



GlobalSign Digital Certificate Solutions

Digital Certificates for the FDA ESG Guide

Acquiring, Setting up, and using a **GlobalSign PersonalSign1 X.509 Digital Certificate** for the FDA ESG WebTrader



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Who should read this document?

Any organization wishing to electronically submit one of the following forms to the FDA via the Electronic Submission Gateway (ESG) WebTrader:

AERS – Adverse Event Reports	Lot Distribution Data
AERS Attachments	ANDA – Abbreviated New Drug Application
H1N1 Lot Release	BLA – Biologics License Application (eCTD and eBLA format)
IDE – Investigational Device Exemption	eCTD – Electronic Common Technical Document (includes DMF)
IND – Investigational New Drug Application (eCTD and eIND)	NDA – New Drug Application (eCTD and eNDA format)
DMF – Drug Master File	Adverse Events
Promotional Materials	Electronic Submissions

See FDA- Table 2: Electronic Submissions Supported by the FDA ESG
<http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>

Introduction:

As stated by the FDA “The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory information for review.

The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach their final destination.”

A prerequisite to establishing a WebTrader account, the on-line mechanism participants use to upload their electronic submissions to the FDA, is to acquire an x.509v3 digital certificate. GlobalSign’s Digital Certificates are recommended by the FDA as a suitable x.509v3 digital certificate for ESG submissions and this guide is intended to clarify the process in obtaining a digital certificate from GlobalSign and preparing the certificate for use with WebTrader account.

Setting up a WebTrader Account Checklist

In the “Setting up a WebTrader Account Checklist” provided by the FDA you are asked to “Obtain a personal digital certificate”. The following procedure in this guide will provide you with detailed instructions on how to setup a WebTrader account including setting up both your ESG test and production account.

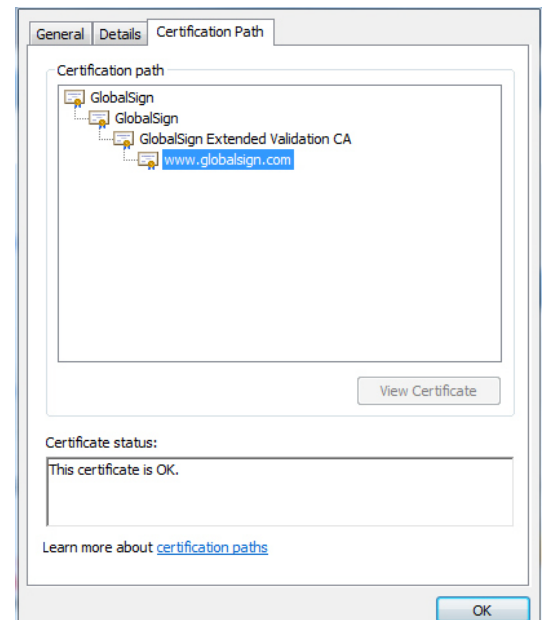
Before you Start	
<input type="checkbox"/>	1. Send an email to esgprep@fda.hhs.gov requesting a WebTrader test account. Provide the following information: Company name, your name, phone number and submission method (WebTrader).
<input type="checkbox"/>	2. Send a Letter of Non-Repudiation to FDA. Click here for more info.
<input type="checkbox"/>	3. Obtain a personal digital certificate. Click here for more information on certificates.
<input type="checkbox"/>	4. Prepare a guidance compliant test submission. Each Center (CBER, CDER, etc.) has published guidance on the preparation of electronic submissions. Refer to the specific center web site for information about guidance compliant submissions. If using FDA eSubmitter for the Center for Tobacco Products, you are not required to send a guidance compliant test submission.
<input type="checkbox"/>	5. Read the User Guide and tutorials on the FDA ESG web site. Review System Requirements . Note: only Internet Explorer 6, 7, 8 and Firefox 2.0.x are compatible with ESG.

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

Before you begin:

Explanation of Digital Certificate:

A digital certificate, or sometimes referred to as a digital ID is the electronic equivalent of an identity credential such as a driver’s license. Since face to face or even examination of “wet-ink” signatures is not practical in the paper intensive work-flow that surrounds the healthcare and other FDA regulated industries, organizations like the FDA rely on electronic credentials issued from trusted Certificate Authorities to verify the authenticity of the participant in an electronic transaction. Public certificate authorities such as GlobalSign, create electronic “trust” by verifying the individual and organization through established methods. If all checks out, then an electronic identity - - digital certificate will be issued. Because this digital certificate is issued from a Trusted Root found in most popular operation systems and browsers such as the Microsoft Root store organizations like the FDA can safely rely on the legitimacy of the electronic identity.



GlobalSign issues digital certificates using the practices outlined in its WebTrust audited Certificate Practice Statement (CPS) <http://www.globalsign.com/repository/>.

System Requirements

Because the FDA requires that your public certificate (aka. p7 or .cer) and corresponding private key aka PKCS12 be exported into a file and saved on your hard-drive, GlobalSign recommends you enroll using the Internet Explorer browser. Vista users should note special security settings that are required to support the certificate installation process. These settings are outlined in the PersonalSign enrollment guide found http://www.globalsign.com/support/ordering-guides/PersonalSign_GCC_Certificate_Enrollment_Guide.pdf.

Quick Step – Process Summary

Admittedly, the process to enroll for a digital certificate for use with the FDA ESG Gateway WebTrader includes many detailed steps. If you follow the steps in the exact order suggested the process from ordering to installing shouldn't take more than 2 or 3 days. The following is a high-level summary of the steps that surround the digital certificate set-up of WebTrader:

1. Order your digital certificate from GlobalSign
2. Install you digital ID using Internet Explorer browser
3. Make a copy of the public certificate (.cer / p7) and submit to FDA
4. Make a copy of the public / private certificate (PKCS12) and submit to FDA

Ordering your FDA ESG Digital Certificate:

When you are ready to register for an ESG WebTrader X.509 V3 digital Certificate, start the order process by clicking on the following link: <http://globalsign.com/authentication-secure-email/digital-id/buy-personalsign-1.html>

Step 1: Select Region

A Step-by-step guide to enrolling and using a FDA ESG GlobalSign PersonalSign 1 Digital Certificate

Digital ID Application

PersonalSign 1

Applying for your GlobalSign Digital Certificate is quick and easy.

Please complete the online application process and contact Sales Support at 1-877-SSLGLOBAL if you have any questions during the process.

