FDA eSubmitter Frequently Asked Questions

This Frequently Asked Questions (FAQ) is meant to provide support for those Industry users interested in submitting an electronic submission to participating Centers within the FDA. This FAQ contains questions and answers that are generic and/or technical in nature. For program specific information, please visit the Links tab in eSubmitter Welcome screen and click on the applicable program to launch its website. If you continue to experience problems or you are not able to find a question that matches your scenario, please send your question to us at esubmitter@fda.hhs.gov. For CVM related technical support or general inquiries, please contact: cvmesubmitter@fda.hhs.gov. For CBER related technical support or general inquires, please contact: CBER_eSubmitter_program@fda.hhs.gov

Questions and Answers

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Installing the Software and System Requirements

Q1. What are the computer and system requirements to run the eSubmitter software?

- Windows Operating System
  NOTE: If installing on Vista, please review the following web page: Instructions for Using eSubmitter on Microsoft Vista.
- Adobe Acrobat Reader v5.0 or greater
- 30 MB of disk space
- Access to a Compact Disk-Recordable drive (CD-ROM Drive)
- Software capable of viewing HTML, such as a Web browser, Microsoft Word, or Adobe Acrobat (you will need the full install version to view HTML)

Q2. Can eSubmitter be used on a Mac operating system (Mac OS X)?

No, eSubmitter cannot be used on Mac OS X at this time. However, we have determined a work-around if you need to install eSubmitter on a MAC OS X, please contact the eSubmitter Help Desk at eSubmitter@fda.hhs.gov.

Q3. Is eSubmitter compatible with Windows Vista?

Early versions of the eSubmitter application were not compatible with the Windows Vista Operating System. However, compatibility issues have been resolved in eSubmitter version 1.28.01 and all subsequent versions. If you have not installed eSubmitter prior to January 8, 2008, you should not encounter any compatibility issues. To download the eSubmitter application, please visit the eSubmitter Website. In addition, be sure to read the web page for Instructions for Using eSubmitter on Microsoft Vista.

NOTE: The application will install the **data** and **output** folders outside of Program Files in the following location: **C:\Users\Public\eSub_Home.** Do not change your Preferences within eSubmitter to move the location of the data and output folders into the eSub directory under Program Files if using a Windows Vista OS.

Q4. I installed eSubmitter on an earlier version of Windows and I have since upgraded to Windows Vista. What are my potential issues?

Please see the web page for Instructions for Using eSubmitter on Microsoft Vista, which explains how to change your preferences within eSubmitter to redirect your data and output folders. If you have existing eSubmitter files, you will need to retrieve your existing submission files from Vista's Virtual Store and restore any backup files that were created in Windows XP or earlier.

Q5. How do I receive software updates from the FDA?

As long as your computer is connected to the Internet and your company does not have a firewall that prevents automatic updates of software, the software auto-updates each time it is opened. There is nothing that needs to be done by the user once eSubmitter has been updated to FDA's latest version of the software.

Q6. What if my company has a firewall that prevents automatic updates of software?

A solution may be to install the software on a company server that allows for auto-updates. Users can access the application from the server.

Q7. What steps must be followed to permit more than one user to access eSubmitter (i.e., install on a shared network)?

The eSubmitter application can be installed on a shared network or server location to be accessed by multiple users. To do this, when downloading the software, change the default location (your local hard drive at C:\Program Files\eSub) to the location of the server from which you wish to work. There is a file locking feature so two users do not access the same submission file at the same time and potentially overwrite each other's work. If you decide to use a server it is important to remember that all files that are attached to the questions in the submission MUST be saved to the server.

Q8. Can the shared network location be restricted, therefore limiting access to the application?

The shared network location where eSubmitter is installed can be restricted through user rights/permissions. Thus, the application will not be visible or the data files protected based on user permissions for the specified network location. eSubmitter does not require a username or password so those users with access to the network location will have access to the application.

Q9. Can eSubmitter be switched from my workstation to a network location?

For the application itself, this would require separate installations. However, the data and output locations can be switched between local and network locations if desired.

Installing the Software and System Requirements (continued)

Q10. Can the submission be prepared from multiple workstations and later consolidated into one final

No, but you can install eSubmitter on a network and enable file locking to allow multiple people to access the same submission

Q11. Is the eSubmitter software Part 11 compliant?

