



U.S. Food and Drug Administration

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FDA Electronic Submissions Gateway (ESG)

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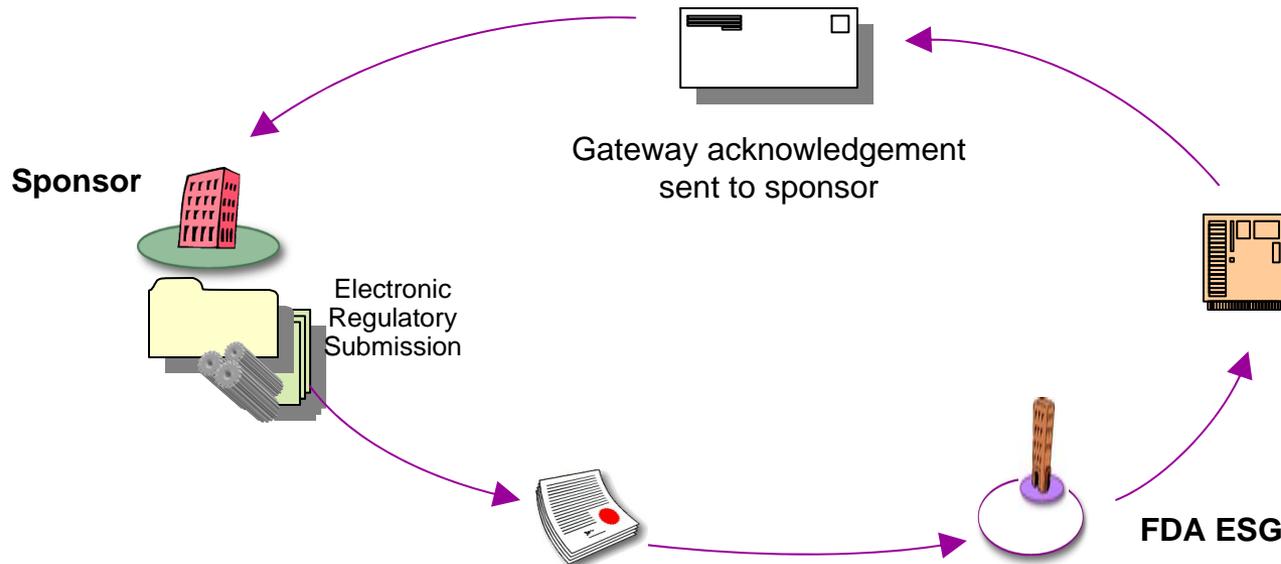
Talking Points

1. **What is the Gateway?**
2. **Receiving Units**
3. **Statistics**
4. **Submission Types**
5. **Submission Options**
6. **WebTrader**
7. **Gateway Cost**
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What is the Gateway?

An agency-wide solution and central transmission point for accepting secure electronic regulatory submissions over the Internet.

The FDA ESG is a conduit, or "highway", that automatically routes submissions to the proper FDA Center of Office. It does not open or review these submissions.



Participating Centers/OPDIVs

- Adverse Event Reporting System (AERS)
- CDER
- CBER
- CDRH
- CVM
- OC
- CTP
- MWP
- CFSAN (production 8/30/2011)
- Health Canada (ongoing discussions)

FDA ESG Submission Statistics

2006 - 2011 Totals	2006	2007	2008	2009	2010	2011	Totals
AERS	55,156	159,562	252,614	300,672	472,142	364,687	1,604,833
CDER	1,639	11,175	24,797	45,510	69,739	61,739	214,599
CBER	294	1,504	2,557	4,483	5,588	4,198	18,624
CDRH	1,575	1,527	4,619	21,296	119,087	164,144	312,248
CVM		288	843	859	945	6,675	9,610
OC			188	16,275	48,232	38,455	103,150
CTP				5	223	112	340
MWP					1,138	1,345	2,483
Totals	58,664	174,056	285,618	389,100	717,094	641,355	2,265,887

Submission Types Received via the ESG

- Post Marketing Safety Reporting
 - AERS (adverse event reports)
 - AERS attachments
 - eMDR
 - HL7/ICSR (Health Level 7/Individual Case Safety Report)
- Registration and Listing
 - SPL
- Pre-Market Regulatory Submissions
 - Licensing (.pdf and eCTD formats)
 - BLA (Biologics License Application)
 - NDA (New Drug Application)
 - ANDA (Abbreviated New Drug Application)
 - Scanned PMA's and 510K's
 - Promotional Materials
 - H1N1/Flu Lot Release
 - LDD (Lot Distribution Data)
 - Investigational
 - IND
 - IDE
 - DMF

Future ESG Release - Submission Type Information

- DDMAC eCTD submissions
 - Targeted for fourth quarter 2012
- VAERS
 - Targeted EOY 2012
- UDID (universal device identification database)
 - TBD
- Paper applications converted to electronic and sent to the Agency via the ESG
 - Yes
 - Review Center Guidance's
 - Call responsible Center staff
 - Send demo's if necessary

FDA ESG – Submission Options

- **FDA ESG Web Interface (WebTrader)**

- Sends submissions via Hyper Text Transfer Protocol Secure (HTTPS) through a web browser per Applicability Statement 2 (AS2) standards
- Low cost option
- Uses Java applet
- Single submission/manual

- **Gateway to Gateway (AS2)**

- Applicability Statement 2 (AS2) Gateway-to-Gateway
 - Electronic submission protocol that uses HTTPS for communications
- Attribute/Header and routing ID information will be used to route submission
- Requires an AS2 compliant gateway software
- Automated Process/Batches

What is the Web Trader

- Web Trader is a requirement from the original FDA ESG RFP (request for proposals)
- The intention of this function was to even the playing field between big PhRMA companies and the rest of the Drug and Biologic Industry in the area of electronic submissions.
- The Web Trader is an applet that is download onto your PC when you log on the FDA ESG webpage using your x.509 version 3 class I digital certificate, if you are an account holder
- It is part of the Axway COTS product suite utilized by the FDA.
- The Web Trader requires that specific versions of JRE and JCE be available on your desktop in order to ensure that the software product functions properly.
- The Web Trader applet copies and packages your submission on your desktop in a secure fashion, transmits the submission in a fully encrypted message to the FDA and then remove any traces of it's presence from your PC.
- This paradigm alleviates the burden of system validation and the associated cost of 21 CFR 11 compliance

What is the Web Trader

- Account holders will need to load required JAVA and Browser on their desktop and setup their proxy/firewall to communicate with ESG.
- ESG requirements constrain desktop technologies for users
- ESG requires JRE 1.5.x and Internet Explorer 6, 7, 8 or Firefox 2.0.x. Often, users have other application that are not compatible with JRE 1.5.x
- Must obtain a digital certificate in order to utilize the FDA ESG.
- The digital certificate (x.509 version 3 class 1) should be 1-3 years in duration

Multi-file or Directory Based Submission

- FDA ESG Web Interface Submissions
 - The FDA ESG Web Interface utilizes the tarring and gzip functions for file/directory consolidation when transmitting multi-file submissions.
 - Because this process is done automatically during the signing of the file, no intervention is required.
- Gateway-to-Gateway (B2B) Submissions
 - Partners are required to both tar and gzip (compress) multi-file submissions.
 - For best optimization when processing and transmitting large multi-file submission files, first "tar" the files and then compress them using gzip.
 - To fulfill this requirement
 - The current AS2 solution will/should have a tar and zip utility prescribed. There are Operating System-specific utilities available for performing the tar operation.
 - If the application does not have tar/gzip capabilities, a utility must be acquired. Please refer to the User Guide on the FDA ESG website for recommended utilities.

Gateway Cost (for WebTrader option)

- **The FDA does not charge for the use of ESG.**
- **The only costs incurred should relate to the following:**
 - Purchase of an x.509 version 3 class I PKI certificate with duration of 1-3 years, typically \$20-\$30
 - Desired network infrastructure improvement (ESG tested using various internet connection bandwidths from a T1 to OC3 line)
 - ESG WebTrader applet does not require installation of software other than JAVA, available for free
 - Cost of desktop support