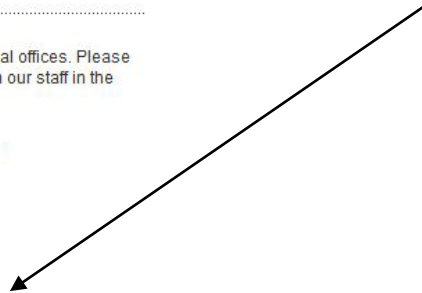
Select your Region

To serve all our worldwide customers, GlobalSign has numerous of Global offices. Please select your Country or Region to ensure you receive the best support from our staff in the most appropriate local office.

- North America - United States & Canada (US pricing in USD)
- South & Central America
- Europe (EU pricing in Euro)
- United Kingdom (UK pricing in GBP)
- Australia & New Zealand
- Asia & Pacific
- Other

[Continue with Certificate Application](#)

Select the Region your organization resides in a click **“Continue with Certificate Application”**



Step 2: Establish your GlobalSign Certificate Center (GCC) account

Start your GCC set-up by completing the following form:

Complete the GCC Account registration by providing information about you as the Account holder. Please note, further in the process you will have the opportunity to enter a different name that you wish to include in the digital certificate in the event you are enrolling on behalf of someone else.

Certificate Application

1. Account Setup

2. Product Details

3. Completed

Account Details

Confirm Details

Account Details

Please specify details for your account. Your account contact will receive notices regarding your Certificate application and will be the main contact associated with your GlobalSign Certificate Center (GCC) account. If you are applying on behalf of someone else, enter their details, and you can specify an additional Technical Contact for yourself later in the application process.

First Name <small>Required</small>	<input type="text" value="Joan"/>
Middle Name or Initial	<input type="text"/>
Last Name <small>Required</small>	<input type="text" value="Smith"/>
Email Address <small>Required</small>	<input type="text" value="jsmith@gethealthy.com"/> <small>Please check email is accurate, this email address will be used in the application process</small>
Phone Number <small>Required</small>	<input type="text" value="555-555-5555"/> <small>e.g. 603-570-7060 or 01622 786766</small>

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Next establish a user name and password that you'll need to remember to access your account. *Note a pre-fix will be added to the user name you establish e.g. "PAR12334_YourUserName." Therefore when you log back into your GCC account you will need to enter the full user name and password when authenticating to the GCC portal.

PLEASE NOTE- Your username will be e-mailed to you once your account has been set up, please remember/save the password you have created.

Opt in to Receive GlobalSign Notices? GlobalSign respects your privacy - please see Privacy Policy for further information	<input checked="" type="checkbox"/> Yes, opt in to receive important GlobalSign notices and offers
--	--

GlobalSign Certificate Center (GCC) Login Details

Your GCC account allows you to manage all your GlobalSign Certificates and provides fast access to ordering additional products and renewing, reissuing and revoking current Certificates. Please create a memorable Username and Password.

Username Required	<input type="text" value="happydays"/> <small>Username is case sensitive and must be 8 - 64 characters. Alpha-numeric values only (A-Z, 0-9)</small>
Password Required	<input type="password" value="●●●●●●●●"/> <small>Password is case sensitive and must be 8 - 64 characters. Alpha-numeric values only (A-Z, 0-9)</small>
Password(re-enter) Required	<input type="password" value="●●●●●●●●"/>

Specify an Additional Billing Contact

You can add a new Billing Contact to administer invoices and receipts for your account.

Click the Enter Billing Contact Details link to create the additional contact.

If you are applying for yourself, you do not need an additional Billing Contact, so please click Next.

[Enter Billing Contact Information](#)

Next 

Step 3: Confirm your registration details and Accept Service Agreement

Review the account details you entered and if accurate, accept the terms of the GCC service agreement and **continue**

Review the Terms of Service Agreement and if you agree please click **“I agree to the terms of service”** and click **“next”**

Terms of Service Agreement

GlobalSign Certificate Center (GCC) Terms of Service

Version 1.3

1 ACCEPTANCE OF TERMS

1.1 Your use of GlobalSigns GlobalSign Certificate Centre (GCC) and any relate

1.2 Unless otherwise agreed in writing with GlobalSign, your agreement with Glot

1.3 If there is any contradiction between the Additional Terms and the GCC T&C.

1.4 You agree to use the Service only for purposes that are permitted by (a) the

2 DESCRIPTION OF SERVICE

2.1 GCC provides users with access to a collection of functions and resources, ir

2.2 You understand and agree that GlobalSign assumes no responsibility for the

3 YOUR REGISTRATION OBLIGATIONS

3.1 In consideration of your use of the Service, you agree to: (a) provide true, ac

4 GLOBALSIGN PRIVACY POLICY

4.1 Registration Data and certain other information about you is subject to our P

5 ACCOUNT, PASSWORD AND SECURITY

5.1 You will receive an account designation upon completing the Service's regist

6 COMMUNICATION TOOLS

I AGREE TO TERMS OF SERVICE

Step 4: Select the certificate validity

The FDA recommends a certificate with a 3-year validity period. Shorter validities will require more frequent registration with the FDA ESG. **Please check off PKCS12 option** and click **Next**.

Product Details - PersonalSign 1

Certificate Validity <i>Required</i> Multi-year offers significant per annum savings	<input type="radio"/> 1 year \$20 <input checked="" type="radio"/> 3 year \$49
Campaign Code	<input type="text"/> <input type="button" value="Apply"/> <small>If you have a Campaign Code such as a Renewal Code please enter and click Apply. This page will be reloaded with your appropriate discount.</small>
Coupon Code	<input type="text"/> <input type="button" value="Apply"/> <small>If you have a one-off Coupon Code for a particular promotion please enter and click Apply. This page will be reloaded with your appropriate discount.</small>
I have an externally generated CSR Check only if you are an Advanced User and have an externally generated Certificate Signing Request (CSR) Otherwise click Next...	<input type="checkbox"/> Yes, I have an externally generated CSR (advanced users only)
PKCS12 Option	<input checked="" type="checkbox"/>
TOTAL COST (Inc. Tax)	\$ 49

Step 5: Enter the Certificate holder’s identity information.

Enter the Email address of the person who will be the certificate holder.

Certificate Identity Details

These details will be vetted and included as the certified identity within your Issued Certificate. Make sure the details entered are correct - we will vet the details you include. To assist you, some details will be pre-populated from previous pages or from your GCC account details, you may overwrite these if needed.