Yes, the software has the ability to maintain all the data files that are produced and submitted to the FDA.

Q12. As eSubmitter requires Windows OS, Adobe Reader 5.0 (or full Adobe Acrobat), and a CD-R, does it require any special permissions for a user on a Win2K/WinXP machine? What exactly does jinstall.exe unpack?

The eSubmitter application is based on Java. The installation program will unpack the application into the user designated location. All files installed will reside in the aforementioned designated location. The files installed include the application and support files, a Java runtime engine (JRE 1.4.2), and install/uninstall information. The JRE installed is specific to this application and should not interfere with other possible JRE's installed (i.e., JRE is not recognized by the OS but instead called by the eSubmitter application directly). The install program will setup menu short-cuts as well as provide uninstall information to the OS, which will require access to the Windows registry. Otherwise, no additional permissions should be required.

Q13. Does eSubmitter introduce any new Digital Linked Library's (DLLs)?

No.

Q14. Does eSubmitter require any specific version of DLLs that are standard on the machine?

No.

Q15. Does eSubmitter communicate outside the local box? Does it use any TCP ports?

Yes. The application uses an internet connection to perform auto-updates of the application and support files (e.g., enhancements, fixes). The auto-update process is called at start-up every time the application is executed. However, if no internet connection is available the application will still execute correctly but no updates will be received. If you use a proxy server there are settings within a configuration of the application to give the application permission to contact its auto-update site.

Q16. Does eSubmitter introduce any vulnerabilities of which you (the developers) are aware?

None of which we are aware.

Q17. Are there any issues that might affect our environment of which I should be aware?

None of which we are aware.

General Information

Q18. What types of submissions can be submitted to the FDA using the eSubmitter software?

As of May 2015, the following FDA electronic submissions are available within the eSubmitter software application:
Center for Drug Evaluation and Research (CDER)
- Generic Drug Facility Electronic Self-Identification

Center for Devices and Radiological Health (CDRH)
- Office of In Vitro Diagnostics (OIVD): In vitro diagnostic (IVD) premarket notification [510(k)], including CLIA Waiver and Categorization applications
- Office of Communication, Education and Radiation Programs (OCER): Radiological Health Reports and Correspondence
- Office of Surveillance and Biometrics (OSB): MedWatch 3500A form for medical device adverse event reports
- Office of Compliance: Medical Device ISO 13485: 2003 Voluntary Audit Report Submission Pilot Program
- Office of In-Vitro Diagnostics (OIVD) and Office of Device and Evaluation (ODE): eCopies

Center for Biologics Evaluation and Research (CBER)
- Office of Blood Research and Review (OBRR): Biologics License Applications for Blood Establishments That Collect Whole Blood and Blood Components, including Source Plasma
- Office of Biostatistics and Epidemiology (OBE): Individual Case Safety Reports (ICSR) Adverse Event Reporting

General Information (continued)

Center for Tobacco Products (CTP)
- Tobacco Ingredient Listing (per sub-sections of Section 904(A) of the Tobacco Control Act)
- Health Data Submissions (per sub-sections of Section 904(A) of the Tobacco Control Act)
- Harmful and Potentially Harmful Constituents (HPHC) (per sub-sections of the 904(A)(3) of the Tobacco Control Act)
- Other CTP submission types not listed above (ESG Transmittal Form)

Center for Veterinary Medicine (CVM)
- Office of New Animal Drug Evaluation (ONADE): All pre-market submissions for New Animal Drug Applications, Abbreviated New Animal Drug Applications, Investigational New Animal Drug Files, Generic Investigational New Animal Drug Files, Veterinary Master Files, and General Correspondence Files

Q19. How can several people work on an individual submission from different computers?

There are two ways that users can collaborate on one submission:

1. eSubmitter can be installed on a network and accessed by multiple users. To do this, see the response to the question: "What steps must be followed to permit more than one user to access eSubmitter (i.e., install on a shared network)?" OR

2. The data file can be passed from one user to another. The submission can be accessed by placing the data file in the data folder and opening it from eSubmitter application.

Q20. Can I create a submission, edit it, save it and return to it to finalize it in multiple sessions?

Yes. You may save and close a submission file at any time. To return to the submission file, click Open Existing Submissions in eSubmitter to select the submission file in progress.

