

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.

Center	Submissions
CBER	AERS – Adverse Event Reports AERS Attachments BLA – Biologics License Application (eCTD and eBLA format) eCTD – Electronic Common Technical Document H1N1 Lot Release IDE – Investigational Device Exemption IND – Investigational New Drug Application (eCTD and eIND format) DMF – Drug Master File Promotional Materials Lot Distribution Data 510K SDTM
CDER	AERS – Adverse Event Reports AERS Attachments ANDA – Abbreviated New Drug Application BLA – Biologics License Application (eCTD and eBLA format) eCTD – Electronic Common Technical Document (includes DMF - Drug Master File) NDA – New Drug Application (eCTD and eNDA format) IND – Investigational New Drug Application
CDRH	Adverse Events Electronic Submissions
CVM	Adverse Events Reports Electronic Submissions
OC	SPL - Structured Product Labeling (includes NDC Labeler Code Request, Establishment Registration and Drug Listing)
Center for Tobacco Products	Electronic Submission

See **Table 2: Electronic Submissions Supported by the FDA ESG** in the FDA ESG User Guide:

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

INTRODUCTION

As stated by the FDA, “The FDA ESG enables the submission of regulatory information for review. The overall purpose of the FDA ESG is to provide a centralized, agency-wide communications point for securely receiving electronic regulatory submissions.

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 accounts.

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

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.

BEFORE YOU BEGIN

EXPLANATION OF DIGITAL CERTIFICATE

A digital certificate, 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.

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

PRODUCT SELECTION

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. <https://www.globalsign.com/fda-esg/>

1. Select the PersonalSign Certificate of your choice and click **Buy Now**.

PersonalSign 1	PersonalSign 2 Pro
Class 1	Class 2
Online only	Email, online & live chat
Email address only (joe.smith@abc.com)	Email address, individual identity & company identity (John Smith, Abc Company, joe.smith@abc.com)
\$20	\$90
-	\$120
\$49	\$150
Buy Now	Buy Now
Renew ▶	Renew ▶

2. The following screen will appear. Confirm your product selection and click **Select and Continue**.

Purchase FDA ESG Certificates
Select your Product:

- PersonalSign 1** 1 Year **\$20**
General purpose Digital Certificate offering email verification only. No identity assurance.
- PersonalSign 2** 1 Year **\$90**
Professional-grade Digital Certificate that proves ownership of email address, identity assurance of individual, plus assurance of Organization existence.

Select and Continue **Go Back**

Please note: You will select the validity period (1-3 years) alter in the application process.

CREATING A GLOBALSIGN ACCOUNT AND PLACING YOUR ORDER

After selecting your product, you will be taken to the following screen where you can enter the information for your new GCC Account.

1. On the **Account Setup** screen, provide 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.

User Information	
First Name <i>Required</i>	<input type="text"/>
Middle Name or Initial	<input type="text"/>
Last Name <i>Required</i>	<input type="text"/>
Email Address <i>Required</i>	<input type="text"/>

Please check email is accurate, this email address will be used in the application process

- Next, establish a username and password that you'll need to remember to access your account. Click the **Next** button when finished.

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

Note: a pre-fix will be added to the user name you establish (i.e. **"PAR####_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.

- Review the account details you entered and the GCC Terms of Service Agreement. Check the box next to **I agree to terms of service** and click the **Next** button.

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 related system or software (collectively, the Service), is subject to the terms and conditions of this GCC Terms of Service (the GCC T&C) between you and GlobalSign. GlobalSign means GlobalSign Inc and any entity which directly or indirectly controls, or is controlled by, or is under common control of GlobalSign Inc., including GlobalSign NV, GlobalSign K.K., and GlobalSign Ltd.

1.2 Unless otherwise agreed in writing with GlobalSign, your agreement with GlobalSign will always include, at a minimum, the GCC T&C. In addition, when using the Service, you and GlobalSign shall be subject to any posted guidelines or rules applicable to GCC T&C, which may be posted from time to time (the Additional Terms) at <http://www.globalsign.com/repository/> All Additional Terms (including but not limited to our Privacy Policy) are hereby incorporated by reference into the GCC T&C. GlobalSign may also offer other services that are governed by different Terms of Service.

1.3 If there is any contradiction between the Additional Terms and the GCC T&C, then the Additional Terms shall take precedence in relation to that Service.

1.4 You agree to use the Service only for purposes that are permitted by (a) the GCC T&C and (b) any applicable laws and regulations, including any laws regarding the export of data or software.

2 DESCRIPTION OF SERVICE

I AGREE TO TERMS OF SERVICE

4. On the **Product Details** page, choose the validity period for your certificate and enter any campaign or coupon codes you want to apply. Click **Next** when finished.
 - a. The FDA recommends a certificate with a 3-year validity period. Shorter validities will require more frequent registration with the FDA ESG.