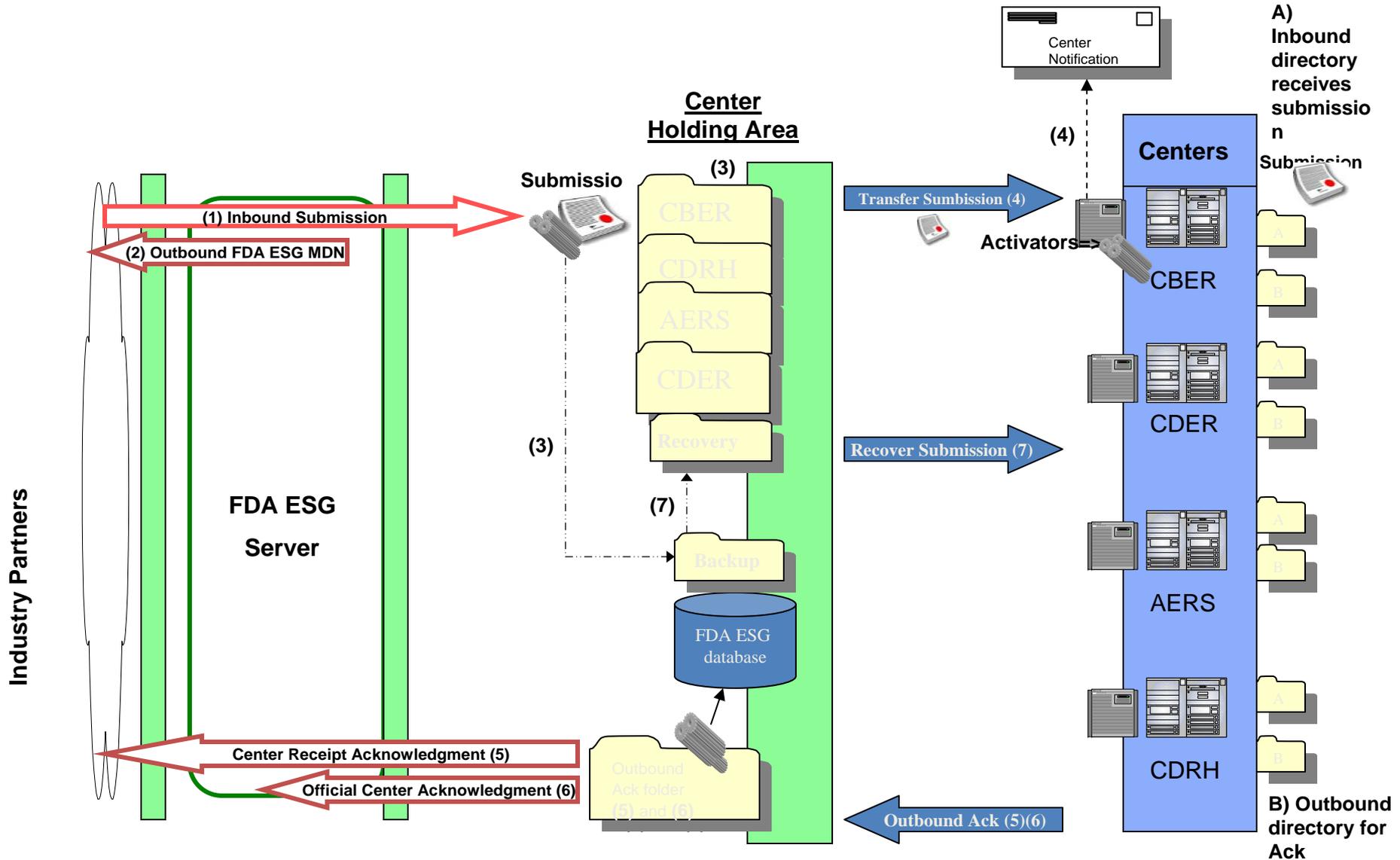
Multiple WebTrader Accounts

- **A company can have multiple WebTrader accounts.**
 - FDA recommends companies to have multiple WebTrader accounts if they have large amounts of submissions
 - Company's naming conventions for multiple accounts is company name followed by user initials or designated number
 - e.g., Sun PhRMA – SRP
 - e.g., Sun PhRMA – 001
- **Testing of multiple accounts:**
 - Each account must send guidance-compliant test submission
 - Only one load test required if the accounts are located in same physical location, or if on the same physical network as the company's previous accounts

Shared Accounts

- **Certificates are not to be shared.**
 - They are associated with individual accounts
- **WebTrader accounts are not to be shared.**
 - Certificates associated with accounts to determine the origin of a submission
 - PKI certificate utilizes public/private key exchange for encrypting and decrypting as the submission signature
 - FDA must be able to establish origin of a submission to supply electronic information for FDA review
 - Use of a PKI certificate and account name determines origin of the regulatory submission
- **The determination of origin is the key factor.**

Processing of an Inbound Submission



Processing of an Inbound Submission

1. FDA ESG receives an inbound submission.
2. FDA ESG sends a Message Delivery Notification (MDN) to the submitter (Message 1).
 - Receipt of an MDN confirms that the submission was successfully received by the FDA ESG.
3. The inbound submission is processed, submission is unpackaged and deposited in the Center Holding Area.
 - A copy of the submission is stored for 10 days in the Backup directory.
4. The submission is automatically transferred to the Center.
 - The official receipt timestamp is applied to the submission.
 - An email is sent notifying the Center that a submission has arrived.
5. A Center Receipt Acknowledgement is automatically generated and sent to the submitter via the FDA ESG (Message 2).
 - This Acknowledgement contains the official receipt timestamp.
6. The Center validates and processes the submission.
 - Depending on the submission, an Official Center Acknowledgement may be sent (Message 3).
 - If errors occur during validation and loading, they will be noted in the Official Center Acknowledgement.
7. If necessary, the Backup copy of the submission may be recovered by the Center.

FDA Electronic Submission Gateway - ROI

Below are a few of the benefits realized following the implementation of the FDA ESG:

- Improves costs, resource requirements, and time efficiencies for both Sponsors and the Agency
- Facilitated moving product teams to a fully electronic submission process
- Obviated need to burn CDs/DVDs or create tapes
- Reduced hardware/software, costs, and resources associated with media creation
- Eliminated QC of submission associated with creating media
- Eliminated courier and FedEx fees associated with Regulatory submissions
- Eliminated paper output
- Reduced costs associated to processing, tracking, and archiving paper

FDA Electronic Submission Gateway – ROI (cont.)

- Reduced costs associated with maintenance of 3 DocuTech printers
- Eliminated need for DocuTech printers (within 1st year of implementation)
- Facilitated redeployment and reduction of resources required to process paper or media-based submissions
- Provided a more efficient and secure transfer of electronic submissions
- Enabled implementation of SAFE Digital Signatures which facilitated additional benefits/gains
- Facilitates earlier receipt of the submission by the Agency and access to the submission by the Reviewer

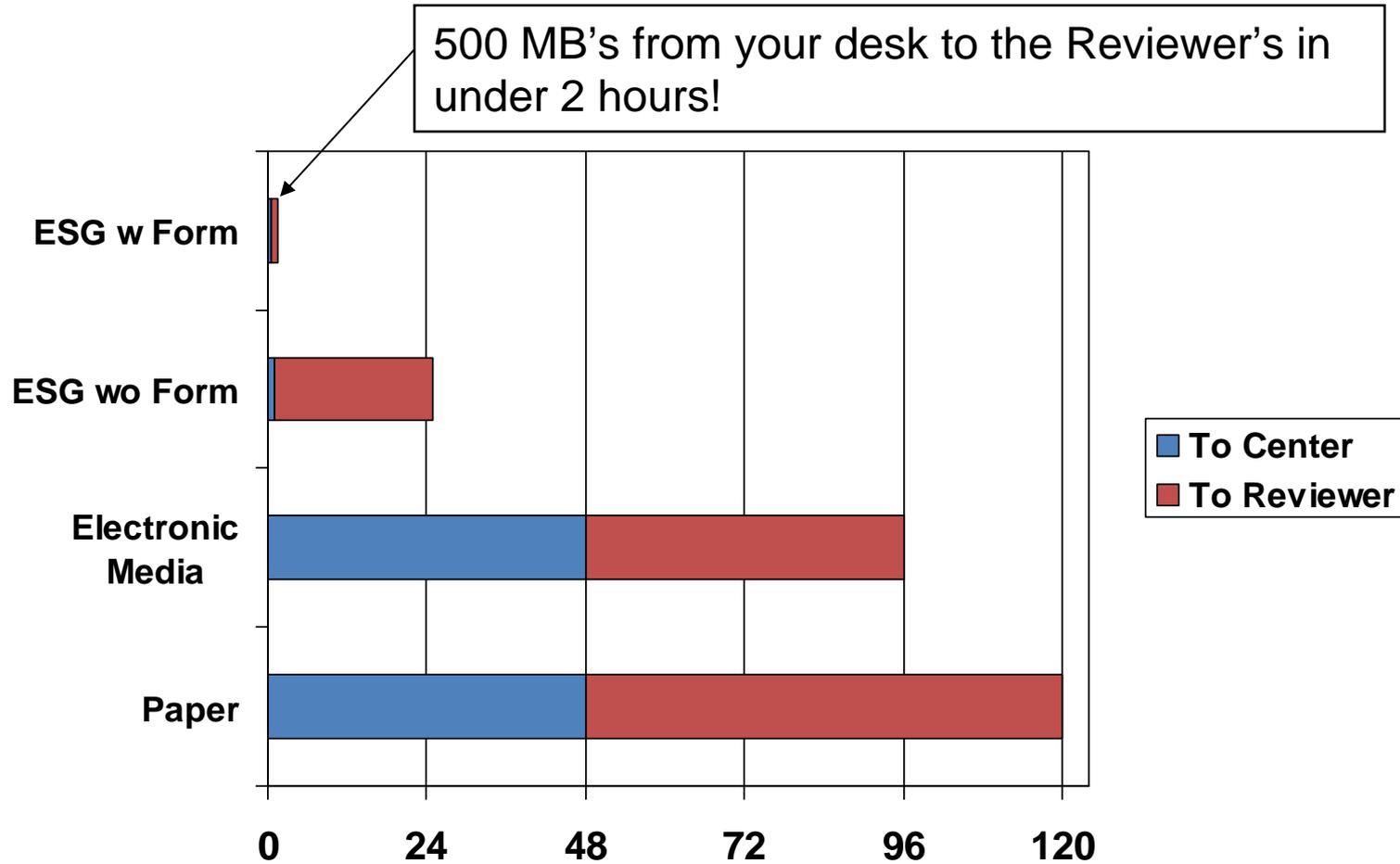
FDA ESG – ROI

Comparative Costs Projections Based on 1500 Submissions

Operating Costs

Item	<u>Traditional Media</u>			<u>ESG</u>		
	Unit Cost	Quantity	Total Cost	Unit Cost	Quantity	Total Cost
Shipping	\$8.25	1500	\$12,375.00	N/A		
Credentials (digital certificates)	N/A			\$20.00	20	\$400.00
Resources:						
Hours	\$63.89	1500	\$95,835.00	\$63.89	104	\$6,644.00
Quarter Hours	N/A			\$15.97	1500	\$23,955.00
Materials:						
CDROM	\$0.15	1490	\$223.00	N/A		
DLT	\$50.00	10	\$500.00	N/A		
Binders (Cover Letters)	\$1.50	1500	\$2,250.00	N/A		
Total Cost			\$111,183.00			\$30,999.00

Processing Times for Submissions by Format



Digital Signatures

- FDA does not require submission of a paper copy for electronic submissions submitted using the FDA ESG.
- FDA forms (e.g., 1571, 356h) and documents require a signature. Accepted signature methods by FDA are:
 - **Scanned signatures**
 - **Digital signatures**
 - **Flattened digital signatures. A flattened digital signature must include (see example):**
 - **the printed name of the signer**
 - **the date and time when the signature was executed**
 - **the reason for signature**
- Please utilize the .pdf self sign signature on the FDA fill-able forms.
- The Agency does not check electronic/digital signatures unless there is a directed inspection involving the submission transmission.

Digital Signatures (cont.)

- Industry should maintain the self sign cert.'s associated with the self sign signature just in case there is a directed inspection.
- The Agency cannot hold electronic signatures to greater level of rigor than paper signatures. The Agency does not check every signature on a paper based document/submission.
- The x.509 version 3 class I certificate employed by the ESG allows the Agency to attribute the origin of the submission.
- The Agency has to be able to determine the origin of a submission. The Agency's General Counsel (GC) articulated this as the standard we had to meet in implementing fully electronic submission transmission.
- The PKI cert (x.509 version 3 class I certificate) accomplishes this through the use of a public/private key exchange.

Digital Signatures (cont.)