Email Address <i>Required</i>	<input type="text" value="janine.marchi@globalsign.com"/> <small>The specified email will be visible within the Issued Certificate in the Common Name field</small>
--------------------------------------	--

Step 6: Establish a one-time only certificate pick-up password

Subsequent to order approval, an email will be sent to the email address specified in the Certificate Identity Details. The email will include a URL to install the digital ID into your local system via Internet Explorer. You will need to record, save, and remember the Pickup Password in order to authenticate to the GlobalSign service.

When the vetting is complete we will send an email to the Applicant to pickup the Certificate. For security, please specify a Pickup Password that will be required to release the issued Certificate. NOTE, the usage for this password is different from the GCC login password provided previously, the Pickup Password is used only for this Certificate application.


Pickup Password Required	<input type="password"/> <small>Password must be a minimum of 8 characters. Alpha-numeric values only (A-Z, 0-9)</small>
Pickup Password (re-enter) Required	<input type="password"/>

PLEASE NTOE- This will be the password you use to “pickup/install/obtain” your Certificate. This is different then the password you created earlier to login to your GCC Account.

Step 7: Enter Credit Card details

GlobalSign does not accept Purchase orders for products under \$500, therefore enter credit card details.

Enter the First Name (or initial) and Last Name exactly as written on your Credit Card.
 Enter the card holder's Address, City, Zip/Postal Code, State, and Country as detailed on your Credit Card statement.

First Name or Initials Required	<input type="text"/>
Last Name Required	<input type="text"/>
Card Type Required	<input checked="" type="radio"/> VISA <input type="radio"/> MasterCard <input type="radio"/> American Express
Card Number Required	<input type="text"/>
Card Expiration Date Required	<input type="text"/> / <input type="text"/> <small>Month / Year (i.e. 01/2014)</small>
Card Validation Number Required	<input type="text"/>  <p>The CVV / security code is the last three digits printed on the back of your card for Visa / MasterCard and on the front for American Express Where do I find the CVV</p>
Statement Street Address Required	<input type="text"/>
Statement City Required	<input type="text"/>
Statement Zip / Postal Code Required	<input type="text"/>

Step 8: Confirm details and Accept PersonalSign Subscriber Agreement

Click “I agree to the Subscriber Agreement” and then “Next”

Step 9: Take note of your GCC User Name and Order number

Saving your GCC User ID and previously established password (**step 2**) will be helpful later on when you wish to log into your account to check status, maintain your digital ID, or optionally, order additional digital certificates.

Application Almost Completed

Thank you for completing the first part of your application. We recommend you print this information for your records. We will shortly send a confirmation email containing this information, however should you not receive the email and need to contact the [Technical Support](#) team, you will need your Order Number.

GCC User ID Your GCC account has been created, log in with this User ID and the Password specified when creating the account.	PAR26113_happydays
Order Number	PC201002051158

What happens next?

An order confirmation will be sent from no_reply@globalsign.com.

Also an automated Approval Email will be sent to the Email Address you have specified. You must be able to receive this Email at this Address and follow the instructions within the email.

Your application will now be vetted. You do not need to do anything else at this time. Should we require additional verification information a Vetting Agent will contact you.

Step 10: Check your email for an Approval request

One step that GlobalSign takes to ensure the request for a digital certificate is legitimate and authorized is to send an email challenge request to the email that was used in the certificate identity details. An order confirmation will be sent from a no_reply email: support@globalsign.com. The recipient of this email must click on the URL and then “**Approve**” the order. **Until this step takes place, GlobalSign cannot begin the organization vetting process.** Click on the URL, review the details, and if accurate, click “I Approve”

Click here to change your security settings

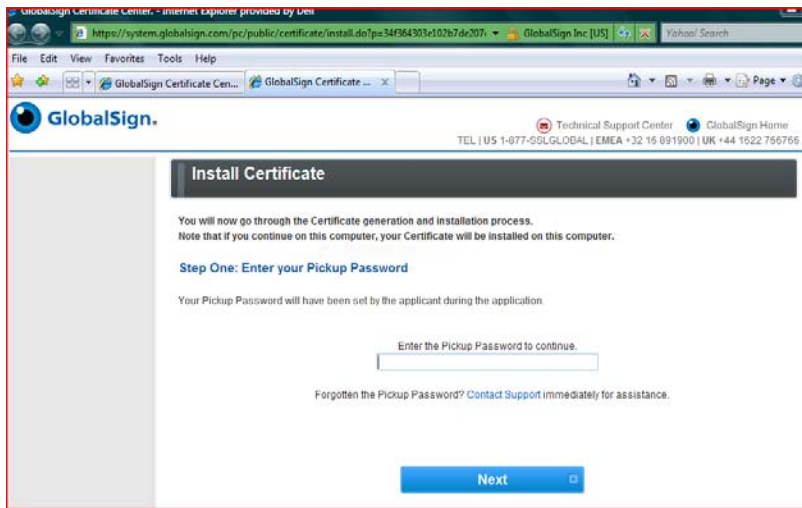
Application Details	
Order ID	PC201002051158
Common Name	Jeff Jones
Contact First Name	Joan
Contact Middle Name	-
Contact Last Name	Smith
Contact Phone	555-555-5555
Contact Email	lila.kee@globalsign.com
Organization (O)	Get Healthy Inc.
Locality (L)	Boston
State (S)	MA
Country (C)	US
Application Email	lila.kee@globalsign.com
Application Date	2010-02-05 19:40:07.702

Please contact support if you require further assistance.

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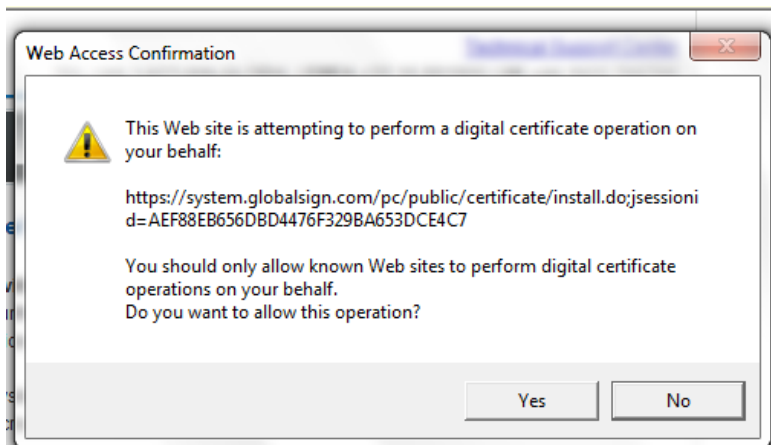
Step 11: Install your FDA ESG PersonalSign1 x.509v3 digital certificate.