1. Account Setup > 2. Product Details > 3. Completed

Product Details >> Certificate Identity Details >> Payment >> Confirm Details

Product Details - PersonalSign 2 Pro

Certificate Validity Required Multi-year offers significant per annum savings	<input type="radio"/> 1 year \$90 <input type="radio"/> 2 year \$120 <input checked="" type="radio"/> 3 year \$150
Campaign Code	<input type="text"/> <input type="button" value="Redeem code"/> <small>If you have a Campaign Code please enter and click "Redeem Code". This page will be reloaded with your appropriate discount.</small>
Coupon Code	<input type="text"/> <input type="button" value="Redeem code"/> <small>If you have a one-off Coupon Code for a particular promotion please enter and click "Redeem Code". 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 This option will create the public and private key on behalf of the subscriber. This is an alternative to the key generation taking place in the Subscriber's browser later in the application process.	<input type="checkbox"/> Yes, use PKCS#12 Option
TOTAL COST (inc. Tax)	\$ 150

5. Enter the email address and identity information of the person who will be the certificate holder. **Note:** For PersonalSign 1 orders, you will only need to enter the email address of the person who will be the certificate holder.

Product Details >> Certificate Identity Details >> Payment >> Confirm Details

Autofill Options

You may choose to use your saved company information to autofill values in your certificate, such as Organization Name, Locality, State, and Country.

Use saved company information

Primary Address

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.

Your Name Required	<input type="text" value="Joe Smith"/> <small>Specify your First (required), Middle/Initial (optional) and Last Name (required)</small>
Organization Required	<input type="text" value="ABC Corp"/> <small>Specify the Organization Registered Name in full, including Inc, Ltd, NV, Plc etc</small>
Locality Optional	<input type="text" value="New York"/> <small>Specify the City or Town in which the Organization is Registered</small>
State or Province Optional	<input type="text" value="NY"/> <small>Specify State or Province in which the Organization is Registered. For US applications you must specify the State in full</small>
Country Required	<input type="text" value="United States - US"/> <input type="button" value="v"/> <small>Specify Country in which the Organization is Registered</small>
Email Address Required	<input type="text" value="jsmith@abccorp.com"/>

- Establish a one-time only certificate pickup 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 install the certificate.

PLEASE NOTE- 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.

If you are applying on behalf of someone else, you may specify an additional Technical Contact in this step.

Click **Next** when finished.

Create Temporary Pickup Password

Please create a temporary pickup password. You will only need this during the installation process. This is not the same as your account password.

If you forget this password you will need to resubmit your order. Please copy it somewhere safe.

Pickup Password Required	<input type="password"/> <small>Password must be a minimum of 1 characters. Alpha-numeric values only (A-Z, 0-9)</small>
Pickup Password (re-enter) Required	<input type="password"/>

Specify an Additional Technical Contact

If you are applying on behalf of someone else, you may specify an additional Technical Contact. The Technical Contact is typically the person who is responsible for the application process and collection of the issued Certificate. Click the [Enter Technical Contact Details](#) link to create the additional contact.

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

NOTE: For PersonalSign 3 Pro applications the Issued certificate will not be sent to the Technical Contact.

Enter Technical Contact Information

Required I have copied this password to a safe location

Back
Next

- Enter Credit Card details and click **Next** when finished. GlobalSign does not accept Purchase Orders for products under \$500.

Product Details >> Certificate Identity Details >> **Payment** >> Confirm Details

Payment Details

Purchase Order Number	<input type="text"/> <small>Enter if you have a PO Number. This will be displayed in your invoice</small>
Payment Method	<input checked="" type="radio"/> Credit Card

Credit Card Details & Billing Address

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"/> <small>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</small>

8. Confirm payment details, review and accept PersonalSign Subscriber Agreement. Click **Next** when finished.
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.

10. Check your email for an Approval Request. GlobalSign sends an **Email Challenge Request** to the email that was used in the Certificate Identity Details to ensure the request for a digital certificate is legitimate and authorized. An order confirmation will be sent from a no_reply email: support@globalsign.com.

Note: 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”

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.

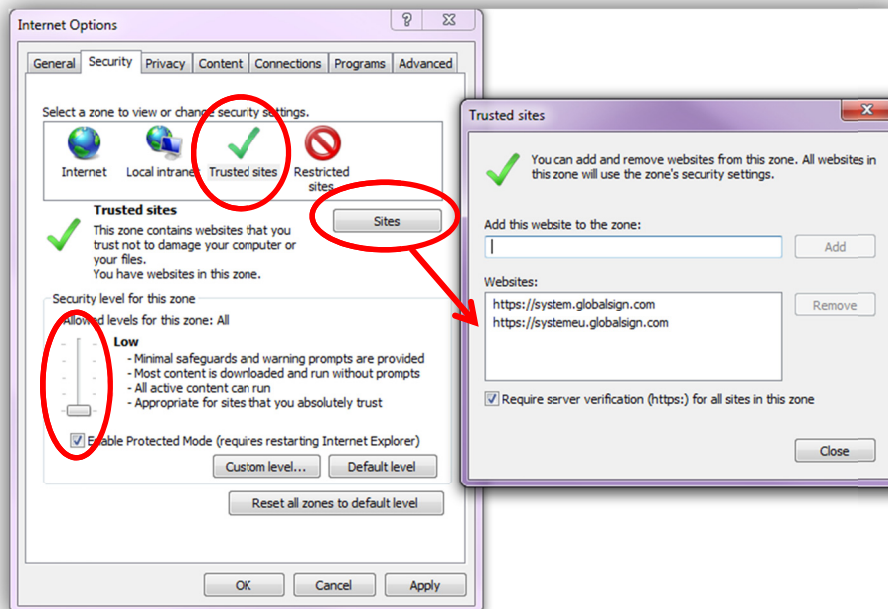
- GlobalSign vetting agents will now review and vet your order. All orders placed go through a vetting process to confirm the identity details of the Certificate holder. When the vetting process is complete, you will receive an email notifying you that your certificate is ready for “pick up” with an installation link.