Q21. Does eSubmitter perform an "autosave"? If it does, can it be turned off?

Yes, the eSubmitter application has the ability to set an auto-save feature. This feature can be customized by going to File>Preferences. When this option is enabled, eSubmitter automatically saves your submission while you work. You can also set the interval for how often you want to save. At default, auto-save is automatically turned on, and set to save files at 10 minute intervals. It is also possible to turn off the auto-save feature from within the Preferences.

Q22. What if a question or section does not apply to my product?

Questions containing business rules were put in place to disable questions that do not apply to certain products. If a question still does not apply to your product, enter "NA" with an explanation as to why the question does not apply. There are numerous questions within the eSubmitter templates that allow you to provide an explanation of why you are not including a section of the submission that the FDA has deemed mandatory.

Q23. Can I cut and paste text into the text boxes in the eSubmitter software?

Yes, but be sure to review the formatting of the pasted text. Pasted text from a Word Document may include unwanted formatting tags. The two ways to prevent unwanted tags are to use Paste Special when pasting text or first copy the text into a Text file and copy and paste the text from the text file into the appropriate eSubmitter question.

Q24. Can an old submission be reused to generate a new submission by editing it to include the new information for a similar product?

Yes, to do this you will need to open the old submission and go to "File>Save As" to create a new submission. The data from the old submission will be copied over to the new submission with the new file name. The template will also be updated into the latest version. If new questions were added to the eSubmitter template, they will need to be completed. If questions were removed from the template, the data from those questions will be removed.

NOTE: This approach should be used to create a supplement (if applicable to the FDA program area to which you are submitting). Check the specific program area website from the eSubmitter home page to verify that a Supplement is applicable.

Q25. What does it mean when I get a message indicating that the eSubmitter template will become "inactive"?

Updates occur to the templates each month. Questions are removed or added; new business rules are implemented; new templates are developed; and standards, guidance, and product codes are updated. In order for the FDA to ensure that users are using the most updated templates, the templates are set to expire one year after a new version is released. If you have been working on an submission using the old template you must submit the submission within one year of the last update for the FDA to be able to load and review your submission. Otherwise you can do a "File>Save As" to update to the latest version of the template.

Attaching Files and File Specifications

Q26. How do I attach files?

Attaching a file to an eSubmitter question is very similar to attaching a file to an email. Please see section 4.1 of the eSubmitter User Manual for more information. Instructions on attaching files in eSubmitter can also be found on page 6 of the eSubmitter Quick Guide, which may be launched from within the eSubmitter tool's Welcome Screen under Menu Options.

For further reference, please see Section 5: "FDA Recommended PDF File Specifications" in the eSubmitter User Manual for specifics regarding the attachment of PDF file types.

Q27. What types of files can I attach?

The eSubmitter tool supports attachment of the following file types:

- Adobe Acrobat files (.pdf)
- SAS System XPORT files (.xpt)
- Extensible Markup Language (.xml, .dtd)
- Image files (.gif, .tif, .jpg)

- Standard Generalized Markup Language files (.sgml)
- MDL Molfiles (.mol)
- Excel files (.xls, .csv)
- Media files (.wmv, .avi)

However, questions may be restricted to only allow certain file types (e.g., PDF only) based on the question and/or program for which you are submitting.

For further reference, please see Section 5: "FDA Recommended PDF File Specifications" in the eSubmitter User Manual for specifics regarding the attachment of PDF file types.

Q28. How should I name the attached files?

Use a descriptive name so the reviewer can easily identify the content of the file. As a best practice, do not use punctuation, spaces, or other non-alphanumeric symbols in file names when naming the files for attachments. When provided, naming conventions located in guidance documents for specific submission types are highly recommended.

Q29. Is the descriptive information section in the File Attachment Dialog also shared with FDA when submitted?

Yes, this information is collected as part of the submission.

Q30. Should I set security settings or passwords on my PDF files that are attached to the questions in the submission?

No, please do not set any security settings on the attached PDF files. This could cause issues when the FDA reviewers access the file, and could result in the rejection of submitted files.

Q31. Which PDF versions are supported by the eSubmitter software?

Adobe Acrobat 5.0 or greater. Please note that there are features in Adobe Acrobat 8.0 that cannot be supported; if you are submitting Adobe Acrobat 8.0 files, please contact technical support at esubmitter@fda.hhs.gov.