- Use 1571 and 356h electronically fill-able forms with your electronic submission transmissions to CDER and CBER via the ESG
 - 1571 (<http://www.fda.gov/opacom/morechoices/fdaforms/1571es.pdf>)
 - 356h (<http://www.fda.gov/opacom/morechoices/fdaforms/356Hes.pdf>)
 - If these forms are not included in your electronic submission transmissions, CBER and CDER will not be able to leverage their automated loading processes. The absence of these forms reduces the Centers automated loading process to a manual process. The affect - a large increase in the time required by the Centers to make submissions available to our review community.
 - 356h and 1571 Form Field sizes
 - The important fields from the Agency perspective are the application number and submission type for documents transmitted for regulatory review via the ESG.
 - The current forms fields have the maximum number of characters allowed.
 - If the form field is not large enough, please abbreviate the text in the field.
 - FDA contractors or administrative reviewers read the submission cover letter and selected text to determine the nature and content of the submission. FDA generated data and information is utilized in FDA submission tracking databases.
 - Increasing the form field size or otherwise altering the forms would require OMB approval

Digital Signatures (cont.)

FAQs

Question: It appears if PDF signature not used, will FDA accept the submission?

Answer: Yes, FDA does not validate the signature during the submission process. Signature validation issues would be addressed as part of an inspection.

Question: Sponsors are concerned that some fields cannot handle the full text.

Answer: Important fields are the application number and submission type.

Question: Use of non-public key Electronic/Digital signatures results in an error message during eCTD validation steps associated with a "secured" pdf file being present within the eCTD (in violation of an ICH eCTD "rule").

Answer: FDA understands that this would/has occurred and would not/has not "turned-back" submissions based upon this. 'It is a by-product of a regional requirement they have for facilitating/enabling expedited processing of the eCTDs.'

Advice/Issue

- If your certificate is not accepted by the FDA registration module or if you have to replace an existing certificate.
 - Enclose the .cer or .p7b file in a .zip file and send as an email attachment to esgreg@gnsi.com
 - Or change the .cer or .p7b extension to .txt and send as an email attachment to esgreg@gnsi.com (please specify the original extension of the file)

FDA ESG Process – Before You Register

- **Understanding Submission Guidelines**
 - FDA Centers have specific guidelines for preparing electronic submissions
 - ESG website provides links to center-specific submission guidelines
- **Submission Types**
 - FDA Center(s) will only accept specific types of submissions
 - see Submission Types by Center on the ESG website for each Center's acceptance requirements

FDA ESG Process – Before You Register (cont.)

- **Submit a Letter of Non-Repudiation Agreement**
 - allows FDA to receive electronically-signed submissions (compliant to 21 Code of Federal Regulations [CFR] Part 11.100)
 - send copy to Office of Regional Operations (ORO) and ESG Project Manager
 - sample letters located on FDA ESG website
- **Obtain a Digital Certificate**
 - FDA ESG uses digital certificates to secure transaction and communications
 - an electronic document that conforms to International Telecommunications Union's X.509 specifications
 - FDA accepts X.509 .v3 certificates, must be valid for 1-3 years
 - use the public key when registering (.p7b or .cer extension)
 - use the private key to sign the submissions (.p12 or .pfx extension)
 - ESG website has information on how to obtain digital certificate
- **Determine Submission Method**
 - web-based (WebTrader)
 - Gateway-to-Gateway (B2B) submissions using industry standards for the transport protocol (AS2)
 - separate registration will be required for each option selected

WebTrader Checklist - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

Registration Summary

Web Trader Registration Wizard Help

Welcome
Select community
Company information
Select certificate file
Review certificate
Login information

Review registration

Registration summary

Review the information below. Click the finish button to submit this registration or click the back button to make changes.

Once you submit this registration, you can use your user ID and password to log on immediately to WebTrader, but you will not be able to successfully send documents until the sponsor authorizes your registration.

Company information

Company name: Acme Drug Company
Sponsor: FDA
User ID: adrugco50
Certificate: CN=Micheal Fauntelory, O=FDA

Primary contact

Contact name: Annie Rice
Phone number: 103-777-0987
E-mail address: arice@adc.com

Alternate contact

Contact name: Jack Payne
Phone number: 103-777-0988
E-mail address: jpayne@adc.com

I hereby certify that the information provided herein is true and that I am authorized to register with the FDA.

Cancel < Back **Finish**

Electronic Submissions Gateway Process – Test Submission

- Becoming a Trading Partner & Sending a Test Submission
 - Step 1 – Request an account on the test environment
 - Executed using a web-based interface
 - Provide contact information
 - Register a valid X.509 version 3 security certificate with the FDA ESG
 - Step 2 – FDA activates the account
 - Letter of non-repudiation on file at FDA
 - FDA verbally validates the registration information
 - Step 3 – Sending Test Submissions
 - Test submissions
 - Guidance compliant - Follow Center guidelines for submitting a compliant test submission.
 - Infrastructure/Network - Send submission up to 7.5 GB
 - Receive a positive Message Delivery Notification (MDN) confirming that the FDA ESG received the submission
 - Receive an acknowledgement from the designated Center
 - Center will review for guidance compliance
 - FDA will notify the trading partner by email if the tests have been successful

Electronic Submissions Gateway Process – Production Submission

- Register with the FDA ESG for Production Submissions
 - Step 1 – Request an account on the production environment
 - Executed using a web-based interface
 - Provide contact information
 - Register a valid X.509 version 3 security certificate with the FDA ESG
 - Step 2 – FDA activates the account
 - Letter of non-repudiation on file at FDA
 - FDA verbally validates the registration information
 - Valid Test Submission results on file
 - DONE! – You are ready to send digitally-signed electronic submissions using the web interface or by using your gateway.
 - Step 3 – Send Production Submissions
 - Initial gateway receipt
 - Center receipt acknowledgement
 - May receive a second Center acknowledgement

Sending a Web-based Submission

The screenshot shows a web application window titled "WebTrader" with a "Help" link and a "Logout" button. The main content area is titled "Send document" and contains several sections for configuring a submission:

- Select who will receive the document**
 - Gateway: FDA
 - Center: *
- Select the contents of the submission**

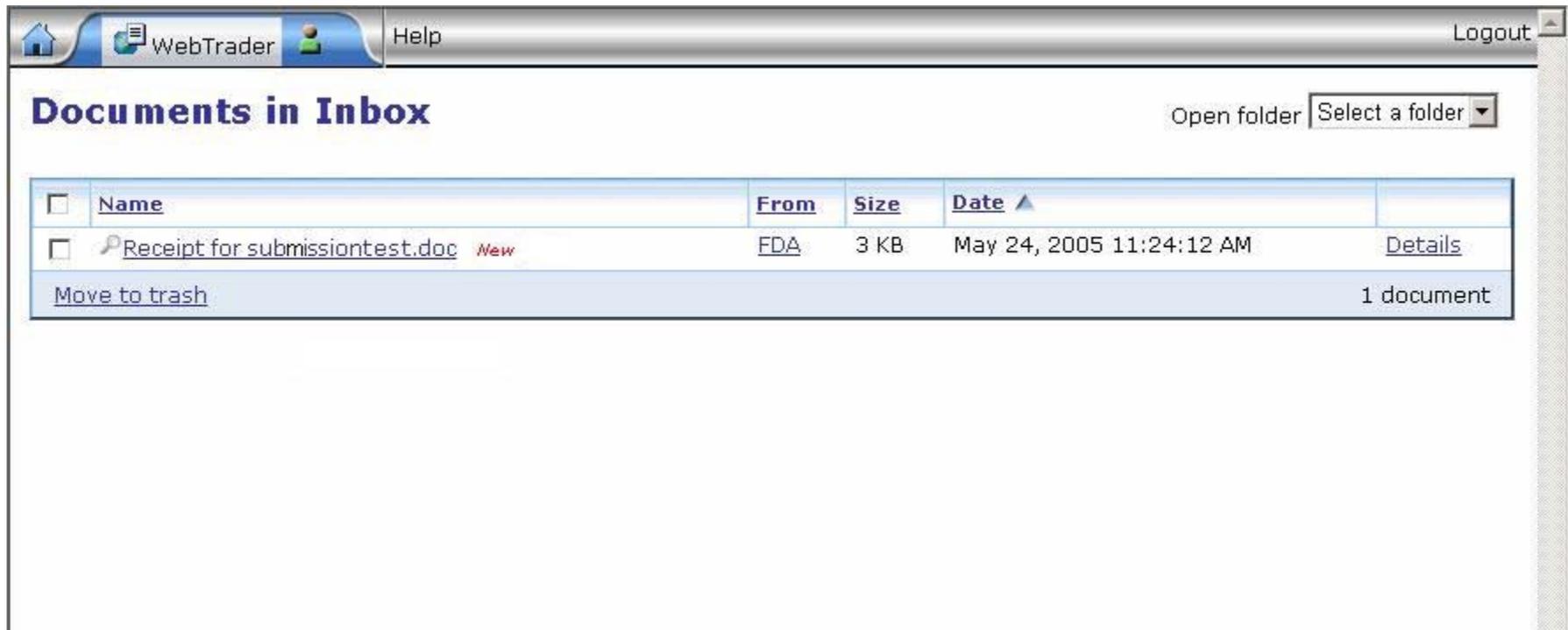
Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

 - Path: *
 - Root directory:
 - Submission type: *
- Select a signing certificate**
 - Current file: No certificate selected
 - New file:
MyCertificate.p12 or MyPrivateKey.pfx

A "Send" button is located at the bottom left of the form.

Document Inbox for Web-based Submissions

The receipt for the submission is displayed here. Click on the **Details** link to view its details. This page also displays notifications of any errors encountered in submission and any acknowledgements sent by FDA.



The screenshot shows a web browser window with a navigation bar at the top containing a home icon, the text "WebTrader", a user profile icon, and a "Help" link. On the right side of the navigation bar is a "Logout" link. Below the navigation bar, the main content area is titled "Documents in Inbox" in a large, bold, blue font. To the right of this title is a label "Open folder" followed by a dropdown menu with the text "Select a folder". Below the title and folder selection is a table with the following structure:

<input type="checkbox"/>	<u>Name</u>	<u>From</u>	<u>Size</u>	<u>Date</u> ▲	
<input type="checkbox"/>	 Receipt for submissiontest.doc <i>New</i>	FDA	3 KB	May 24, 2005 11:24:12 AM	Details

Below the table, there is a light blue bar containing the text "Move to trash" on the left and "1 document" on the right.

Document Inbox for Web-based Submissions

The receipt for the submission is displayed here. Click on the **Details** link to view its details. This page also displays notifications of any errors encountered in submission and any acknowledgements sent by FDA.