Subsequent to approval, you will receive another email notifying you that your digital certificate is ready to be “picked up”. Before you can start the installation process, take note of the previously mentioned system requirements and have the certificate pickup password you previously established in **step 6** handy. Using Microsoft Internet Explorer, click on the URL provided in the email and it will prompt you for the Certificate Pick up Password that was established at registration:



Step 12: Allow the digital certificate creation operation to begin.

Vista users will be prompted with an “Web Access Confirmation” request. Click “Yes” to proceed.



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Step 13: Select the Cryptographic Service Provider

Click **Next**, maintaining the default settings of “yes, make this Certificate exportable” and “Microsoft Enhanced Cryptographic Provider v1.0”.

Install Certificate

Step Two: Select the Cryptographic Service Provider (CSP)

The CSP is used to generate the cryptographic keys within your Certificate. We have listed the CSPs found on your computer. For further assistance on using CSPs and which may be appropriate if you are installing your Certificate onto a hardware device such as crypto USB, view the [CSP Support Guide](#).

Please note! Depending on your browser / Operating System setup, there may be a information bar or Pop Up asking you to install "Microsoft Certificate Enrolment Control" displayed at the top of this page. If so, you MUST allow this to run. It is a safe program that your browser uses to install your certificate. To run it, click on the information bar or Pop Up and follow the instructions.

Make Certificate Exportable?	<input checked="" type="checkbox"/> Yes, make this Certificate exportable Check if you wish to allow the Certificate and associated cryptographic keys to be exportable. This means you can back up the Certificate or move it to another computer at a later time.
Cryptographic Service Provider	Microsoft Enhanced Cryptographic Provider v1.0

Please click Next and wait. Do not click Next again and do not close the browser, the process may take a few seconds.

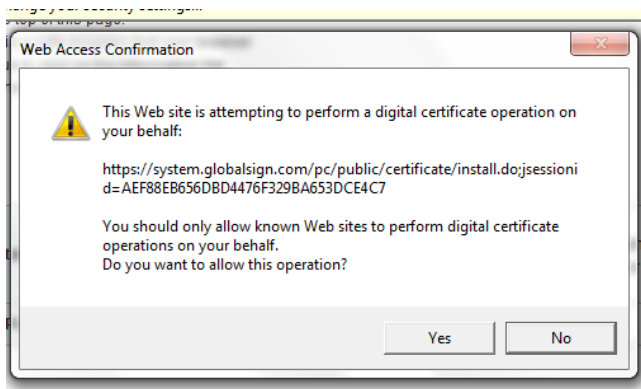
Next

Click “Yes, make this Certificate exportable”

Choose “**Microsoft Enhanced Cryptographic Provider v1.0**” as your Cryptographic Service Provider.

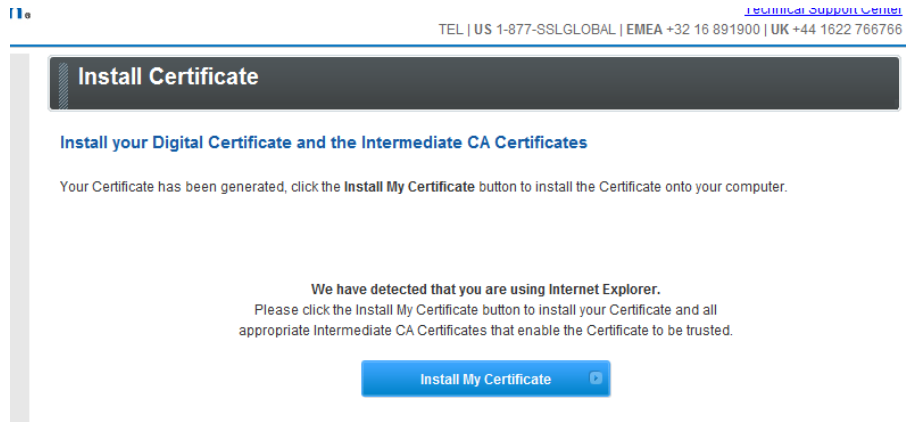
Step 14: Allow the Certificate operation to take place.

Click “Yes” at the Web Access Confirmation Prompt

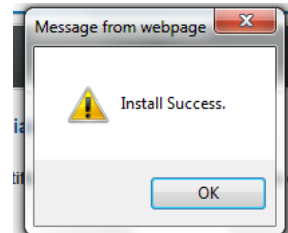
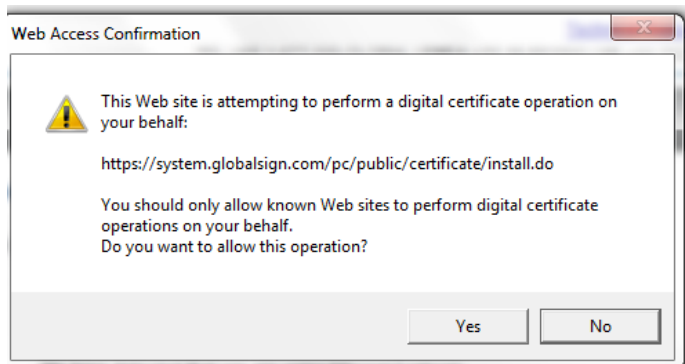


Step 15: Install you certificate

After the certificate processing is complete, click **“Install My Certificate”**



And once again allow the digital certificate operation by clicking **“Yes”**. You have completed the installation process, when you see the following Prompt: Click **“OK”**



