



VCU Office of the Vice President
for Research and Innovation

**TIP SHEET:
Setting up a WebTrader Account with the FDA ESG**

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WebTrader is a web-based interface used to send documents and receive receipts and acknowledgments from the FDA. Setting up a WebTrader account with the FDA can take about 2 weeks to complete. For assistance with ESG related items, please contact ESGHelpDesk@fda.hhs.gov, or refer to the FDA's checklist for setting up a WebTrader account <https://www.fda.gov/industry/create-esg-account/setting-webtrader-account-checklist>. Timelines listed below are approximate and based on FDA reported timelines and our previous experience.

Day 1 – Request account and obtain certificate

1. Send an email to ESGHelpDesk@fda.hhs.gov requesting a WebTrader test account. To request the account, make the subject of the email “New WebTrader Test Account Registration”, include “Submission Method: WebTrader” in the email, and attach a Letter of Non Repudiation. Note that you cannot proceed with step #4 until you receive an email back from FDA with registration information. The email from FDA is typically received **within a day**.
 - a. For more information on Non-Repudiation Letters, click on the FDA link: <https://www.fda.gov/industry/about-esg/appendix-g-letters-non-repudiation-agreement>
2. Send a hard copy Letter of Non-Repudiation to the FDA. This should be done as soon as possible, but **within 2 weeks** or your account may be disabled.
 - a. The letter must be sent to (If using USPS, do not ship via priority mail express):
Lowell Marshall
Electronic Submissions Gateway
U.S Food and Drug Administration
3WFN, Room 7C34
12225 Wilkins Avenue
Rockville, MD 20852
3. Obtain or create a personal digital certificate*. The following link will allow you to generate your own self-signed certificate for the sole purpose of using for the ESG at no cost: <https://esgcertificate.assyst.net/>. Once the required information is filled out and the submit button is hit, a zip file will be downloaded that contains your public and private key. We recommend moving these keys to your desktop. The public key will be uploaded to WebTrader when registering, and the private key will be uploaded to WebTrader when submitting documents. Keep track of the password you generate for the certificate and the location of the certificate on your computer (e.g. Desktop).
*Click here for more information on personal digital certificates and available options: <https://www.fda.gov/industry/about-esg/esg-appendix-c-digital-certificates>

Day 2 – Register your account

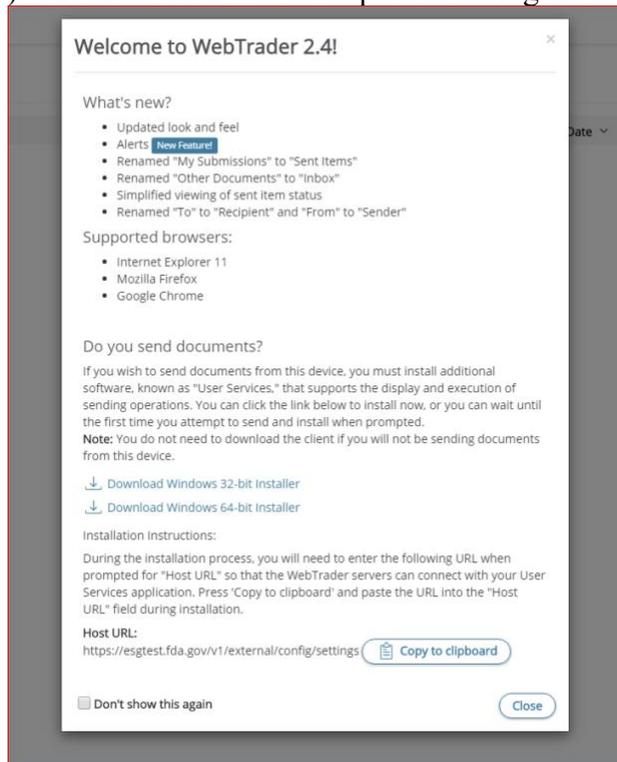
4. Once the FDA reply email is received (generated from step #1), complete the steps to register for a WebTrader test account provided in the email. You will need the public key (.p7b or .cer) for your personal digital certificate to complete this step (generated from step #3).



- a. Go to <https://esgtestreg.preprod.fda.gov/>
- b. Insert the registration username and password provided in the FDA email
- c. Follow the prompts for registering your WebTrader account. Note: The Primary Contact must be a real person (this field may have changed to “Type a name to help identify this certificate”); the "Company Name" is actually an account name and must be unique throughout the entire ESG test system. We recommend appending your initials to your company name (e.g. Duke University-ABC). Additional instructions to assist with registering can be found [here](#).
- d. You should receive a WebTrader test account activation email from FDA when your account is ready, this may take up to **48 hours**.