Certificate Type	Average Issuance Time
PersonalSign 1	Same business day , issued as soon as the automated approval email has been approved.
PersonalSign 2 Pro	Issued within two to three business days unless supporting documentation is needed during the vetting process.

INSTALLING YOUR CERTIFICATE BEFORE BEGINNING INSTALLATION

Due to the added security Microsoft has added to newer version of Internet Explorer, you will need to make sure the following steps are completed before installing your Certificate. Missing even one step can cause an error at the final stage of installing the Certificate, which will result in the entire process needing to be restarted.

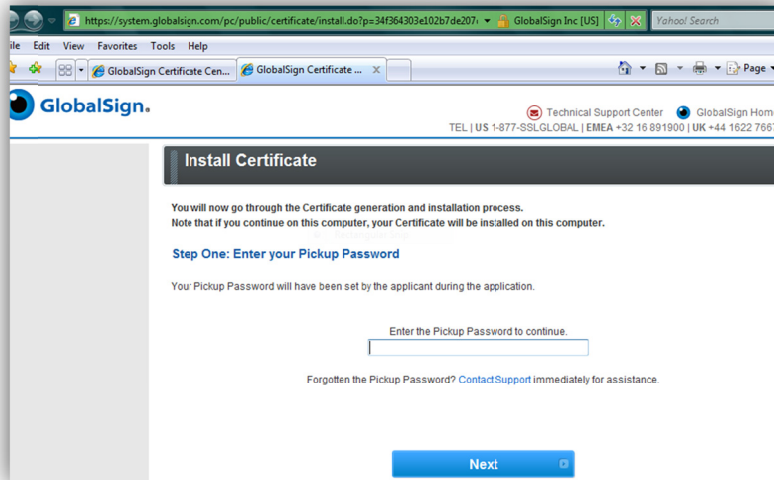
- Open Internet Explorer, click the **Tools** dropdown (located in the upper right corner of your window), and select **Internet Options** from the very bottom of the list.
- Click the **Security** tab at the top of the **Internet Options** window and select **Trusted Sites** under the green checkmark.
- Using the sliding rule, adjust the **Security Level** to **Low**.
- Click the **Sites** button and add the following addresses as trusted websites. Click **Close** when complete.
 - <https://system.globalsign.com>
 - <https://systemeu.globalsign.com>
- Click **Apply** on the **Internet Options** window to finalize the settings and then click **OK**.



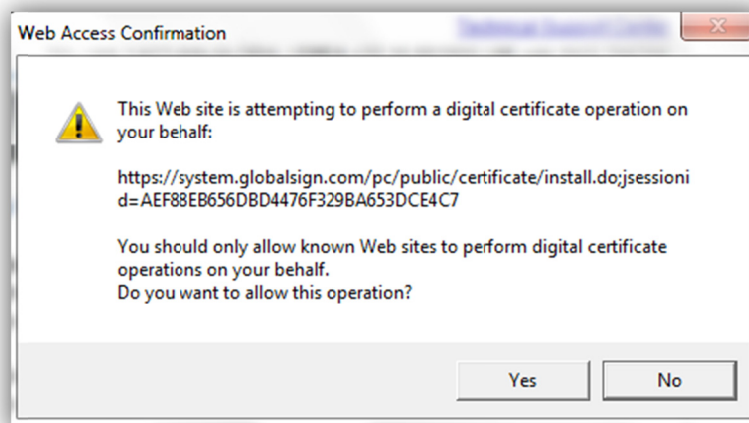
INSTALLING YOUR CERTIFICATE USING MICROSOFT INTERNET EXPLORER

GlobalSign recommends using Internet Explorer to facilitate the installation process.

1. Using Microsoft Internet Explorer, click on the URL provided in the pickup email. You will be prompted for the Certificate Pickup Password that was established during registration.



2. Vista and Windows 7 users will be prompted with a **Web Access Confirmation**. Click **Yes** to allow the digital certificate creation operation to proceed.



3. Next you will see the **Select the Cryptographic Service Provider** screen.
 - a. Ensure the box next to **Yes, make this Certificate exportable** is checked.
 - b. Ensure Microsoft Enhanced Cryptographic Provider v1.0 is selected as the Cryptographic Service Provider.
 - c. Review the Subscriber Agreement and check the box.
 - d. Click **Next** when finished.

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

GlobalSign Subscriber Agreement for PersonalSign Certificates Version 1.3

PLEASE READ THIS AGREEMENT CAREFULLY BEFORE USING THE DIGITAL CERTIFICATE ISSUED TO YOU OR YOUR ORGANISATION. BY USING THE DIGITAL CERTIFICATE, YOU ARE AGREEING TO BE BOUND BY THE TERMS OF THIS AGREEMENT. IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, PROMPTLY RETURN THE UNUSED DIGITAL CERTIFICATE OR CANCEL THE ORDER WITHIN 7 DAYS OF ISSUANCE TO GLOBALSIGN FOR A FULL REFUND. IF YOU HAVE PROBLEMS UNDERSTANDING THIS AGREEMENT, E-MAIL US AT legal@globesign.com

This GlobalSign PersonalSign Subscriber Agreement ("Agreement") is effective as of the

I AGREE TO THE SUBSCRIBER AGREEMENT

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 the **Install My Certificate** button on the following screen to install your certificate and Intermediate CA Certificates.