Prepare for ESG Test account- Exporting Public Key

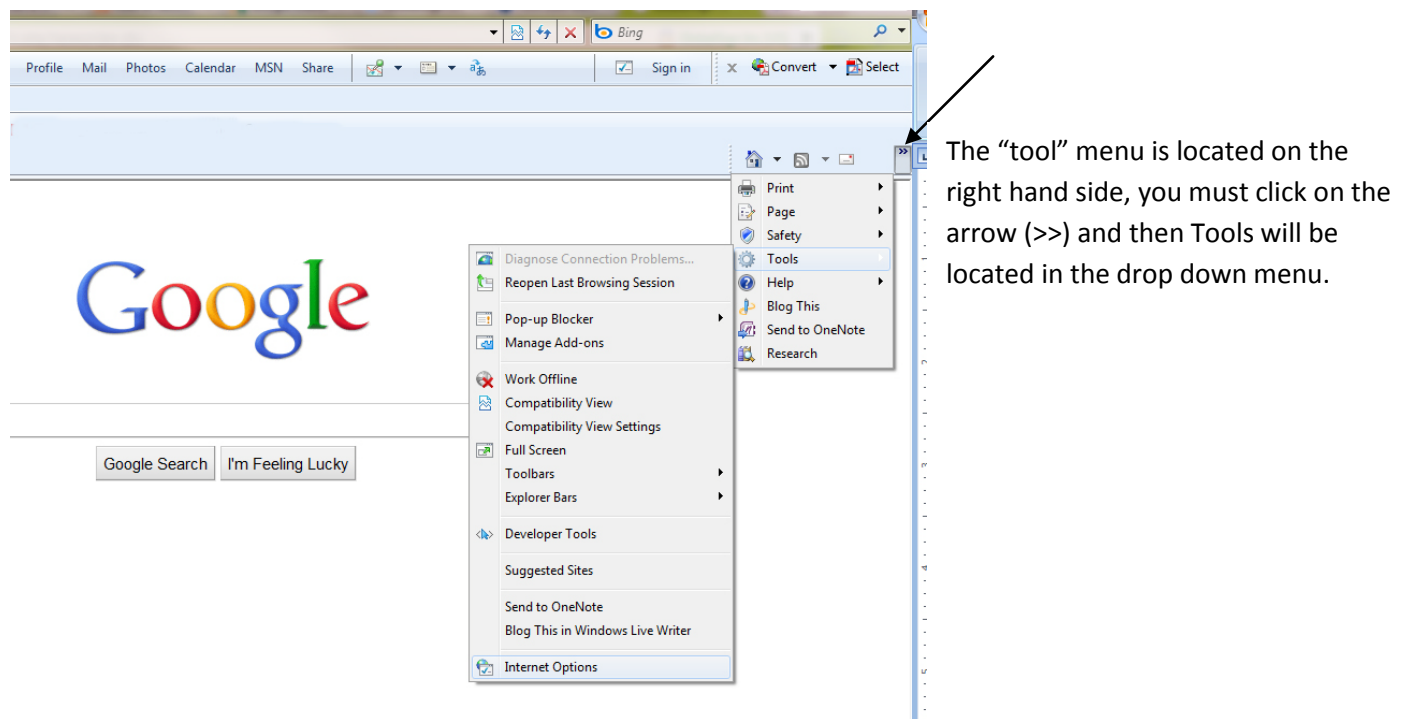
As described in the FDA’s “Setting up a WebTrader Account Checklist”

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm> and FDA User Guide <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm> section 4.1 step 12 the establishment of a test account will require you to browse for your digital certificate.

A copy of the digital certificate, (aka. .cer or .p7b) you recently installed will need to be “**exported**” and delivered to the FDA as part of the test account set-up. Below are step-by-step instructions on how to create your .cer or .p7b file.

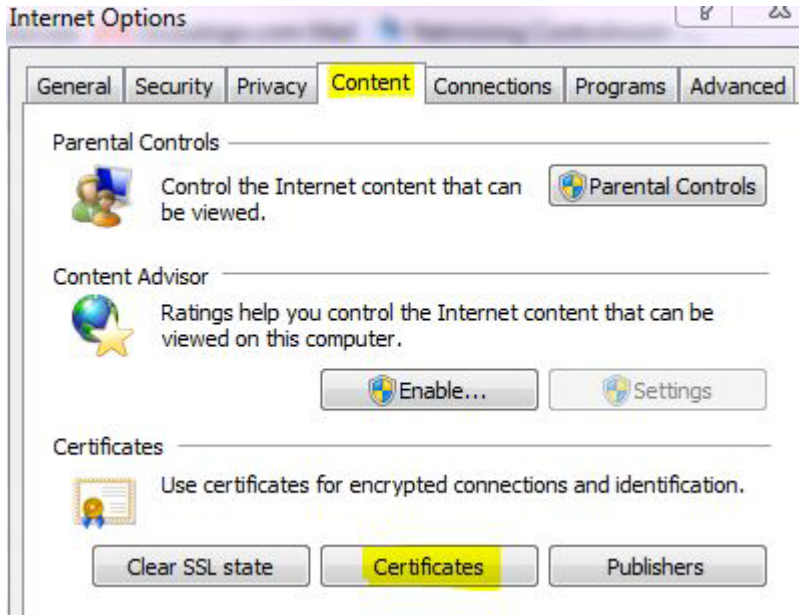
Step 1: Open Internet Explorer

Click Tools>Internet Options

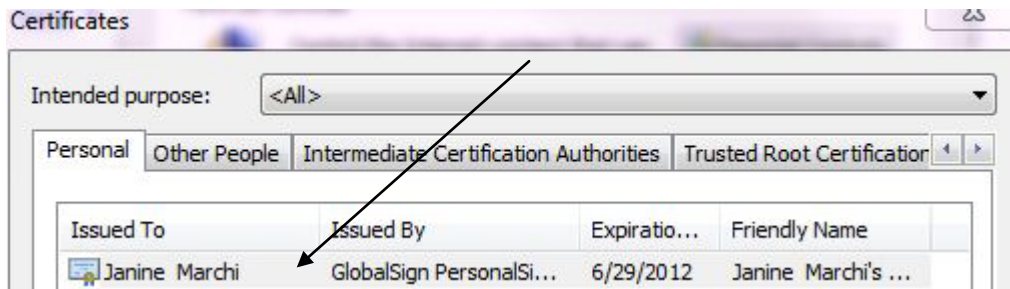


Next the **Internet Options** window will appear, Click on the “**Content**” tab and then click the button “**Certificates**”

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Highlight the digital certificate you recently enrolled for and click “**Export**” button.