Q32. Can I use bookmarks in my PDF attachments?

Yes. In fact, using meaningful bookmarks in the PDF files is very useful to the FDA reviewers. It facilitates a faster review time, especially when the attached files are large.

Q33. Can I attach pictures or plug-ins to the questions in the eSubmitter submission?

Although it is acceptable to use plug-ins to assist in the creation of a submission, the review of the submission should not require the use of any plug-ins other than any provided by Adobe as part of Acrobat, and must be compatible with Adobe Acrobat 5.0 or greater.

Q34. Can I scan documents and include them as attachments?

Yes, but please run Optical Character Recognition (OCR) to make the PDFs searchable and allow for copying and pasting of the text.

Attaching Files and File Specifications (continued)

Q35. What is the recommended font for the PDF attachments?

Times New Roman 12-point is the preferred font. Fonts smaller than 12-points should be avoided whenever possible.

Q36. What if I get a message that says my file cannot be viewed because it cannot be located?

This message may indicate that the file is not in the same location as it was when it was first attached. There are two ways to fix this error:

1. Move the file back into the original location OR
2. Remove the file from the file attachment list and reattach the file from its current location.

Q37. What if I want to make a change to an existing file after it has been attached to a question in the submission?

If you need to make a change to the file after it has been attached, you must go to the file at its current location, make the change and save it to the same location. The content of an attached file can change but the location of the file cannot.

Warning: You will not be able to package correctly if the location of the file changes after it has been attached to a question in eSubmitter and prior to packaging. Should you need to change the location of a file after it has been attached in eSubmitter, you will need to re-attach the file in eSubmitter to the question response after the file has been moved.

Q38. Can file attachments (or data and output files) be stored in SharePoint, or must they reside on the local PC or a network share?

No, eSubmitter cannot access files from a web-based application such as SharePoint during packaging. The files must be accessible from the file system so they can be located and incorporated into the final submission package.

Completing and Packaging Submissions

Q39. Is the .ZIP output file the only format for electronic submission?

The packaged output from eSubmitter is a .ZIP file. This is the only electronic format for submission output if using eSubmitter. The FDA program for which you are submitting to may have a paper form or other electronic means in place as an alternative to submitting via eSubmitter.

Q40. How can I verify that all my file attachments are included in the submission zip file?

The attached files will be listed during Step 2 of the packaging process. In addition, they are also stored within the zip file that is generated after the submission has been packaged properly. They can be opened and reviewed.

NOTE: DO NOT ALTER THE ZIP FILE IN ANY WAY when you review the attachments. This will cause issues loading your submission and will require that you resubmit.

Q41. What do I do if I "package" the submission and then decide to make a change?

Open the submission and make the change then simply repackage the submission. Do not add files directly to the zip file without attaching them to the appropriate question in eSubmitter. These files will not be considered part of the submission.

Q42. What happens if I change the location of the files after packaging and I try to re-open the submission in eSubmitter?

If the data or output files are not in the original location, the software will not be able to open the submission files. To fix this, you should restore the files to their original location. To determine this location, go to **File** > **Preferences** > **File Location** tab in the eSubmitter application. The file path of the location where your data and output files should be stored is displayed.

You can move the files back into this location OR change the file path location by clicking on the **Select Location** folder icon and navigating to the new location where your data and output files are stored. The new path should display in the text field. For more detailed instructions on setting the file locations in user preferences, see page 19 of the eSubmitter User Manual.

Q43. How can I store the submissions for record keeping in my company?

The complete packaged zip file (which contains the submission data (.xml) file and any file attachments) can be named and stored just like any other electronic document.

Completing and Packaging Submissions (continued)

Q44. Can a submission be retracted if in error?

If you have created a submission in eSubmitter, you may delete it at any time if created in error. However, if you have transmitted a submission to FDA, either on CD or via the ESG, it cannot be retracted. You may contact the

Q45. Is there a limit to the size of a single submission (attachments and images included)?

We have successfully tested up to 4 GB however it does take time to package anything greater than 2GB but it will work. It just takes more time to process and package.

Q46. Can digital signatures be used to sign my submission and any other required signed documents?

This will depend upon the submission type and program for which you are submitting. As of May 2015, the following is acceptable for each program regarding digital signatures and the FDA Electronic Submissions Gateway (ESG). Please verify with the program website that these guidelines have not changed. Program websites are accessible from the eSubmitter home page.