Install Certificate

Install your Digital Certificate and the Intermediate CA Certificates


Your Certificate has been generated, click the **Install My Certificate** button to install the Certificate onto your computer.

We have detected that you are using Internet Explorer.
Please click the Install My Certificate button to install your Certificate and all appropriate Intermediate CA Certificates that enable the Certificate to be trusted.

Install My Certificate

- You will receive another **Web Access Confirmation** request. Click **Yes** to continue.

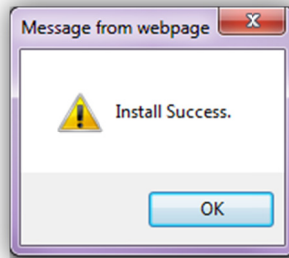
Web Access Confirmation

 This Web site is attempting to perform a digital certificate operation on your behalf:

<https://system.globesign.com/pc/public/certificate/install.do>

You should only allow known Web sites to perform digital certificate operations on your behalf.
Do you want to allow this operation?

6. You have completed the installation process when you see the following message.



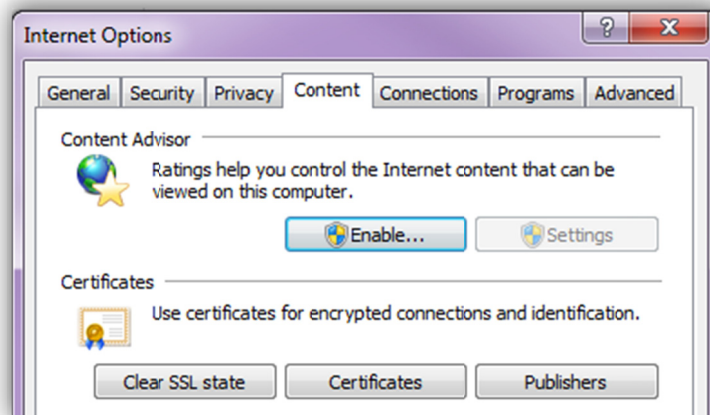
APPLYING FOR A FDA ESG TEST ACCOUNT

Before setting up a product account for the ESG, the FDA requires you to apply for a test account and successfully complete a test submission. The following sections outline how you will need your certificate to complete the process.

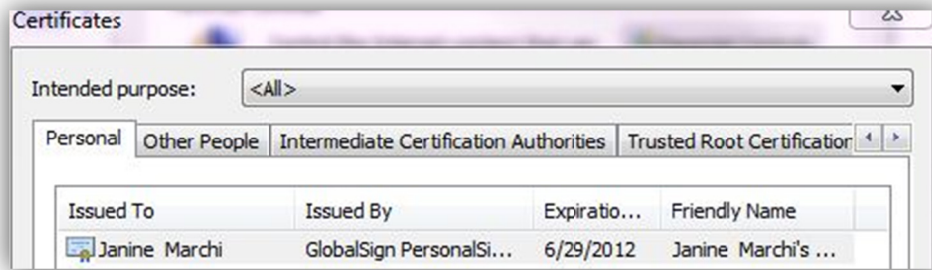
PREPARE FOR FDA ESG TEST ACCOUNT- EXPORT PUBLIC KEY

As described in step 6 of the FDA's "Setting up a WebTrader Account Checklist", <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>, and section 4.1 of the FDA User Guide, <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>, 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 setup. Below are step-by-step instructions on how to create your .cer or .p7b file.

1. Open Internet Explorer, click the **Tools** dropdown (located in the upper right corner of your window), and select **Internet Options** from the very bottom of the list.
2. Click the **Content** tab at the top of the **Internet Options** window and then click the **Certificates** button.



3. Highlight the appropriate digital certificate and click the **Export** button.



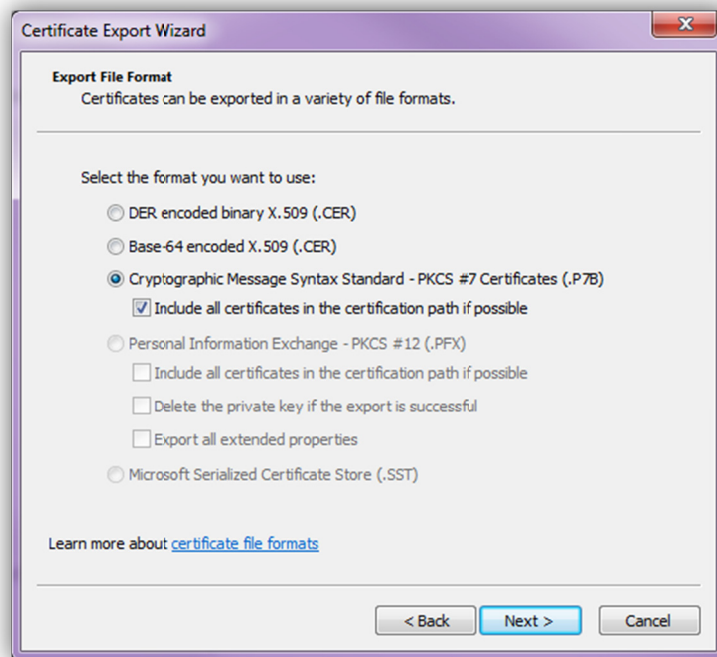
4. This will start the **Certificate Export Wizard**. Click **Next** to continue.