Step 2: Public Certificate

A welcome window will appear, click next



Step 3 Certificate Export Wizard

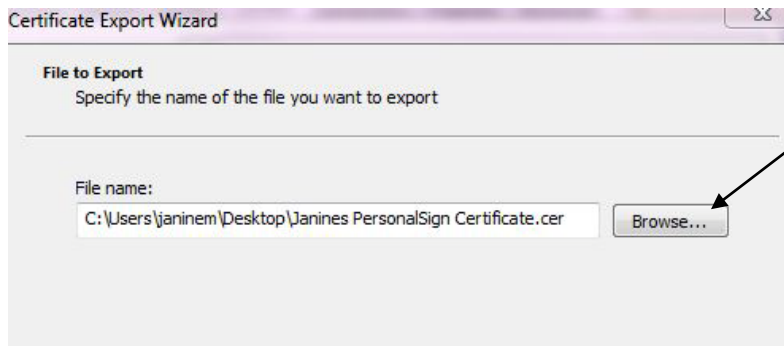
1. Select **No, do not export the private key** option and click on the **Next** button.



2. Select the options as shown on the screen below. Click on the **Next** button.

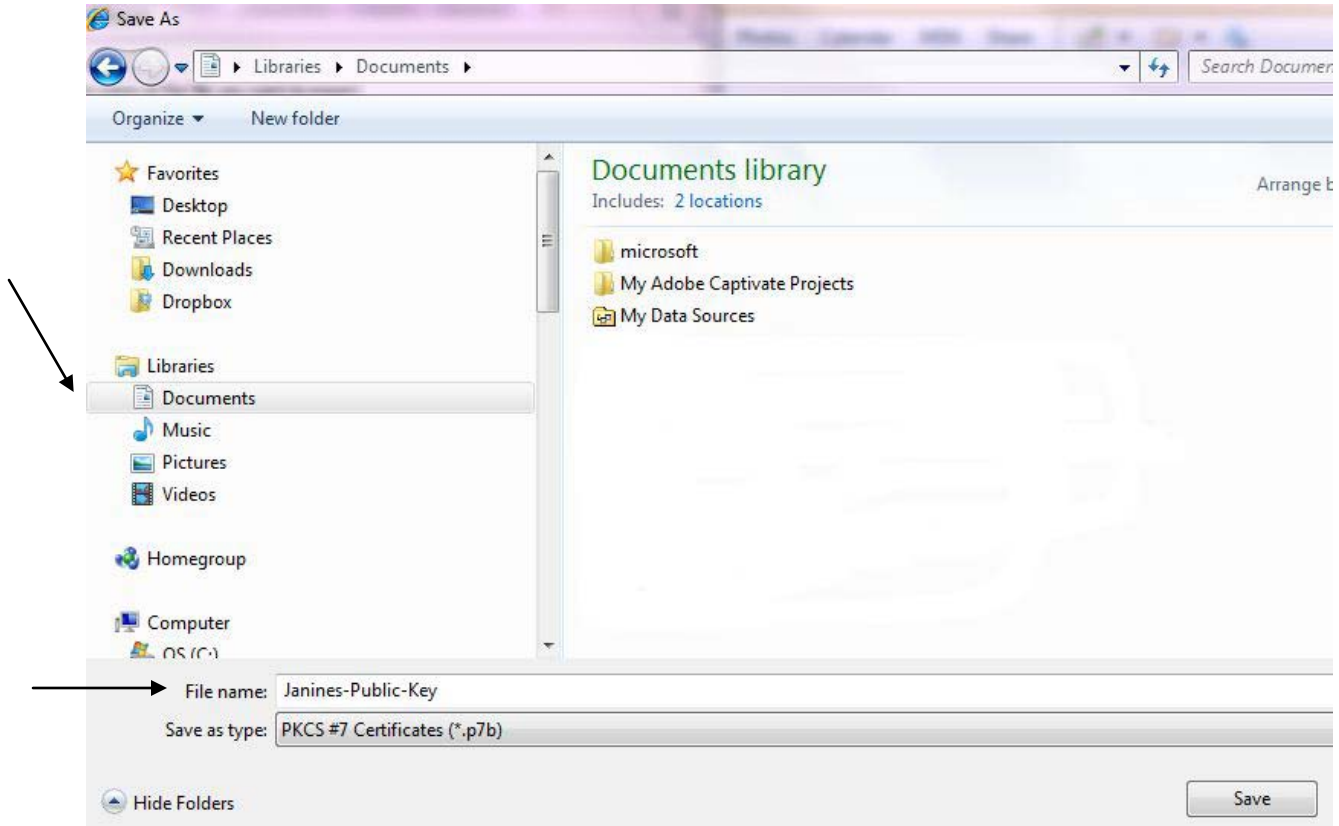


3. The following screen will appear for you to name your file and choose where to save it. **Click Browse.**



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4. Give a file name and select the location where you want to save the file. We recommend you save the file in a location where you can easily find such as your desktop or “documents” file. To choose the folder, simply click on the location. Once finished, Click **save**.

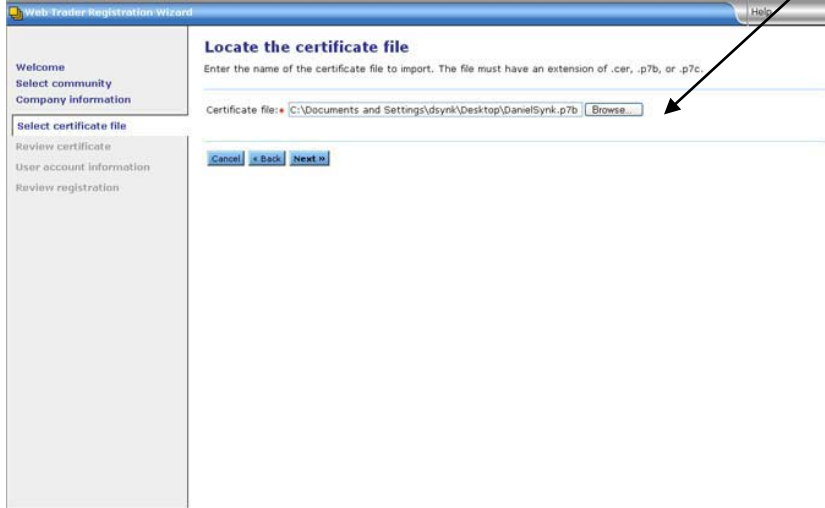


Now that you have saved the file in a familiar location you will need to remember this location until you setup your “**Test WebTrader Account**” which is required by the FDA.