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying `https://esgtest.fda.gov/ui/webtrader/FolderView?name=webtrader.folder.inbox`. The page title is "Documents in Inbox" and it features a "WebTrader" header with a "Logout" link. A table lists the following documents:

<input type="checkbox"/>	Name	From	Size	Date	Details
<input type="checkbox"/>	Receipt for test.txt	FDATST	3 KB	Jun 1, 2006 5:36:19 PM	Details
<input type="checkbox"/>	1147275557944.2331@lntap02.txt <i>New</i>	FDATST	422 bytes	May 10, 2006 11:43:59 AM	Details
<input type="checkbox"/>	1147275721659.2351@lntap02.txt <i>New</i>	FDATST	421 bytes	May 10, 2006 11:43:59 AM	Details
<input type="checkbox"/>	Receipt for AERS_TEST3_wEDI%.XML <i>New</i>	FDATST	3 KB	May 10, 2006 11:42:02 AM	Details
<input type="checkbox"/>	Receipt for alerts_xml%.txt <i>New</i>	FDATST	3 KB	May 10, 2006 11:39:18 AM	Details
<input type="checkbox"/>	1146865048617.834@lntap02.txt <i>New</i>	FDATST	422 bytes	May 5, 2006 5:43:26 PM	Details
<input type="checkbox"/>	1146864546398.814@lntap02.txt <i>New</i>	FDATST	422 bytes	May 5, 2006 5:39:27 PM	Details
<input type="checkbox"/>	Receipt for testsub.txt <i>New</i>	FDATST	3 KB	May 5, 2006 5:37:29 PM	Details
<input type="checkbox"/>	Receipt for testsub.txt <i>New</i>	FDATST	3 KB	May 5, 2006 5:29:09 PM	Details
<input type="checkbox"/>	1146856667604.848@lntap02.txt <i>New</i>	FDATST	421 bytes	May 5, 2006 3:26:26 PM	Details
<input type="checkbox"/>	1146856761585.868@lntap02.txt <i>New</i>	FDATST	181 bytes	May 5, 2006 3:26:26 PM	Details
<input type="checkbox"/>	Receipt for testsub.txt <i>New</i>	FDATST	3 KB	May 5, 2006 3:19:22 PM	Details
<input type="checkbox"/>	Receipt for testsub.txt <i>New</i>	FDATST	3 KB	May 5, 2006 3:17:48 PM	Details
<input type="checkbox"/>	1146854208038.944@lntap01.txt <i>New</i>	FDATST	422 bytes	May 5, 2006 2:42:40 PM	Details
<input type="checkbox"/>	1146854257350.964@lntap01.txt <i>New</i>	FDATST	422 bytes	May 5, 2006 2:42:40 PM	Details
<input type="checkbox"/>	1146854318576.984@lntap01.txt <i>New</i>	FDATST	181 bytes	May 5, 2006 2:42:40 PM	Details
<input type="checkbox"/>	Receipt for testsub.txt <i>New</i>	FDATST	3 KB	May 5, 2006 2:38:39 PM	Details
<input type="checkbox"/>	Receipt for testsub.txt <i>New</i>	FDATST	3 KB	May 5, 2006 2:37:37 PM	Details

ESG Outages

- The ESG is a 99.5% uptime system 24/7/365
- Let's Talk About Computer System Reality
 - Things fail in spite of your best contingency plans
 - No one can account for Acts of GOD
 - What is an Act of GOD
 - Weather (hurricanes, tornadoes, blizzards)
 - Earthquakes
 - Equipment Failures occur even when proper maintenance and redundancies have been built into a system and they are tested.
 - We had two Acts of GOD during the week of August 22
 - Earthquake, 5.9 on Richter Scale August 23rd
 - Hurricane, Irene August 27th
- Ok, so you have become dependant upon the ESG and you are wondering what you should do in the case of an outage?
- First thing – do not panic

ESG Outages (cont.)

- Since May 6, 2006 the ESG has been hard down less than twelve times (90% of those instances occurred before 2009)
- Outages range from three up to 48 hours
- The ESG has suffered from an occasional performance issue.
- Performance issues are infrequent.
- What is the process once a system wide outage or incident has been confirmed?
 - We send notification to all stakeholders via our Listserv
 - Post the system outage on the FDA Industry Systems (FIS) webpage
 - ESG System Status link is on the ESG webpage and system interface

ESG Outages (cont.)

- Regulated Industry aka account holders will be notified once the system is functional or if it has been determined that it will take more than 48 hours to bring the system back up.
- More than 48 hours have never elapsed on any outage before we brought the system up back up.
- Typical outage is six to twelve hours.
- Ok – I know you are wondering what is the most affective manner to proceed with your submissions in the case of an outage?

ESG Outages (cont.)

- Recommendations

- Follow email for our updates
- At 24 hours burn a copy of your submission to media and wait 24 more hours before considering sending the media based submission
- Notice will be sent if the ESG will down for more that 48 hours.

- Realities

- It takes 3-5 business days to process media based submissions at the FDA.
- We do not want to overload our document rooms with a glut of media due to an outage of less than 48 hours
- Even delaying the transmission of a submission 24 to 48 hours will still place the submission in the reviewers hands faster than sending it to the FDA on media via courier.
- Call the review division and discuss options

SPL Support

- FDA ESG provides links from it's webpage to the SPL webpage/information for the convenience of its potential account holders
- The FDA ESG helpdesk found at esgreg@gnsi.com is not the appropriate group to handle queries regarding account holders SPL message
- The FDA ESG helpdesk forwards your concerns to the SPL group in an attempt to facilitate obtaining an answer to your query
- The FDA ESG is not equipped to address questions on electronic submissions content. Those queries are sent to the OPDIV in question.
- We will remind that OPDIV in question a an account holder presents a question that has not been responded to in a two week period per our policy

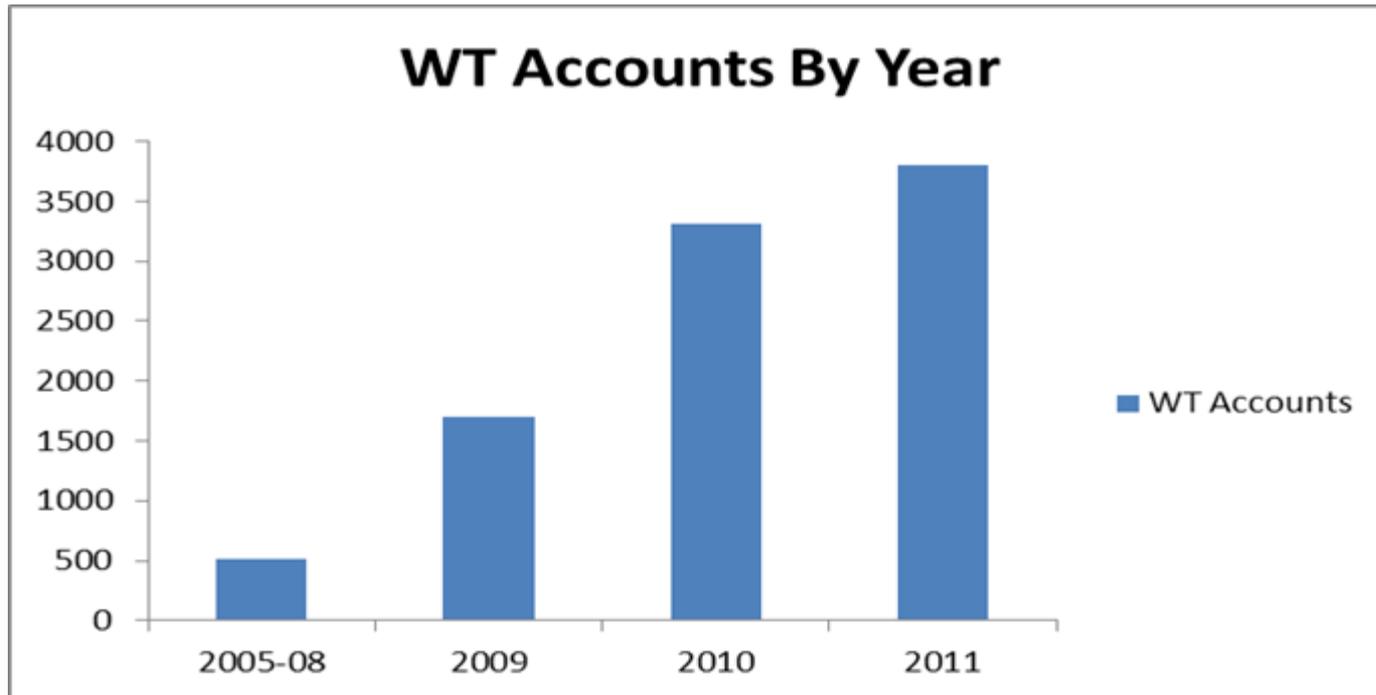
WebTrader Hosted Facility/Site

- WebTrader is a JAVA applet-based submission transmission method supported by ESG



WebTrader Accounts

- Over 97% of the Production accounts in ESG are WebTrader accounts



WebTrader Benefits

- Web based system
 - Does not require installation of a complicated, expensive gateway.
- Inexpensive
 - Only cost is ~\$20/year for a digital certificate
 - Highly cost effective for companies that send submissions frequently
- Easy to use once installed

WebTrader Challenges

- Setup can be difficult and in some case requires it requires IT support
 - Many small companies do not have IT staff
 - Not cost effective for infrequent users
 - High level of user frustration evident from help desk emails
- ESG requirements constrain desktop technologies for users
 - ESG requires JRE 1.5.x and Internet Explorer 6, 7, 8 or Firefox 2.0.x. Often, users have other application that are not compatible with JRE 1.5.x.
- Requires additional support from ESG helpdesk

What is the Proposed Solution?

- The proposed WebTrader Hosted solution is a Citrix based solution.



- Solution will be hosted in an FDA approved and secure environment.

Benefits of WebTrader Hosted Solution

- Improved User experience
- No setup required on the User desktop
- No constraints on desktop technology
- Less help desk support

What are the drawbacks of WT Hosted Solution?

- Introduces an additional login (for access to Citrix)
- Can't be used for large submissions (>1 GB)

ESG Resources and Contacts

- **Website:** <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>
 - Registration Information
 - System Requirements
 - User Guide and Tutorials
 - Digital Signatures and Certificates
 - System Status and Help Desk
 - Links to submission guidelines
- **Email for preparation/Registration/Policy:** esgprep@fda.gov
 - For questions and assistance in setting up test and production accounts
- **Email for technical issues:** esgreg@gnsi.com
 - This email is for system and submission related issues
- **FDA project manager: Michael Fauntleroy**
 - Email: michael.fauntleroy@fda.hhs.gov
 - Phone: 301-827-5132
 - Address: Office of the Director (HFM-25)
Center for Biologics Evaluation and Research
Food and Drug Administration
11400 Rockville Pike, Room 4119
Rockville, MD 20857



Most Frequently Occurring Errors – WebTrader Registrations

- **Correct JRE (Java Runtime Environment) or JCE (Java Cryptography Extension) not installed**
- **Firewall rules not set to allow communications over port 3080**
 - **Firewall port 3080 must be open for WebTrader applet to send submissions to FDA**
 - **WebTrader User Interface communications done through port 443**
- **Certificate fails on import**
 - **Send the certificate to esgreg@gnsi.com**

Common WebTrader Problems

When registering for an account, I get an error stating that: The Company Name is already in use.