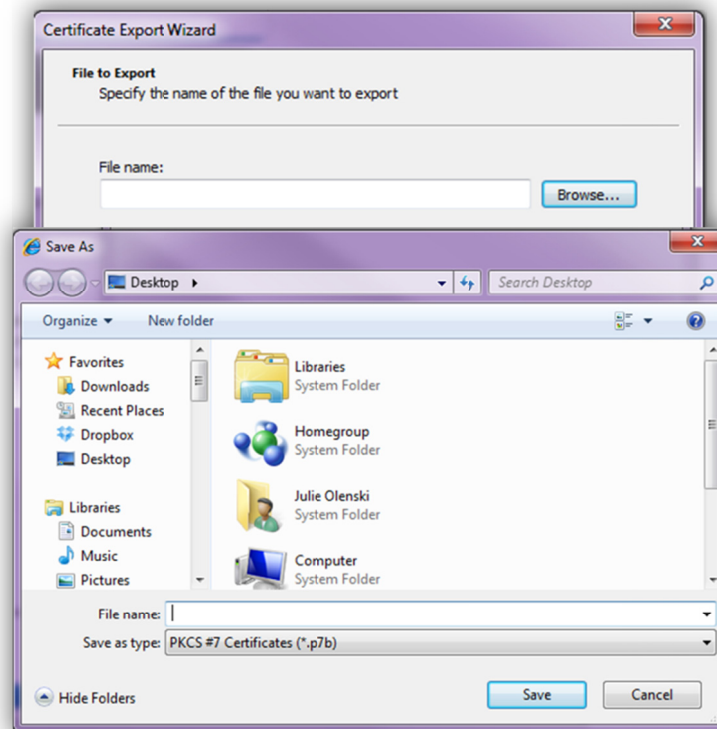
5. Select the **No, do not export the private key** option and click the **Next** button.



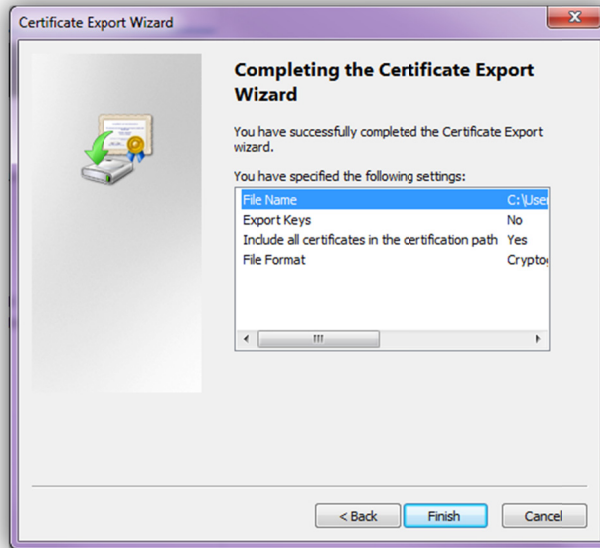
6. Select the **Export File Format** options as shown on the screen below. Click the **Next** button when done.
 - a. Cryptographic Message Syntax Standard – PKCS #7 Certificates (.P7B)
 - b. Include all certificates in the certificate path if possible



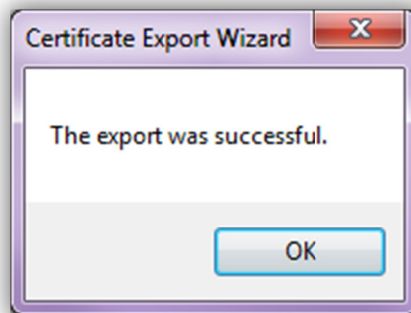
7. Click the **Browse** button to navigate to where you would like to save your certificate file. We recommend you save the file in a location where you can easily find such as your desktop or **Documents** folder. Enter a **File Name** and click **Save**.



8. Back on the **Certificate Export Wizard** window, click the **Next** button to continue with the export.
9. Click the **Finish** button on the following screen to complete the export.



10. You will know the export is complete when you receive the following confirmation.

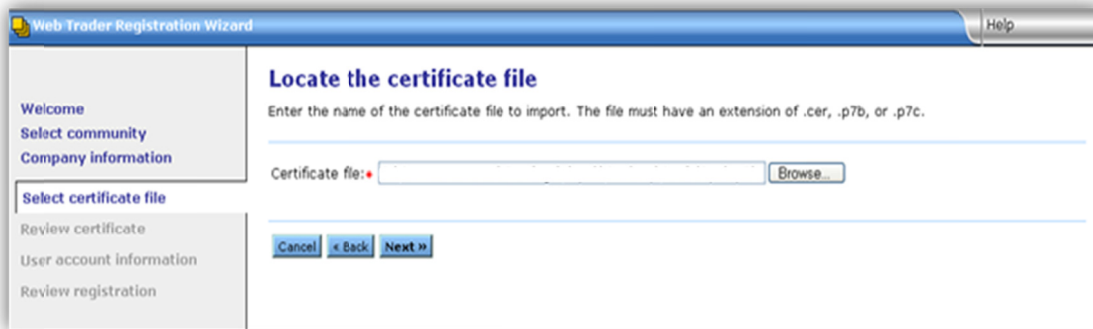


11. You will need to remember the location where you just saved your public key in order to set up your **WebTrader Test Account**, as required by the FDA