Complete instructions for setting up your Web Trader Test Account can be found in the FDA User Guide at <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>

Web Trader Account Test Setup Process

During the setup process of the Web Trader Account it will ask you to “Locate the Certificate File” (This is referring to the public key file that you exported in the previous step”)



Click **Browse** and find the Certificate file that you exported and saved in the previous step.

Next the “**View Certificate Details**” Page is displayed, this page is to review the Certificate Information and to make sure all data fields are correct. Click next after reviewing.



The next steps will allow you to complete the setup process for the test account.

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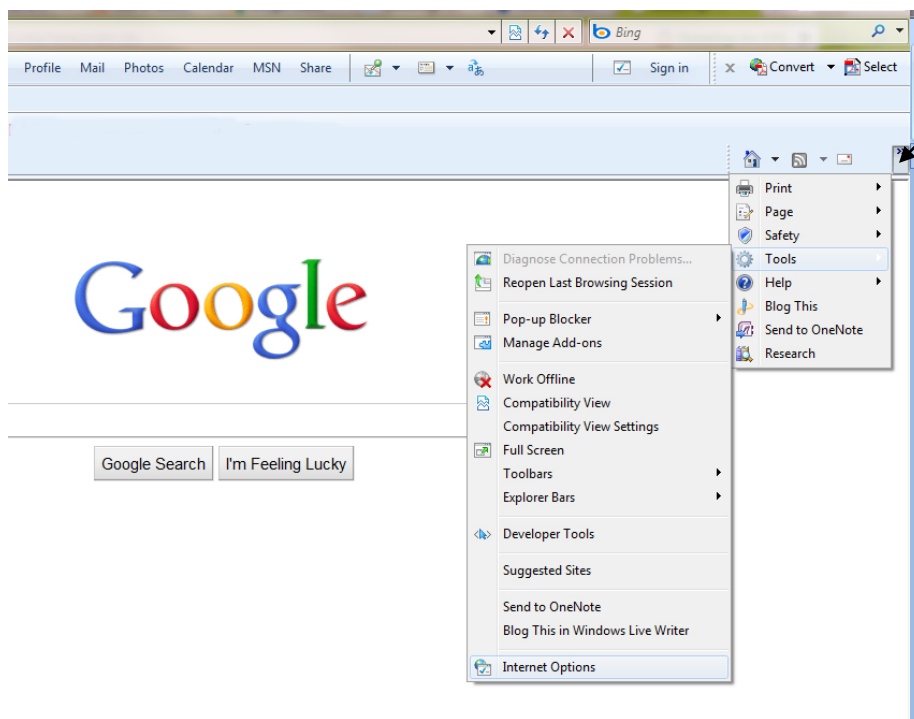
Once your Test Web Trader Account for submissions has been completed, the FDA requires you to send a test submission.

For this process, the FDA needs the “private” key of your certificate. You already exported and uploaded your “public” key in the previous steps so now you must repeat these steps to export your “private key”

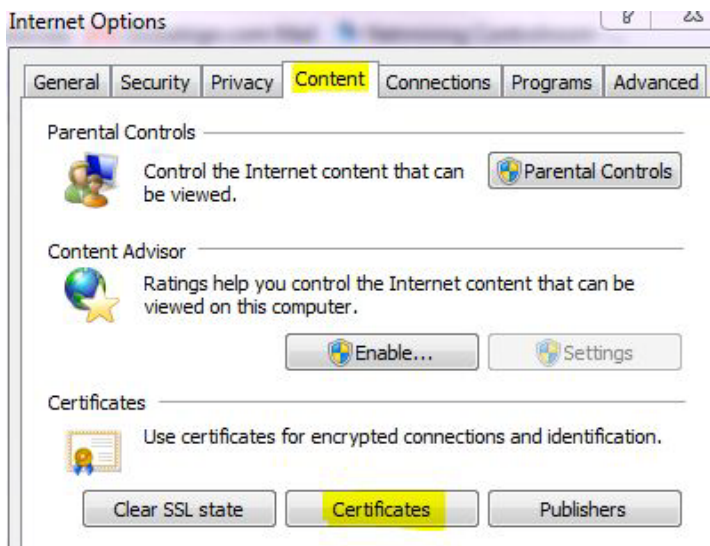
Prepare for Sending a Test Submission- Exporting Private Key

Step 1: Open Internet Explorer

Then Click on Tools>Internet Options



The “tool” menu is located on the right hand side, you must click on the arrow (>>) and then Tools will be located in the drop down menu.

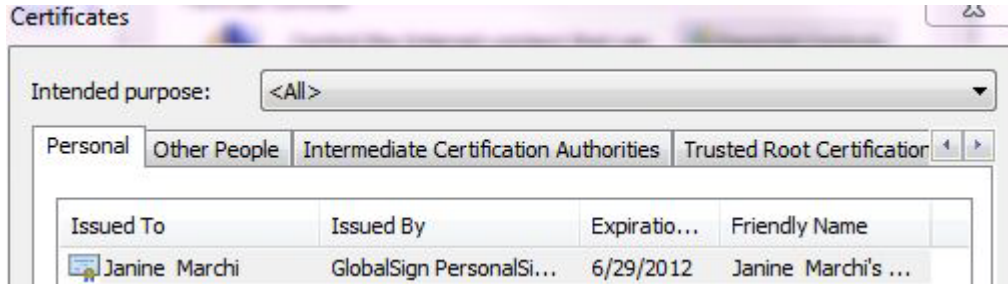


Next the **Internet Options** window will appear, Click on the “**Content**” tab and then click the button “**Certificates**”

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Highlight the digital certificate you recently enrolled for and click “Export”

1. Select the certificate and click on **Export**, Click on **next** on the next screen



2. Step 2: Export Wizard- Select **Yes, export the private key** and click on the **Next** button.



3. Select the options as shown below and click on the **Next** button.

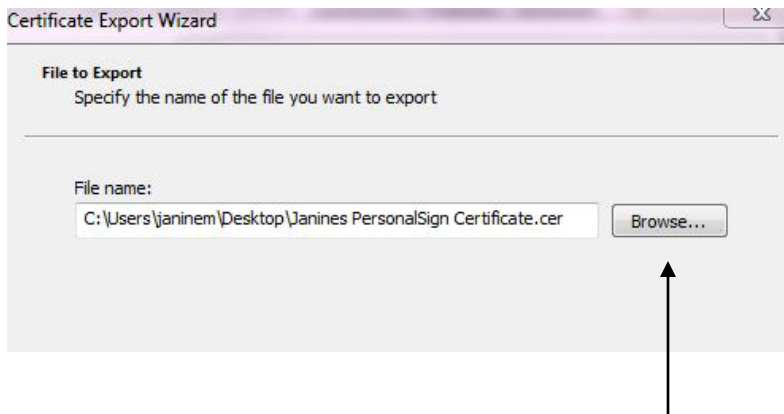


Step 3: Create a password for your private key.