The “Company Name” is actually an account name and must be unique throughout the entire ESG test (or production) system. Other companies have mitigated this by appending a unique identifier to the company name, like the WebTrader user’s initials.

When trying to log in, I get the error: Enter a valid user ID and password.

The username and password combination that you entered was not a valid combination for any account. Make sure you are using the correct username and password, and note that both are case-sensitive.

When trying to log in, I get an error: Your user account has been locked out by the system.

The username that you entered does not currently have an enabled account. This could be because the account has not yet been approved, or that there have been too many consecutively failing login attempts.

Common WebTrader Problems (cont.)

I just registered for an account, but when I try to log in, I get an error: **Your user account has been disabled.**

After you register, we need to approve your account before you are able to log in.

After logging in, I see a red box with: **“Error downloading unlimited strength Java Cryptography Extensions (JCE)”**.

The error means that the unlimited strength Java Cryptography Extensions (JCE) are not correctly installed. For more information on the JCE install, please see:

http://www.accessdata.fda.gov/esg/userguide/webhelp/Java_Runtime_Edition.htm

When signing a submission, I received an error: **Could not retrieve private key.**

This error means that either the file you picked to use as a signing certificate was not an actual private key file, or that you incorrectly entered the unlocking pass phrase.

The FDA does not (and can not) know the pass phrase for your certificate.

Common WebTrader Problems (cont.)

I see the following error in the receipt: Message signed with certificate that is not configured on the sender.

When sending a submission, it is signed using a private key (a .pfx file). The FDA ESG must have the public key (a .cer or .p7b file) from the same certificate on file in your account to verify the signature.

Send the public key to esgreg@gnsi.com along with the name of your account.

Do I have to send all the tests to get a production account?

Every test account has to send an FDA-compliant submission to the appropriate center to receive a production account. Other tests vary, as specified at:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

I sent a request for technical support to esgprep@fda.hhs.gov and did not receive a response within four hours.

The correct e-mail address for all technical support for the ESG is esgreg@gnsi.com.

Common WebTrader Problems (cont.)

Can my company have another account in production now that the first has been approved?

Every production account has to have a matching test account, and the test account must have submitted the appropriate tests and been approved individually for production. Please see:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

Can I use the same cert for both my Test account and my Production account?

Yes, you can. We encourage this as both can then be updated at the same time when the certificate expires.

Can I register for a second account?

Each user can have only one active account, allowing for as many submissions as you would like. If you need to retire an existing account, you could then register for a new account.

How many people can share one account?

Accounts in the ESG cannot be shared. Each individual must have their own account. There is no limit to the number of accounts that one company may have.

Common WebTrader Problems (cont.)

Have you received my test submissions?

In the WebTrader inbox, there will be a link to the receipt and acknowledgement if the ESG server and the FDA center server (respectively) have received the submission. If there are no errors in the text of these files, then the submission has been received successfully.

This also applies to production submissions.

I sent in my submission, and I have a receipt, but I do not have an acknowledgement.

Receipts and acknowledgements can contain error messages. If there is an error message in the receipt, then no acknowledgement will ever be sent, because there was no attempt to deliver the submission to the center server.

I haven't received my e-mail ACKs.

The ESG does not send any acknowledgements by e-mail. Acknowledgements are only received through the WebTrader interface.

Electronic Submissions Gateway

Thank you

Appendix

Supplemental Information - Installing Certificates

After you make the choice from the above list follow the on screen instructions to complete the purchase. CA will send you an email with PIN number and a link to a website where you can import/install the certificate. Accept all defaults and say “yes” to all pop-ups, your certificate will be installed in your browser. Note, if you are using WebTrader, you do not have to install the certificate on the same machine that you will be using. Once the certificate is installed in the browser you can export the public and private keys out and use them where ever you want. B2B system users will need to install the certificates in their system. Configuring the certificates may defer from sponsor to sponsor depending on what gateway software being used.

Purchasing and Installing Your Digital Certificate

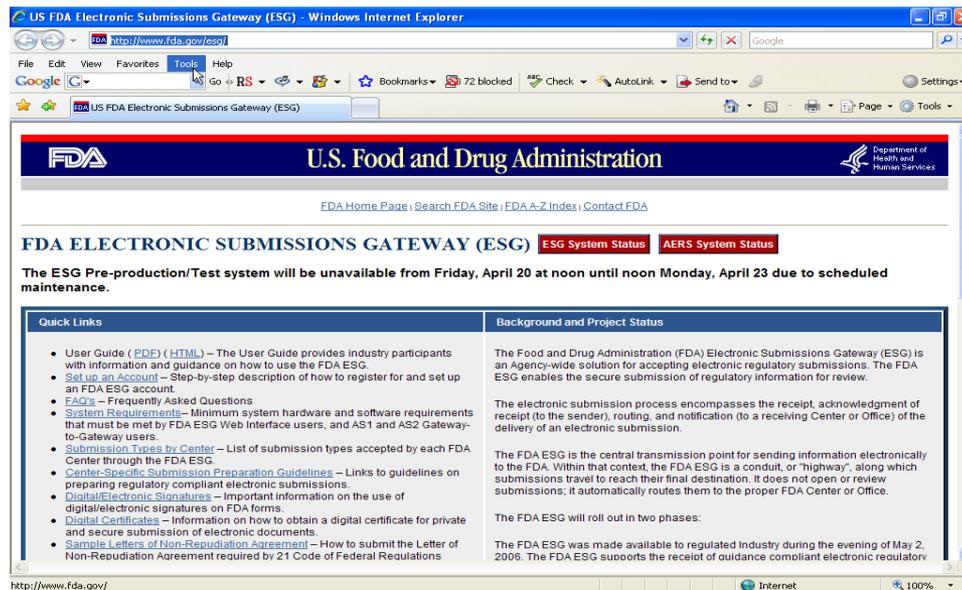
- **Identify company personnel who are designated to send electronic submissions through the Electronic Secure Gateway (ESG).**
- **Identify the computers they will use to send electronic submissions. Digital certs are computer specific.**
- **Purchase your x509 digital cert (.cer) from a vendor of choice. Online purchase is the fastest method.**
- **Once purchased, you should receive an email with the URL to the secure vendor site and your digital ID.**
- **Ensure that you login from the computer you intend to use to send submissions through the ESG.**

Supplemental Information - Purchasing Certificates

- If you are trying to use an outsourced certificate, the following are the companies that sell the X.509 certificates (Displayed in alphabetical order). Click on the link to go to website where you can purchase the certificate.
 - Geotrust:
http://www.geotrust.com/products/client_certificates/my_credential.asp
 - GlobalSign:
http://www.globalsign.net/digital_certificate/personalsign/index.cfm
If you select this, buy PersonalSign2 Pro™ Certificate with one year validity
 - Verisign: <http://www.verisign.com/products-services/security-services/pki/pki-application/email-digital-id/index.html>

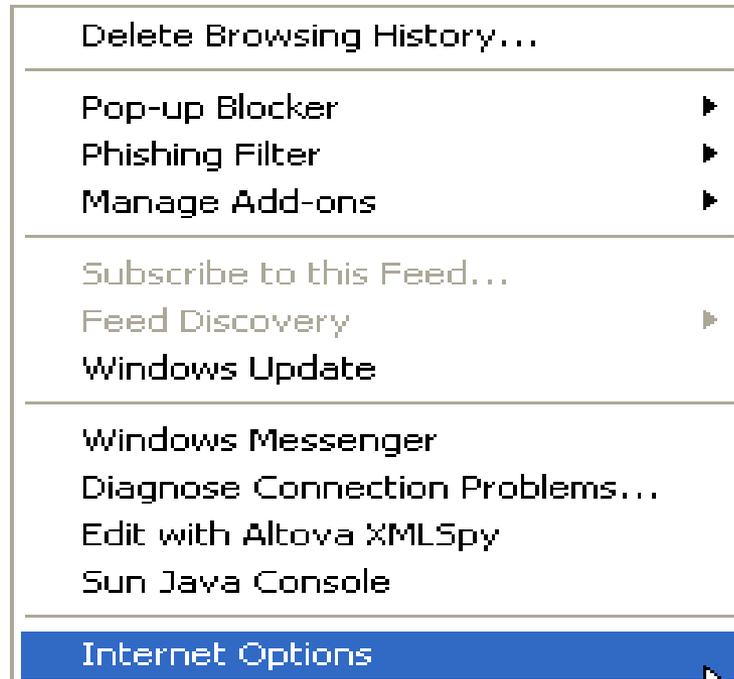
Purchasing and Installing Your Digital Certificate (cont.)

- Login to the vendor site, input your digital ID, and the site will install the digital cert (.cer). This is usually done using some sort of install wizard. Choose the default options during each step.
- Open Internet Explorer. Choose Tools



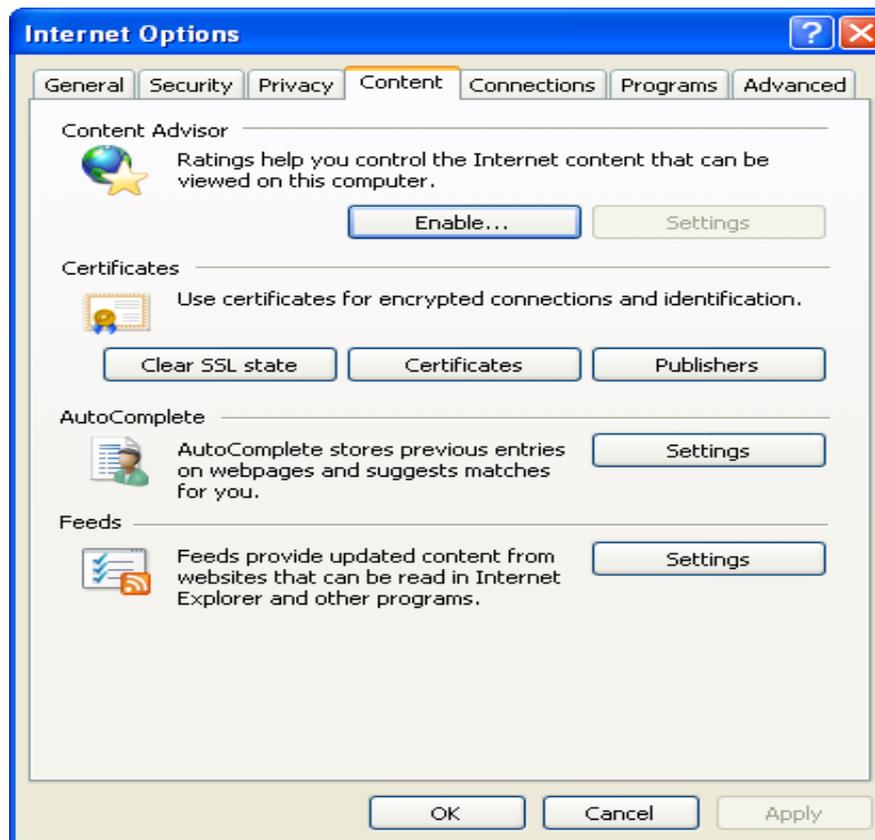
Purchasing and Installing Your Digital Certificate (cont.)

