.
- ▶ Configuration of Adobe signature block
 - Contact information **MUST** have your valid email address
- ▶ Adobe versions supported
 - FDA CVM will support the current Adobe Acrobat release and the last two releases
 - Example: We will support Acrobat 8, Acrobat 7 and Acrobat 6
 - FDA current version is Acrobat 7
- ▶ Gateway submission folder
 - A user created folder on your PC
 - Multiple submission forms within a single transmission
 - When using Web Trader ALL transmissions must be directory transmissions (see demo for information)



Other Important Information (cont'd)

▶ Stakeholder notification

- Multiple notifications will be zipped. You must unzip these notifications

▶ Transmission identifier

- The Gateway assigns a Unique Identifier Number (UID) to each transmission received by the Gateway
 - Example: 117743645528.38118@llntap02
- CVM will add additional information to the UID to further distinguish your transmission
 - Example 117743645528.38118@llntap02-2-1

Added



Stakeholder Registration

- ▶ New registration process
- ▶ Registration can be accomplished by:
 - Mailing a letter to FDA CVM
 - Sending an email to CVMD@FDA.HHS.GOV with “Register” in the subject line and attaching a PDF file containing the registration letter
- ▶ Stakeholder Coordinators are key to the electronic registration process
 - Only Coordinators can register new stakeholders
 - Only Coordinators can delete registered Stakeholders
 - Each applicant company must have at least one registered coordinator
 - You may have multiple coordinators – we recommend having at least two



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. 0910-0454 Expiration Date: 3/31/2010
<small> PAPERWORK REDUCTION ACT STATEMENT: A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a current valid OMB control number. The public reporting burden for the collection of information is estimated to vary from 5 to 10 minutes, with an average of 8 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, 7500 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:	<input type="text"/>	<input type="text"/>
Stakeholder Company Name:	<input type="text"/>	
Company Address 1:	<input type="text"/>	
Company Address 2:	<input type="text"/>	
City:	St/Prov:	Postal Code:
Country:	<input type="text"/>	
Stakeholder Phone:	<input type="text"/>	
Stakeholder Email Address:	<input type="text"/>	

II. **SECTION II – Digital Signature Validation:**

I certify that the applied digital signature is mine.

Stakeholder Name:	<input type="text"/>	<input type="text"/>
Stakeholder Email Address:	<input type="text"/>	



Stakeholder Registration Process

- ▶ Registering new stakeholders
 - The Coordinator completes Section 1 of the Manage Form (FDA 3538) for the new stakeholder and digitally signs the form
 - The Coordinator transmits the completed Manage Form using the Gateway
 - ESS II receives the transmission, creates the new stakeholder and emails the new stakeholder requesting his/her digital signature verification
 - After receiving the email the new stakeholder completes Section II of the Manage Form and digitally signs the form
 - The new stakeholder transmits the completed form using the Gateway
 - The stakeholder is now allowed to transmit submissions

Until this process is completed all transmissions from the new stakeholder will be rejected



Questions

- ▶ Demo to Follow



Today's Demo

- ▶ Demonstrate New Form Functionality
- ▶ Show the Gateway WebTrader Interface
- ▶ Show The Gateway Inbox
- ▶ Show the ESS II Registration Process
- ▶ Show Sponsor Response
 - Show Zipped Return