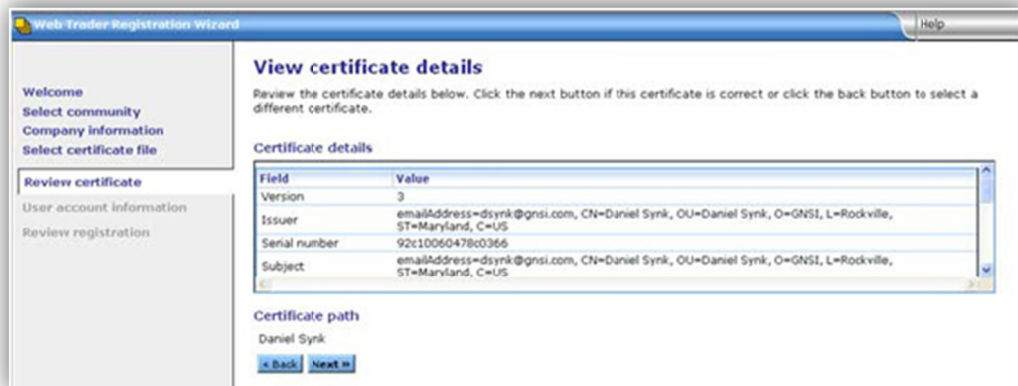
SETTING UP YOUR WEBTRADER TEST ACCOUNT

Complete instructions for setting up your **WebTrader Test Account** can be found in section 4 of the FDA User Guide: <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>

Part of the setup process involves locating the certificate file you exported in the previous steps of this guide. Click **Browse** and find the certificate file you exported and saved in the previous step.



Next the **View Certificate Details** page is displayed. Review the certificate information to make sure all data fields are correct. Click **Next** after reviewing.

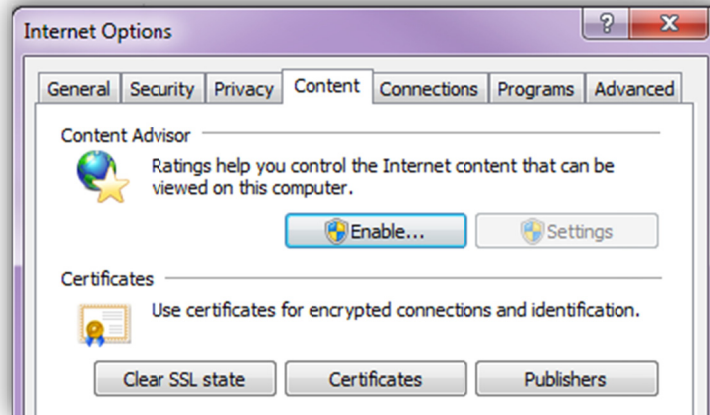


The next steps will allow you to complete the setup process for the test account.

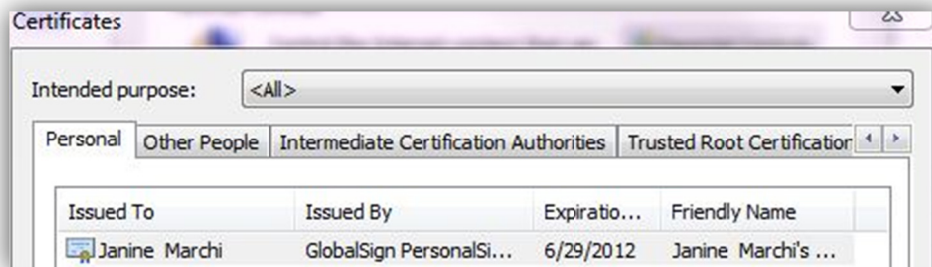
PREPARE FOR SENDING A TEST SUBMISSION – EXPORT PRIVATE KEY

Once your Test WebTrader 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 those steps to export your “private” key.

1. Open Internet Explorer, click the **Tools** dropdown (located in the upper right corner of your window), and select **Internet Options** from the very bottom of the list.
2. Click the **Content** tab at the top of the **Internet Options** window and then click the **Certificates** button.



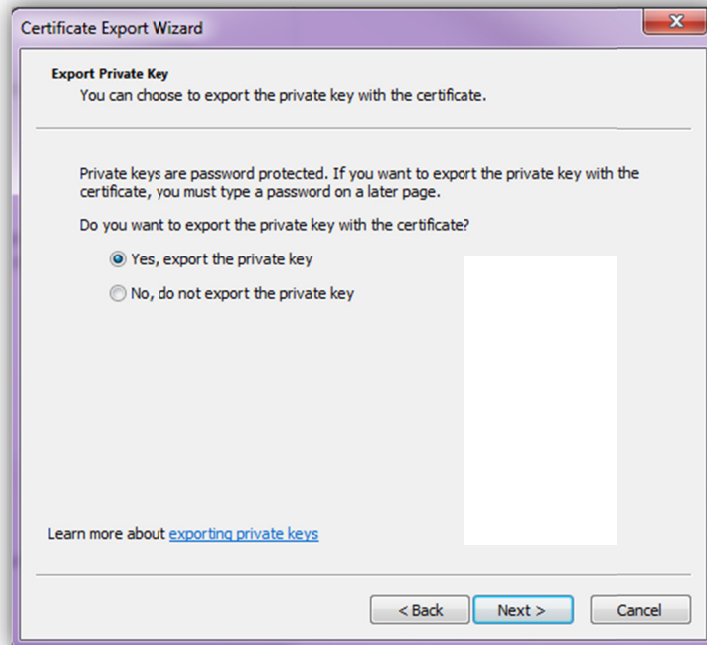
3. Highlight the appropriate digital certificate and click the **Export** button.