CDER Program:

- Generic Drug Facility Electronic Self-Identification: Digital signatures are not accepted at this time for GDUFA submissions. The CDER program only accepts submissions via the FDA ESG.

CDRH Programs:

- OIVD's 510(k): Digital signatures are not accepted at this time for OIVD 510(k) submissions. In the future, the digital signature will be available in conjunction with the FDA ESG.
- Radiological Health Reports and Correspondence: Digital signatures are accepted and required when utilizing the FDA ESG to submit reports and correspondence. See note below regarding the FDA ESG. RadHealth Submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CDRH in lieu of using the ESG.
- eMDR MedWatch 3500A Form: The eMDR program accepts digital signatures and utilizes the FDA ESG for transmission of the submission package. eMDR submissions may only be sent through the FDA ESG.
- Medical Device ISO 13485: Digital signatures are not accepted at this time for Medical Device ISO 13485 submissions. However, the CDRH program accepts submissions via the FDA ESG, as well as sending in by CD.
- eCopies: Digital signatures are not accepted at this time for eCopies submissions. eCopies submissions are accepted via CD and mailed to CDRH.

CBER Program:

- OBRR BLA/BLS Submissions: Digital signatures are accepted and required for signing the necessary FDA OMB forms (Form 356h and Form 2567, when applicable). However, the CBER program does not accept submissions via the FDA ESG at this time.
- ICSR Adverse Event Reporting: Digital signatures are accepted and required when utilizing the FDA ESG for transmission of the submission package.

CTP Program:

- Tobacco Product Ingredient Listing, Health Data Submissions, and other CTP submission types not listed: Digital signatures are accepted and required when utilizing the FDA ESG to submit ingredient listing and additional health data. Submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CTP in lieu of using the ESG.
- Harmful and Potentially Harmful Constituents (HPHC) Submissions: Digital signatures are accepted and required when utilizing the FDA ESG to submit. See note below regarding the FDA ESG. HPHC submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CTP in lieu of using the ESG.

CVM Program:

- ONADE: Digital signatures are accepted and required when utilizing the FDA ESG to submit eSubmitter electronic submissions to CVM.

Note regarding FDA Electronic Submission Gateway: CDRH's Radiological Health submissions program, the eMDR program and the CTP utilize the FDA ESG, an agency-wide entry point for all electronic submissions. CDRH and CTP use the ESG to receive all electronic forms. The ESG authenticates and validates electronic submissions and routes it to the appropriate Center. Please visit http://www.fda.gov/esg/ to register as a trading partner for an initial ESG test account. Upon successful transmission of the test submission, your account will be promoted to a production account.

Completing and Packaging Submissions (continued)

Q47. Can the digital signature password that was issued to one person be used by another as long as it is for the same company?

The digital signature accepted in eSubmitter is an Adobe self-signed digital signature. The signature is for a single individual and the password issued is determine by the user during the creation of the Adobe digital signature. The signatures and passwords are not determined by FDA. For more information on how to create your digital signature and packaging in eSubmitter using digital signatures, see the applicable quick guides located within the manual folder in the eSubmitter directory.

Q48. Are there any other rules for digital signatures?

For information and guidelines on digital signatures, see the applicable quick guides located within the manual folder in the eSubmitter directory. These quick guides may also be launched from within the Packaging Wizard in eSubmitter.

The PDF Packaging A Submission Using Digital Signatures provides step-by-step instruction for packaging using digital signatures and the PDF Adobe Digital Signatures provides step-by-step instruction for creating self-signed Adobe digital signatures.

Q49. Can eSubmitter be used to compile a submission prior to finalizing our FDA Electronic Submissions Gateway (ESG) account set up?

Yes, the FDA ESG and the eSubmitter application are two separate systems. You will need the ESG account setup finalized prior to actually sending in the packaged submission generated in eSubmitter (if using the ESG to transmit your submissions). However, you may begin working on your electronic submission using eSubmitter prior to completing the FDA ESG account setup requirements.

Q50. Is the submission available for viewing by the submitter once submitted to FDA?

The submission is always available for viewing from your internal records as it resides on your local machine or network. FDA does not, however, provide access to view submission content previously submitted due to security purposes.