Day 4 – Download WebTrader and send test submission

5. Once the WebTrader test account activation email is received from FDA (step #4.d), proceed with setting up WebTrader on your computer.
 - a. Go to <https://esgtest.fda.gov/login>
 - b. Insert the User ID and Password you generated during the registration process described in step #4.c. (Do not use the ID and password provided in the email from FDA).
 - c. Once signed in, a window prompt will appear (see example below). Copy the Host URL and download the required Installer (e.g. “Download Windows 64-bit Installer”). The Host URL will be requested during the installation process.





- d. Follow the link to view the WebTrader Tutorial document, which includes additional details on installing WebTrader (see Section 2.1):
<https://www.fda.gov/media/102736/download>
6. Once WebTrader is installed, send a test submission. It may take up to **1 week** to hear back from the ESG Helpdesk regarding submission status.
 - a. You will need to perform a Guidance Compliance Test by creating and submitting a guidance compliant document according to preparation guidelines. (For additional details click here: <https://www.fda.gov/drugs/forms-submission-requirements/electronic-regulatory-submission-and-review>.) Skip to step #6.b if your institution already has active WebTrader Account(s).
 - i. For non-commercial/research IND guidance compliant test submissions in non-eCTD format, you can use any PDF and we recommend the file be saved in this folder structure for the test submission: Create a folder on the Desktop and name the folder “IND_TEST”, then create a subfolder named “m1”. Save the PDF in the “m1” folder.
 - ii. Login to <https://esgtest.fda.gov/login>
 - iii. Hit “Send Document”
 - iv. Select “CDER” from the Center dropdown menu, and select “EIND” from the Submission Type dropdown menu.
 - v. Click the “+Add documents” and select the folder created in step #6.a.i named “IND_TEST” that is saved on the Desktop. The folder should highlight in bold and grayed out if correctly selected. Then hit the blue “Select” button at the bottom of the window.
 1. Note: Cursor should have arrow icon ↖ to select the folder, instead of hand👆. The hand will open the folder instead of selecting it.
 - vi. Next, select your private key on your computer for the Signing Certificate, enter your certificate password, and hit “Send”.
 - vii. The FDA will review your guidance compliant test submission and then notify you via email that your WebTrader Account has migrated to production within **5 business days**. If you have received the migration email, you can now skip to step #7.
 - viii. If you did not receive an email within 5 business days, login to <https://esgtest.fda.gov/login> and click “Inbox” and then click the “Receipt for IND_TEST”. Copy and paste the Core ID (Submission Message ID) in an email to ESGHelpDesk@fda.hhs.gov and notify them of the date you submitted the test submission.
 - b. You will need to perform a connectivity test for your new WebTrader Account (this only has to be done when you first set up your account):
 - i. Login to <https://esgtest.fda.gov/login>
 - ii. Hit “Send Document”



- iii. Select “GWTEST” from the Center dropdown menu, and select “ConnectTest” from the Submission Type dropdown menu.
- iv. Click the “+Add documents” and upload any PDF.
- v. Next, select your private key (ends in “.pfx”) on your computer for the Signing Certificate, enter your certificate password, and hit “Send”. After sending, you may receive a popup saying “untrusted certificate chain: Upload failure occurred due to an untrusted certificate chain. Click 'Trust certificates' and retry your upload.” Follow these instructions and select “trust certificates” and proceed with sending the test submission.
- vi. After you receive an Acknowledgement (check “Inbox” in WebTrader), send an email to ESGHelpDesk@fda.hhs.gov with the Acknowledgement’s Core ID (Submission Message ID).
- vii. The FDA will review your test submission, which may take up to **1 week**. You will receive an email from the ESG Helpdesk regarding submission status.

Day 11 – Begin submitting through WebTrader

7. Once you have received an email from the ESG Helpdesk with production account confirmation, you can now begin submitting through the ESG using WebTrader.
 - a. Log in to <https://esg.fda.gov/login> with the same user ID and password you created when you registered for your test account. (Note: do not use <https://esgtest.fda.gov/login> for actual FDA submissions, this is only for test submissions)
 - i. You may see the same pop window pictured in step #5.c asking you to download the installer. You can click the “Don’t show this again” because the installer was already downloaded during step #5. If the “Alerts” tab in WebTrader shows a record indicating the same message, click “Trust Connection” if available under “Actions”.

***Additionally, there are FDA instructions for updating a personal digital certificate that can be found here: <https://www.fda.gov/industry/about-esg/esg-appendix-c-digital-certificates#7>