- **Choose Internet Options. The Internet Options Window will launch.**
- **Choose Internet Options**



Purchasing and Installing Your Digital Certificate (cont.)

- Choose the Content Tab and the Certificates Button
- Choose the Content Tab and the Certificates Button

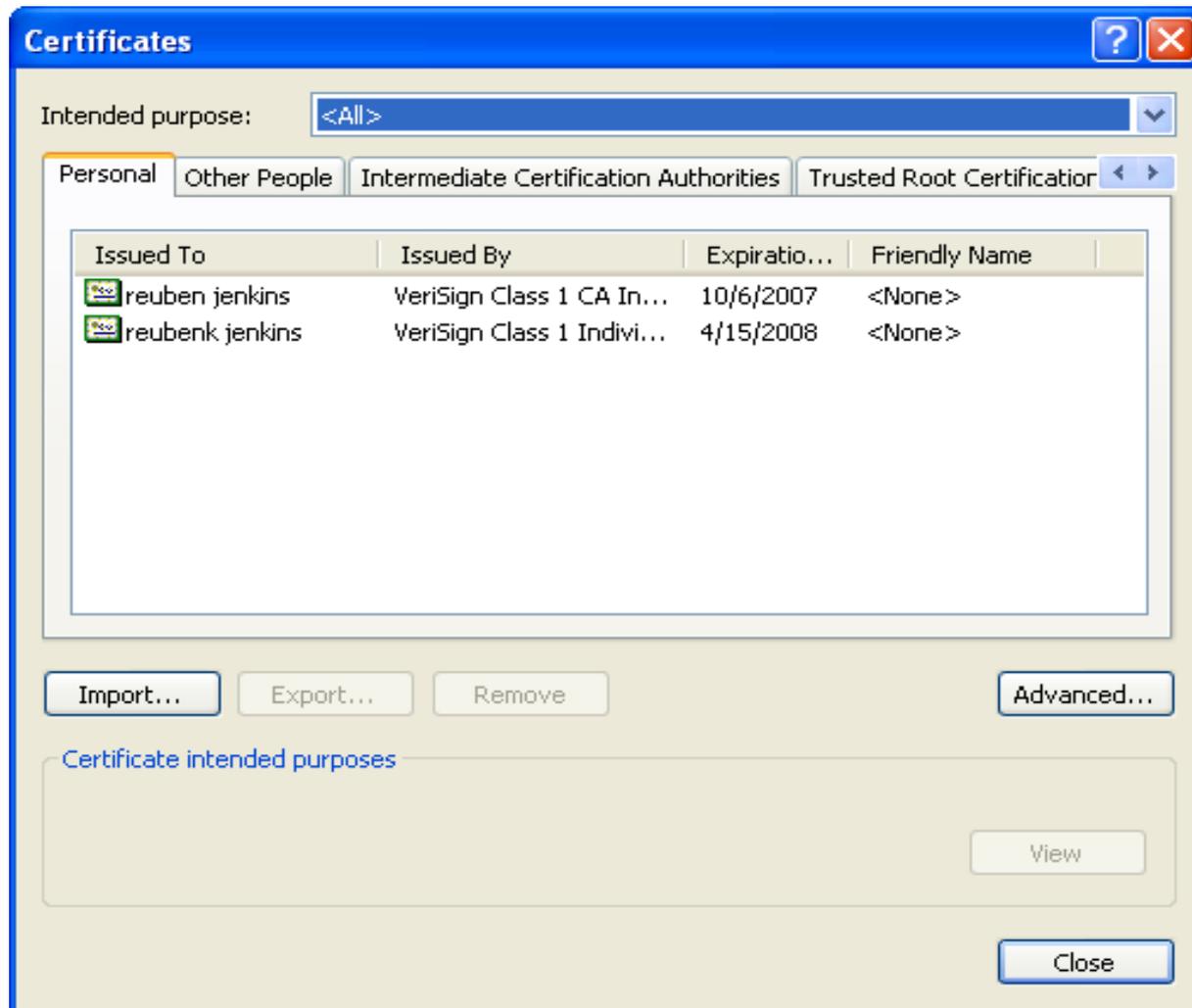


Purchasing and Installing Your Digital Certificate (cont.)

- **You will be directed to the Internet Explorer Certificates Window. The Personal tab is the default option. This is the location where the installation process should store your digital cert (.cer).**

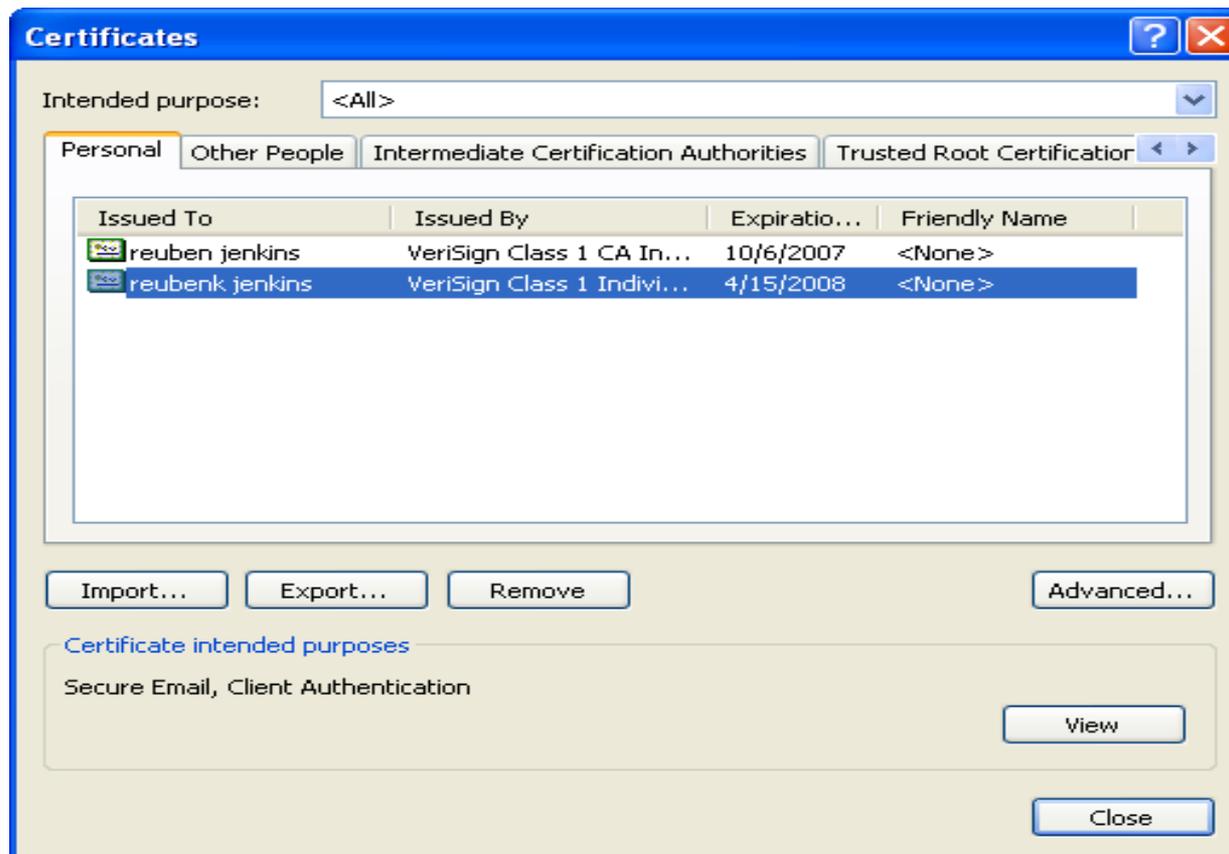
If the digital cert (.cer) is not in this location, please contact your vendor to identify the digital cert (.cer) location. To complete the ESG registration process you must know the location of your digital cert (.cer).

Purchasing and Installing Your Digital Certificate (cont.)



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- Highlight the digital cert (.cer) and the Export Button will become available.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- Choose the Export button and the Certificate Export Wizard Window will launch. Choose Next.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Wizard – Export Private Key Window will launch. Choose the default option. Choose Next.



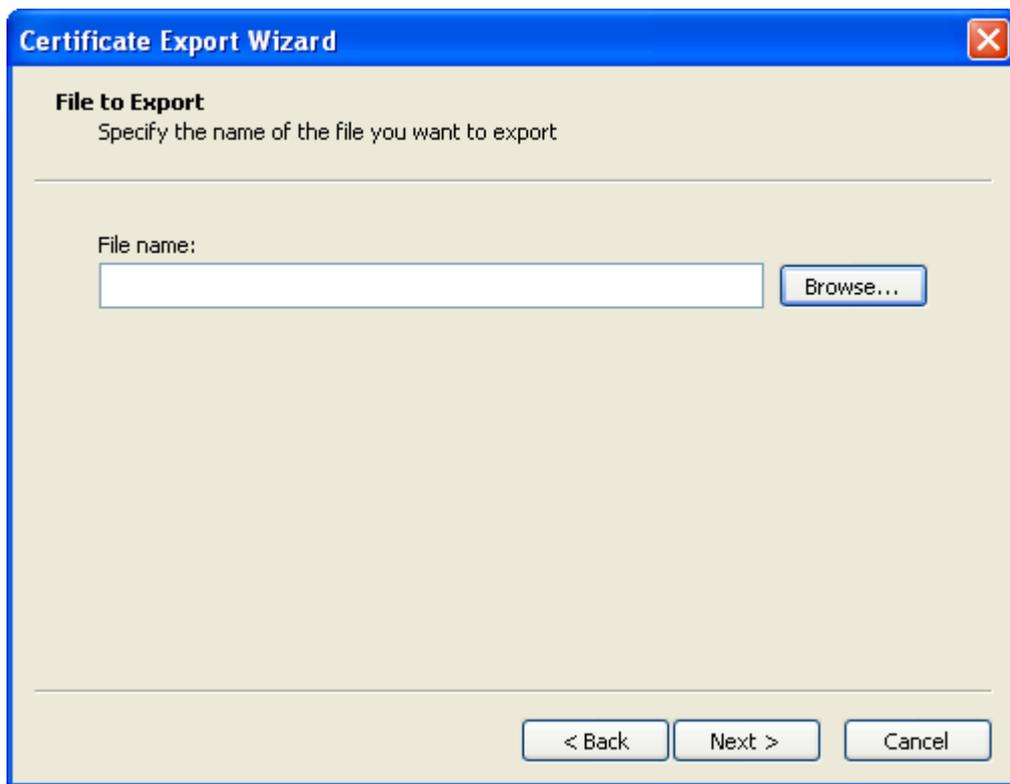
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Wizard – Export File Format Window will launch. Choose the default option. Choose Next.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