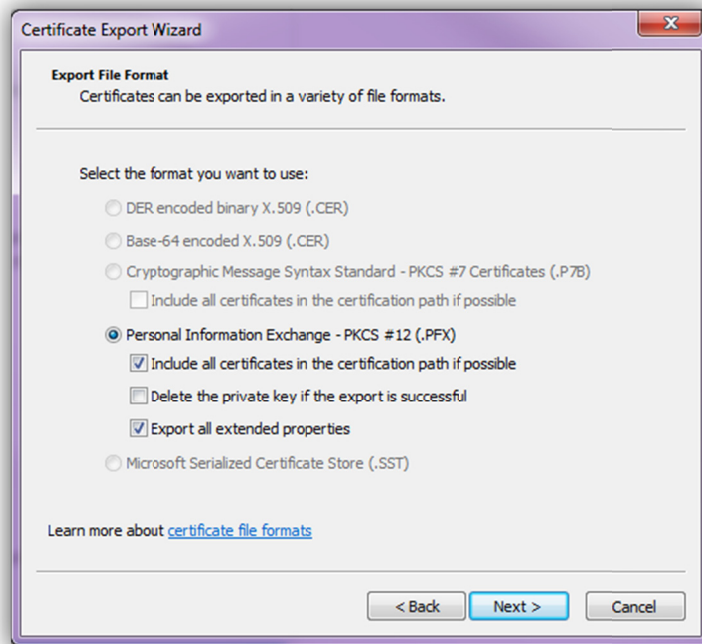
4. This will start the **Certificate Export Wizard**. Click **Next** to continue.



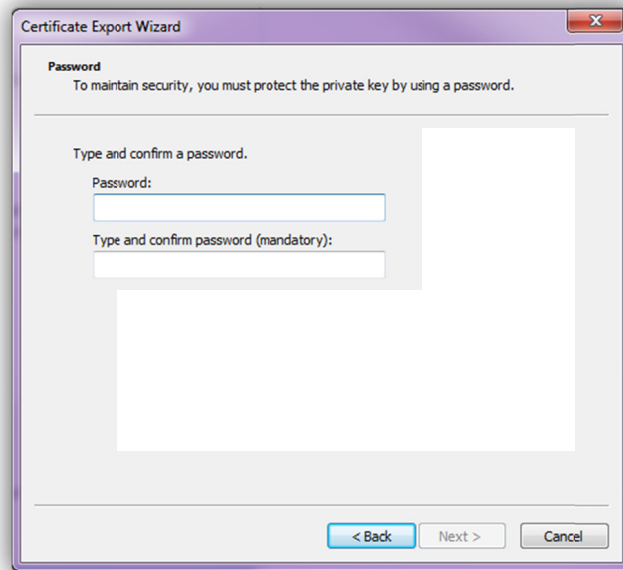
5. Select **Yes, export the private key** and click the **Next** button.



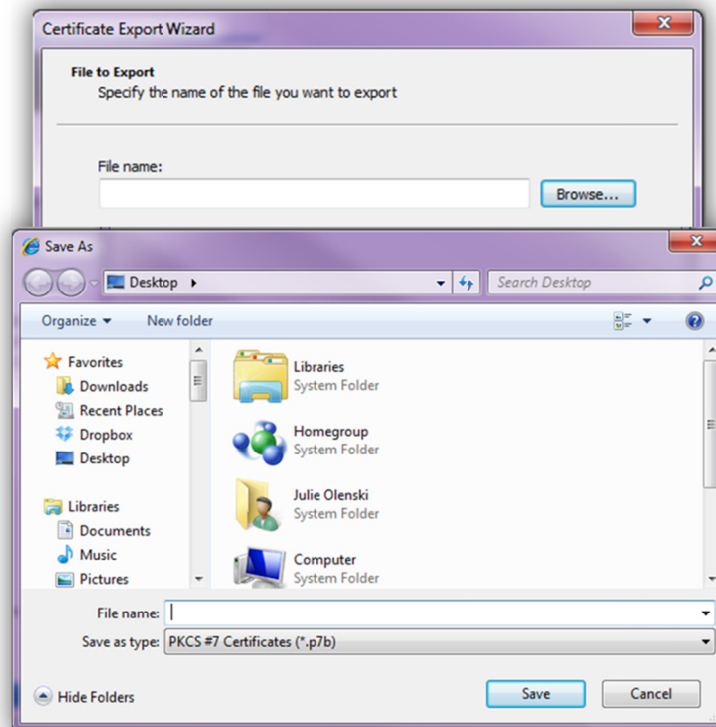
6. Select the **Export File Format** options as shown on the screen below. Click the **Next** button when done.
 - a. Include all certificates in the certification path if possible.
 - b. Export all extended properties.



