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)

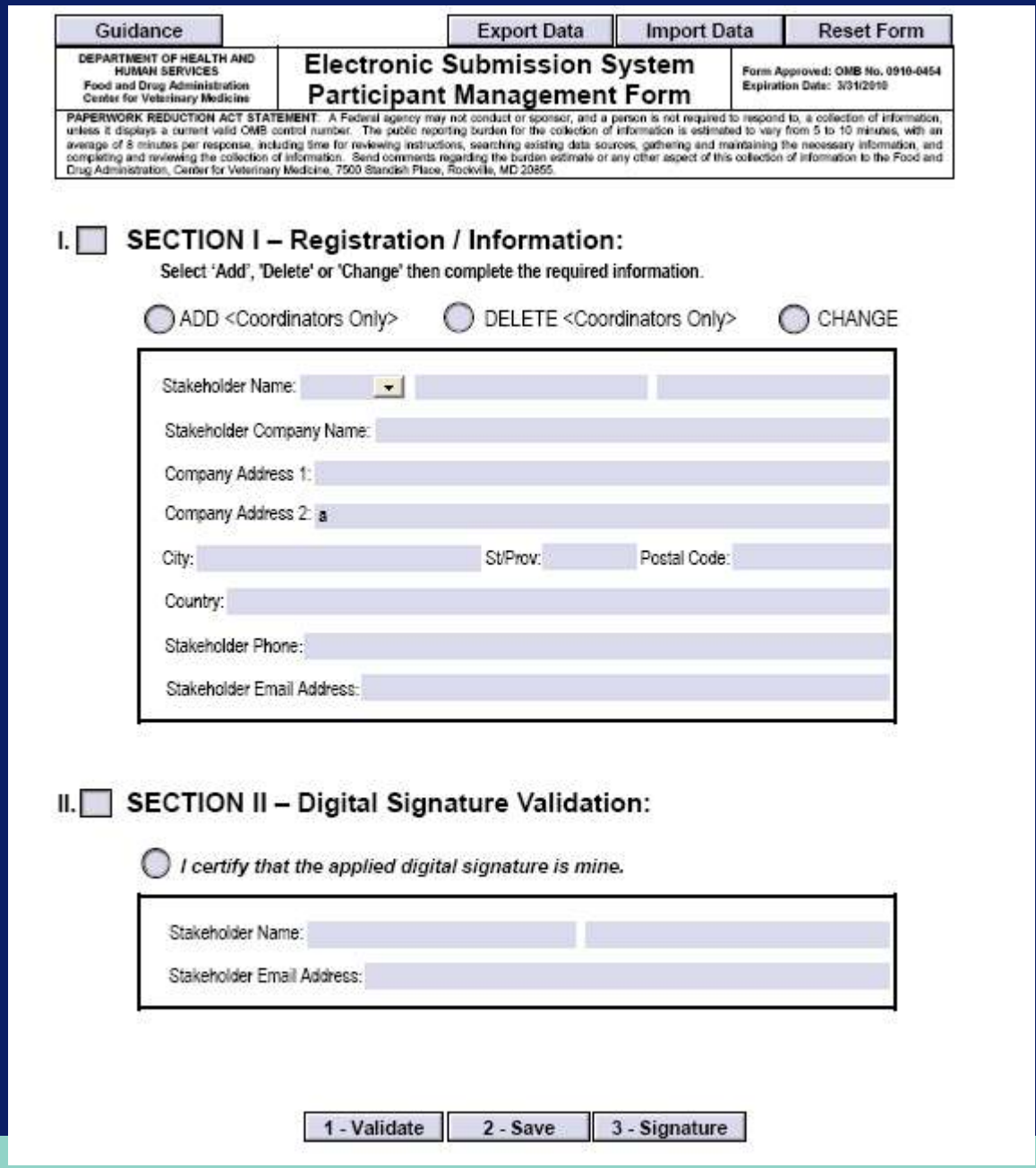
- Stakeholder notification
  - Multiple notifications will be zipped. You must unzip these notifications

- Transmission identifier
  - The Gateway assigns a Unique Identifier Number (UID) to each transmission received by the Gateway
    - Example: 1177436455528.38118@llntap02
  - CVM will add additional information to the UID to further distinguish your transmission
    - Example 1177436455528.38118@llntap02**-2-1**

Added

Stakeholder Registration

- New registration process
- Registration can be accomplished by:
  - Mailing a letter to FDA CVM
  - Sending an email to CVMDCU@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

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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: a
City: St/Prov: Postal Code:
Country:
Stakeholder Phone:
Stakeholder Email Address:

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

○ *I certify that the applied digital signature is mine.*

Stakeholder Name:
Stakeholder Email Address:

1 - Validate | 2 - Save | 3 - Signature

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