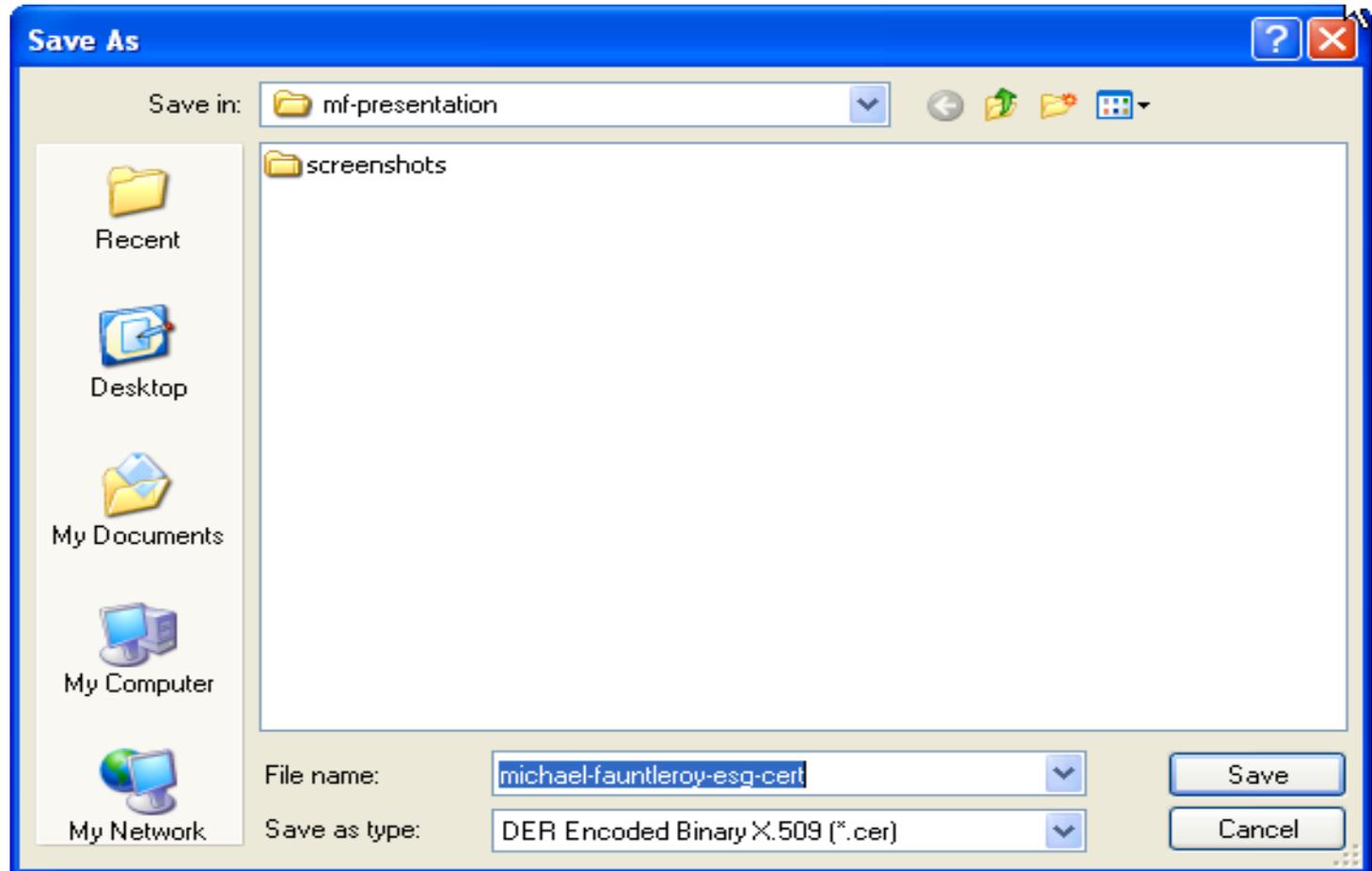
- The Certificate Export Wizard – File to Export Window will launch.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

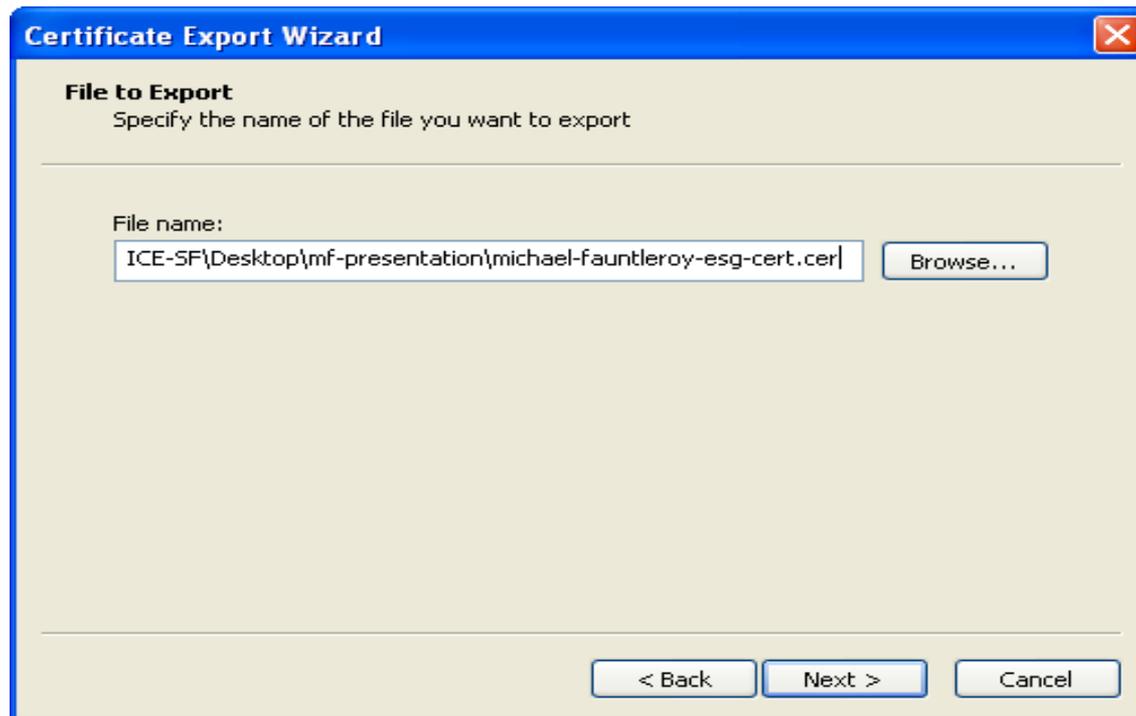
- **Choose Browse. The Save As Window will launch. Navigate to the location where you want to store the exported digital cert (.cer).**
- **Create a name for the digital cert (.cer). We recommend something that will remind you that the digital cert (.cer) supports the ESG. Choose Save**

Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Wizard will return you to the Certificate Export Wizard – File to Export window. The storage path for your digital cert (.cer) will be inserted in the File Name area. Choose Next.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Window – Completing the Certificate Export Wizard Window will launch. Choose Finish.



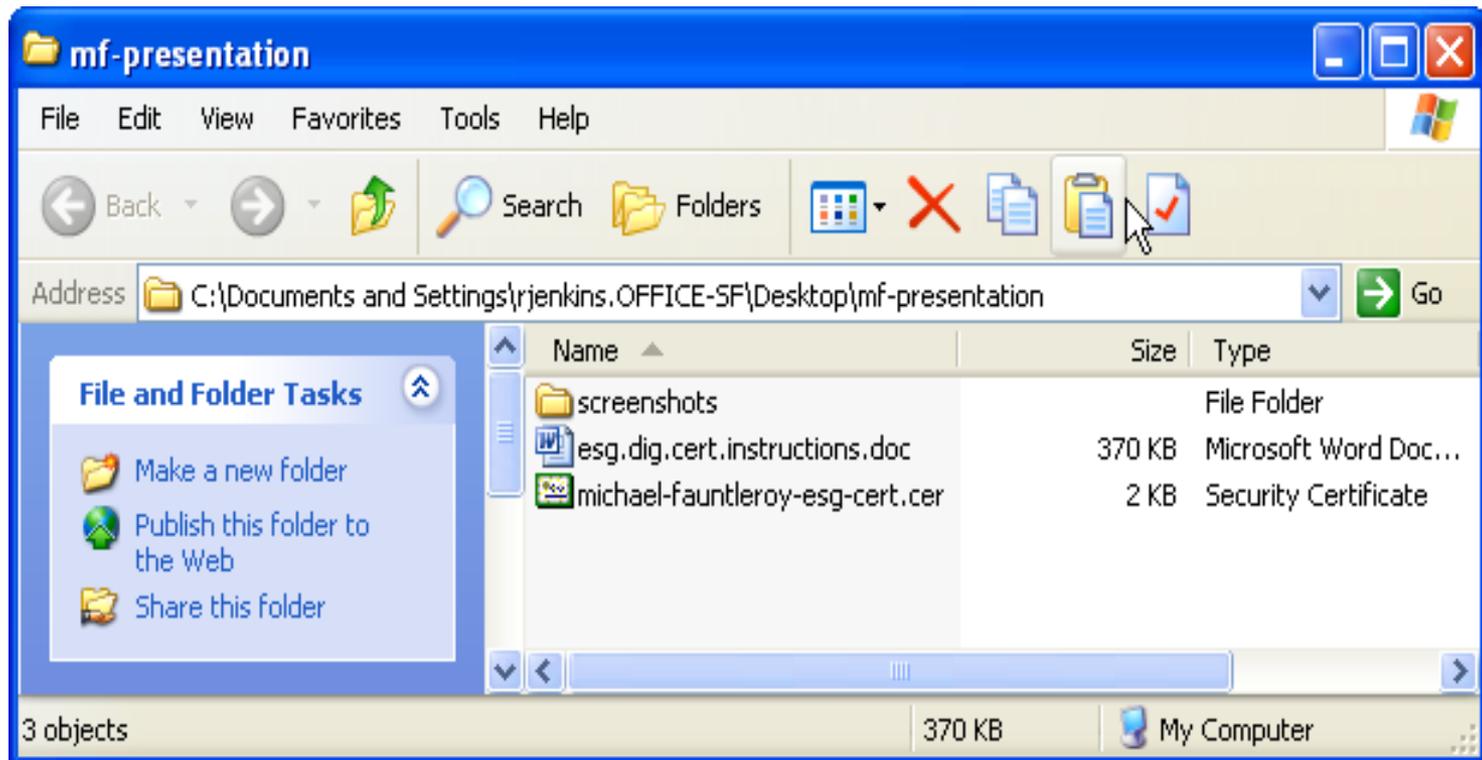
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- If the export was successful, the Certificate Export Wizard will display the message below after you choose Finish.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- Navigate to the digital cert (.cer) storage location to verify a successful export.