1. Confirm the password and click on the **Next** button. If you forget the password you can export the private key again and create a password.

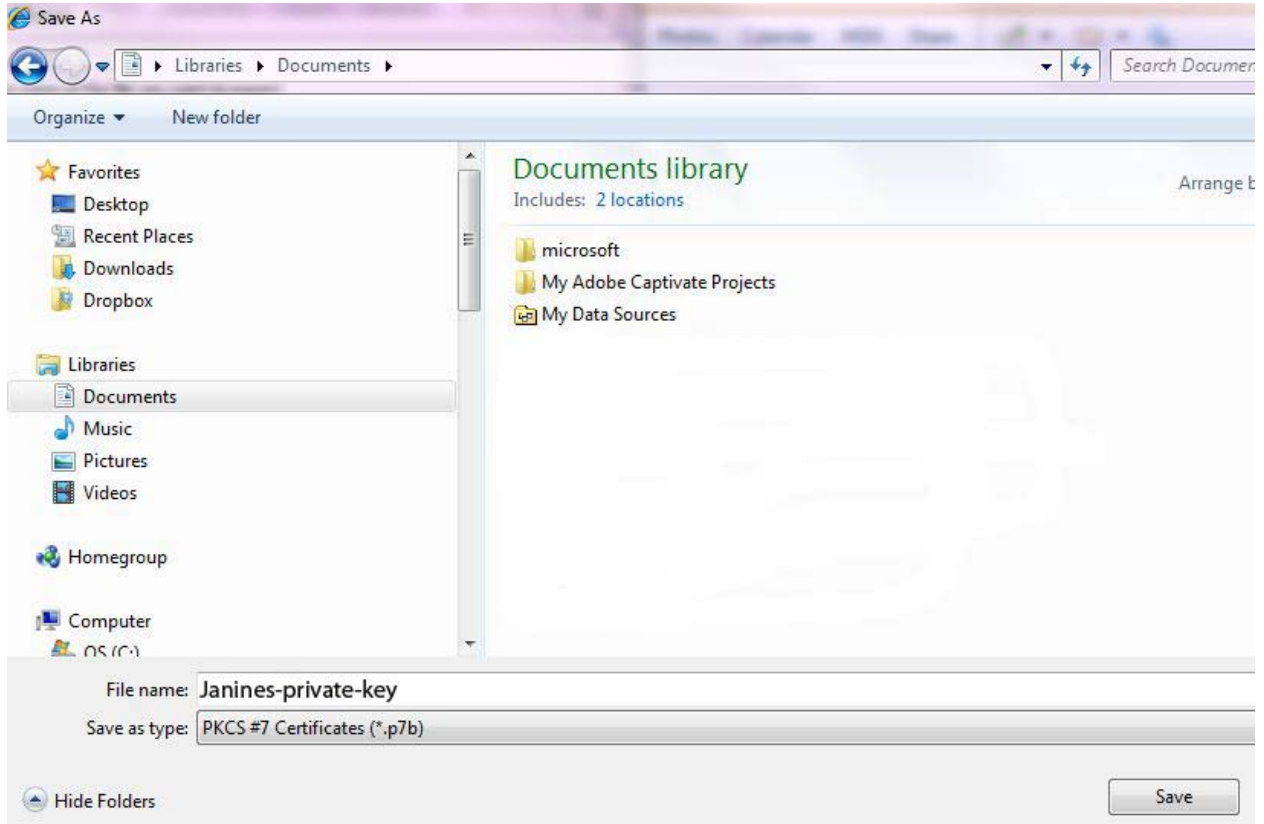


2. The following screen will appear for you to name your file and choose where to save it. **Click Browse.**



A Step-by-step guide to enrolling and using a FDA ESG GlobalSign PersonalSign 1 Digital Certificate

3. Create a file name and select the location where you want to save the file and click on the **Next** button. We recommend you save the private key file in a location you are familiar with such as “documents” file or “desktop”. You will need to locate this file on your computer once you are ready to setup your production account.



On the next screen, click on **Finish** and then click on **OK**.

A Step-by-step guide to enrolling and using a FDA ESG GlobalSign PersonalSign 1 Digital Certificate

Now your public key and private key of your certificate have both been exported. You will use your private key (.p12 or .pfx) file when you send documents to the FDA. Below is a screen shot of what the screen will look like when you are sending/uploading a document to submit to the FDA.

The screenshot shows a web browser window with the title 'WebTrader' and a 'Logout' link. The main heading is 'Send document'. Below this, there are several sections:

- Select who will receive the document:** Gateway: FDAVM, Center: GWTEST.
- Select the contents of the submission:** Path: C:/Documents and Settings/dsynk/My Documents/testSubm, Root directory: C:/Documents and Settings/dsynk/My Documents, Submission type: Connectivity Test.
- Select a signing certificate:** Current file: C:\Documents and Settings\dsynk\My Documents\Desktop docs\Desktop Items\DanielSynk.pfx, New file: C:\Documents and Settings\dsynk\My Documents\Desktop c\MyCertificate.p12 or MyPrivateKey.pfx.

A 'Send' button is located at the bottom left. An arrow points from the 'New file' section to the text below.

“Select a signing Certificate” this is asking you to locate the .p12 or .pfx file that you exported in the previous step, the private key. Click “browse” and locate the file in your computer’s hard drive wherever you saved it in the previous step.

For more detailed information on setting up a test account and sending submissions to the FDA, please view the FDA’s user guide at

<http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>

GlobalSign Resources

Submitting to the FDA FAQs

<http://www.globalsign.com/authentication-secure-email/digital-id/fda-faq.html>

Getting Help

Every GlobalSign Enterprise customer has a dedicated Account Manager who is on hand to help with any commercial and technical queries you may have about managing your Digital Certificates. GlobalSign also provides technical support through our Client Service departments around the world. www.globalsign.com/support

Support: Open a support ticket <http://www.globalsign.com/help/>

Sales: sales@globalsign.com | 1-877-775-4562

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