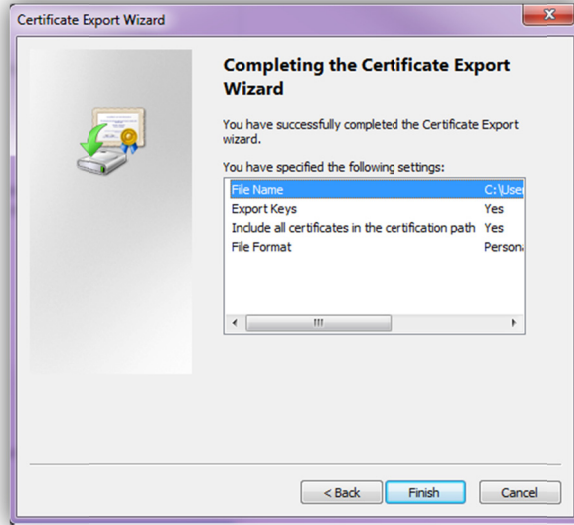
7. Enter a password for your private key and click the **Next** button. If you forget the password, you can export the private key again and create a new password.



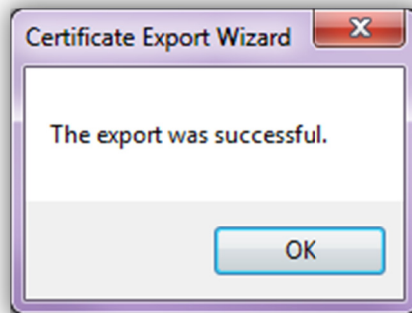
8. Click the **Browse** button to navigate to where you would like to save your certificate file. We recommend you save the file in a location where you can easily find such as your desktop or **Documents** folder. Enter a **File Name** and click **Save**.



9. Back on the **Certificate Export Wizard** window, click the **Next** button to continue with the export.
10. Click the **Finish** button on the following screen to complete the export.



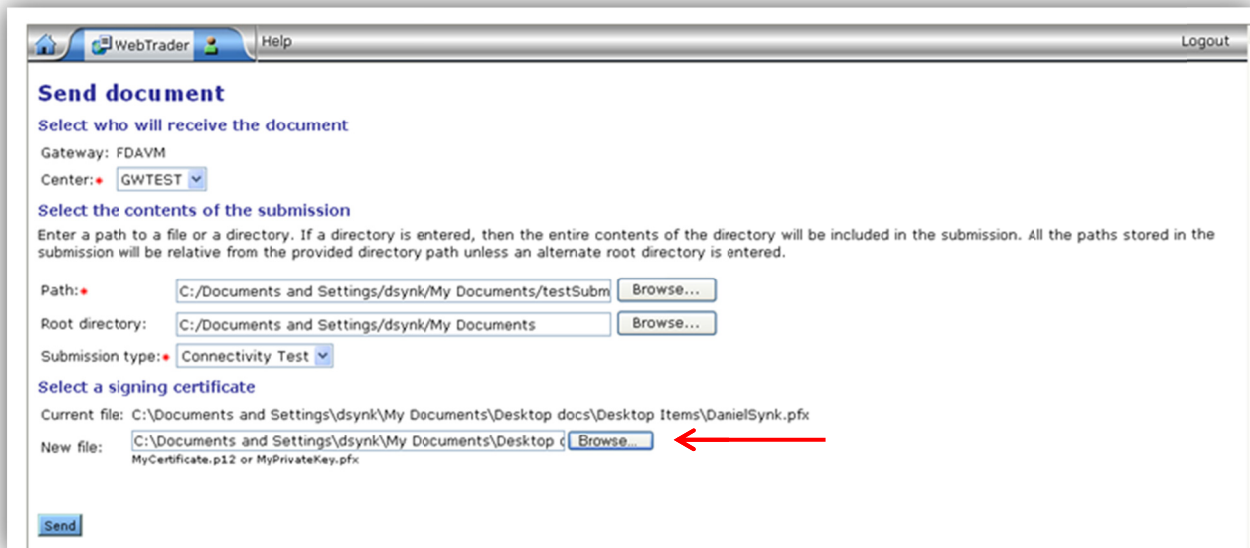
11. You will know the export is complete when you receive the following confirmation.



12. You will need to remember the location where you just saved your public key in order to complete a test submission, as required by the FDA.

COMPLETING A TEST SUBMISSION

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 via the ESG.



Under the **Select a signing certificate** section, you need to locate your private key file (.p12 or .pfx) that you exported in the previous section of this guide. Click **Browse** to locate the file.

For more detailed information on sending test submissions to the FDA, please see section 4.3 of the FDA's user guide at <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm> .

Once your test submission has been reviewed by the FDA, you will be able to move forward with setting up a product account and making submissions.

GETTING HELP

GlobalSign provides technical support through our Client Service departments around the world. You can find additional technical support using our PersonalSign products to submit documents to the FDA ESG at: <https://www.globalsign.com/fda-esg/faq.html>.

GlobalSign Americas

Tel: 1-877-775-4562
www.globalsign.com
sales-us@globalsign.com

GlobalSign EU

Tel: +32 16 891900
www.globalsign.eu
sales@globalsign.com

GlobalSign UK

Tel: +44 1622 766766
www.globalsign.co.uk
sales@globalsign.com

GlobalSign FR

Tel: +33 1 82 88 01 24
www.globalsign.fr
ventes@globalsign.com

GlobalSign DE

Tel: +49 30 8878 9310
www.globalsign.de
verkauf@globalsign.com

GlobalSign NL

Tel: +31 20 8908021
www.globalsign.nl
verkoop@globalsign.com