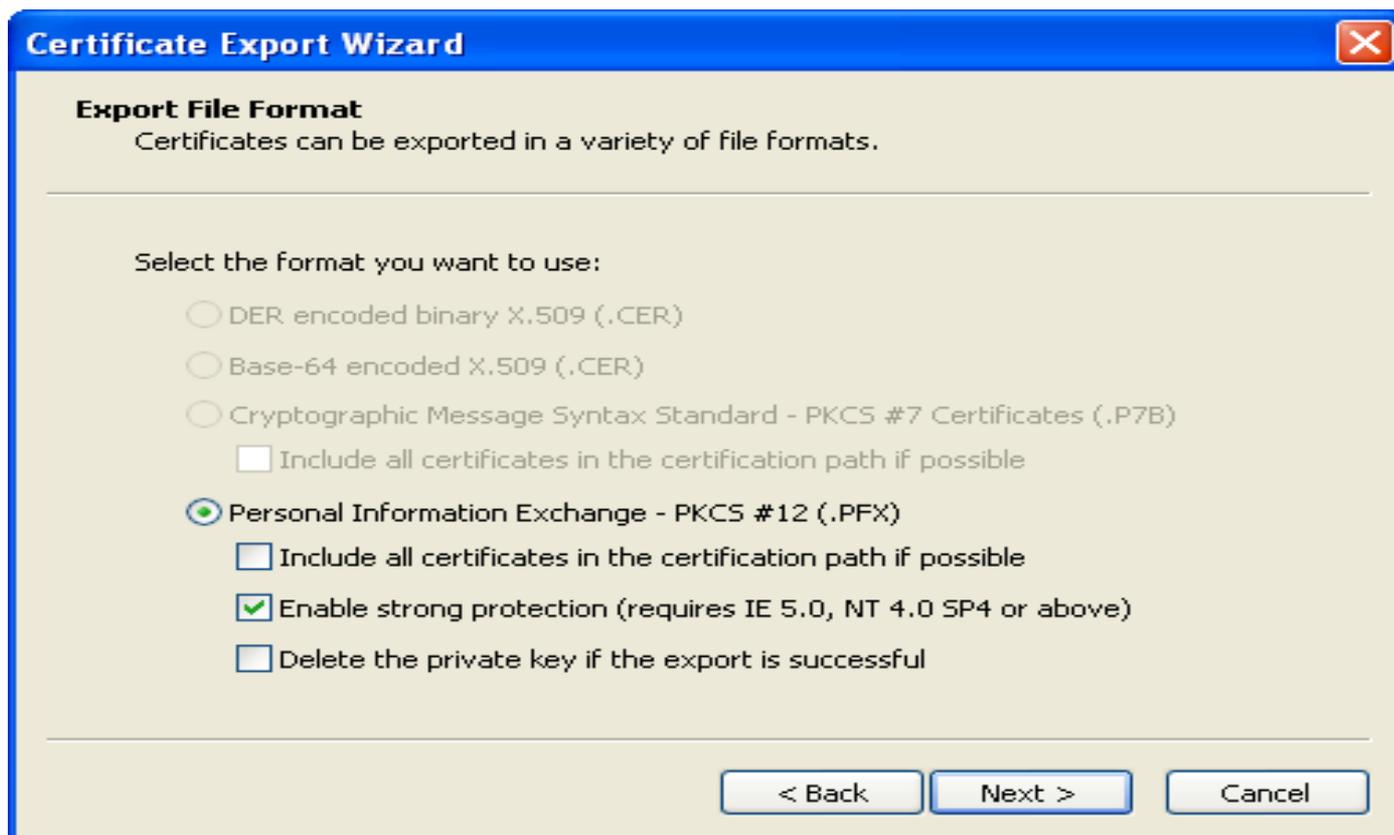
Additional Information

- Once you have established your test account and the ESG personnel have verified, approved, and accepted your digital cert (.cer), you will need to create a .pfx file format version of your digital cert (cer).
- During the submission transmission process, the ESG will prompt you for the .pfx version of your digital cert and a password. Once the password is verified, your digital cert (.pfx) will attach itself to each and every file you transmit through the ESG.

Additional Information

- **Converting your digital cert from a .cer to a .pfx file for file/submission transfer through the ESG.**
- Follow steps in slides 9 and 10.
- **The Certificate Export Wizard – Export Private Key Window will launch. Choose the “Yes, export the private key” option. Choose Next.**

Additional Information



Certificate Export Wizard [Close]

Export File Format
Certificates can be exported in a variety of file formats.

Select the format you want to use:

- DER encoded binary X.509 (.CER)
- Base-64 encoded X.509 (.CER)
- Cryptographic Message Syntax Standard - PKCS #7 Certificates (.P7B)
 - Include all certificates in the certification path if possible
- Personal Information Exchange - PKCS #12 (.PFX)
 - Include all certificates in the certification path if possible
 - Enable strong protection (requires IE 5.0, NT 4.0 SP4 or above)
 - Delete the private key if the export is successful

< Back Next > Cancel

Additional Information

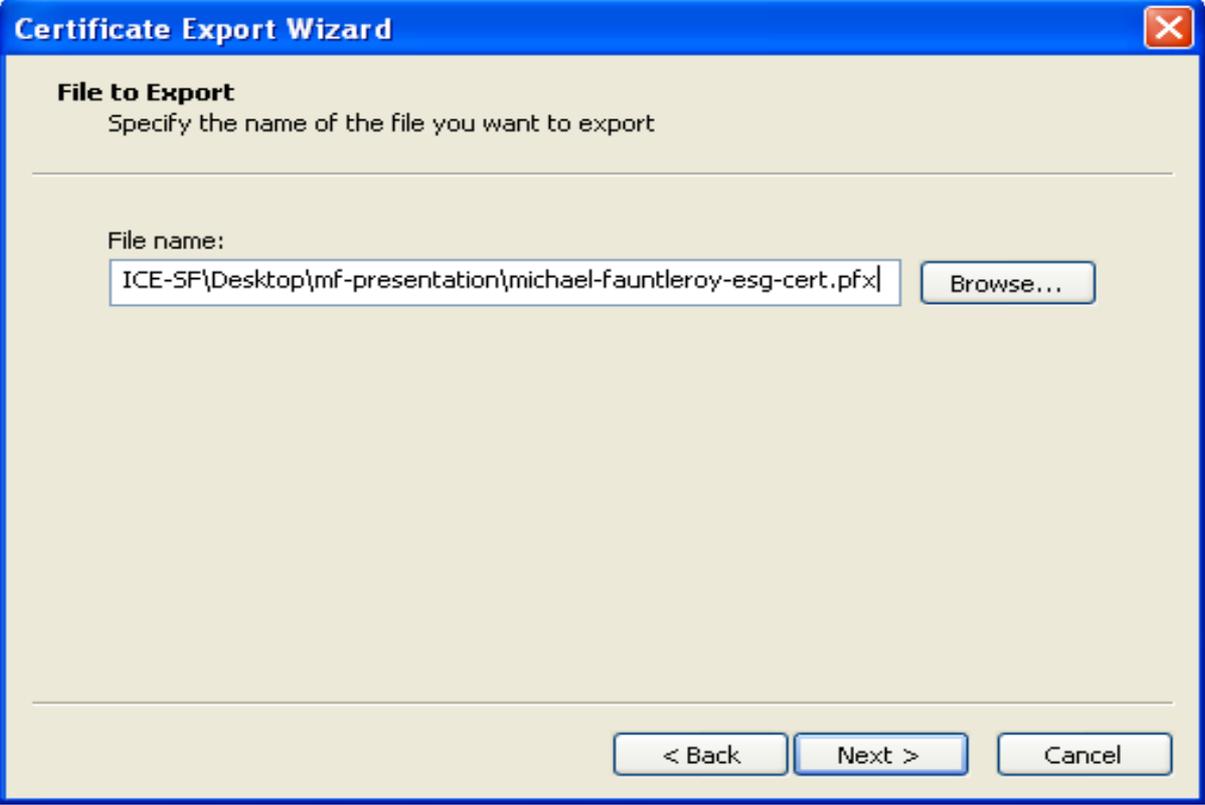
- The Certificate Export Wizard – Password Window will launch. Enter and confirm Password. Choose Next. (Remember this password! The ESG will ask for it when you transmit files!)



The screenshot shows a Windows-style dialog box titled "Certificate Export Wizard" with a red close button in the top right corner. The main heading is "Password" in bold. Below it, a message reads: "To maintain security, you must protect the private key by using a password." A horizontal line separates this message from the input area. The instruction "Type and confirm a password." is followed by two text boxes. The first is labeled "Password:" and contains seven asterisks. The second is labeled "Confirm password:" and also contains seven asterisks. At the bottom of the dialog, there are three buttons: "< Back", "Next >", and "Cancel".

Additional Information

- You must browse to determine a storage location for the digital cert (.pfx) and name the file appropriately. Choose Next.



The image shows a Windows dialog box titled "Certificate Export Wizard". The window has a blue title bar with a close button (X) in the top right corner. The main area is light beige and contains the following text and controls:

- File to Export**
Specify the name of the file you want to export
- A horizontal line separates the title from the input area.
- File name:**
A text input field containing the path: `ICE-SF\Desktop\mf-presentation\michael-fauntleroy-esg-cert.pfx`
- A "Browse..." button to the right of the text input field.
- At the bottom of the dialog, there are three buttons: "< Back", "Next >", and "Cancel".

Additional Information

- The digital cert (.pfx) will be exported. Navigate to the digital cert (.pfx) storage location to verify a successful export.

