



Dear CBER eSubmitter User,

This document is intended to serve as your complete checklist during the creation, packaging, and mailing of your eSubmitter submission. For support on any of the items listed below, please refer to the links and information provided in this document.

1. Did you compile your submission using the eSubmitter software tool?

For help with the compilation of your submission, refer to:

▶ The eSubmitter [Quick Guide](http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM162419.pdf) at:
<http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM162419.pdf>.

▶ The eSubmitter [User Manual](http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM162401.pdf) at:
<http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM162401.pdf>.

2. Did you create a self-signed digital signature?

For help with digital signatures in Adobe Acrobat, refer to the “Creating Digital Signatures Quick Guide” and “eSubmitter Quick Guide: Packaging with Digital Signature” documents.

The Quick Guide documents `PackagingSubmissionUsingDigitalSignatures.pdf` and `AdobeDigitalSignatures.pdf` can be found within the “manual” folder in the eSubmitter directory (installation folder). The default location of these documents is `C:\Program Files\eSub\manual`, although this may be different if you installed the eSubmitter application somewhere other than the default location. These documents can also be launched from the Hint text in Step 3 of the Packaging process within eSubmitter.

3. If you have not submitted a letter of non-repudiation for a previous submission, did you mail the letter of non-repudiation? See Appendix A for a sample non-repudiation letter.

4. For IND submissions: Did you package the submission using the eSubmitter software, generating the eCTD folder structure output?

For BLA/BLS submissions: Did you package the submission using the eSubmitter software, generating a submission .ZIP file?



For help with packaging your submission, refer to the eSubmitter [Quick Guide](#).

If you will be submitting via CD-ROM, follow steps 5-7. If you will be submitting via the Electronic Submissions Gateway (ESG), follow steps 8-10.

CD-ROM:

5. **For IND submissions:** Did you copy the aforementioned eCTD folder structure (unaltered after being packaged) to a CD and label the CD as instructed in Appendix B?

For BLA/BLS submissions: Did you burn the aforementioned .ZIP file (unaltered after being packaged) to a CD and label the CD as instructed in Appendix B?

6. Did you mail the properly labeled CD to CBER at following address?

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave
WO71 – G112
Silver Spring, MD 20993-0002

7. Did you send an email notification (using the template in Appendix C) including company name, appropriate application number (BLA), and shipping information to the following individual to notify CBER that an eSubmitter submission has been sent?

To: Janet O'Brien [JanetD.O'Brien@fda.hhs.gov]

Electronic Submissions Gateway (ESG):
(for detailed instructions on using the ESG, refer to the [FDA ESG User Guide](#) at <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>)

8. Did you obtain and set up your ESG WebTrader account?

To obtain an ESG account, see the following checklist:
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>.

For ESG questions and to request an ESG WebTrader account, contact



esgprep@fda.hhs.gov.

9. ***For ESG submissions only:*** Did you submit your submission package through the ESG following the instructions on the Transmit Submission Package screen?

For help with transmitting your submission, refer to the eSubmitter [Quick Guide](#).

10. ***For ESG submissions only:*** Did you receive the Message Delivery Notification (MDN) and an acknowledgement from the Center to which the submission was sent?

If you have any questions regarding your submission, you may contact CBER eSubmitter user support at [CBER_eSubmitter_program@fda.hhs.gov].

If you have completed all of the above steps, you have successfully submitted your eSubmitter application for review. Thank you for your submission!



APPENDIX A:

eSubmitter: Letter of Non-Repudiation

Participants of eSubmitter will be signing their submissions electronically. For this reason, your organization will need to submit a letter of non-repudiation to the FDA. Please see sample wording below and navigate to the FDA website for more information:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113964.htm>

[Company Letterhead]

[Today's Date]

Office of Regional Operations, Room 3007
12420 Parklawn Drive
Rockville, MD 20857

Re: Electronic Signature Certificate Statement

To Whom It May Concern:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that [Company Name], intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional hand-written signatures.

Sincerely,

[Hand-written signature]

[Name of Company Representative]

[Company Representative Title]

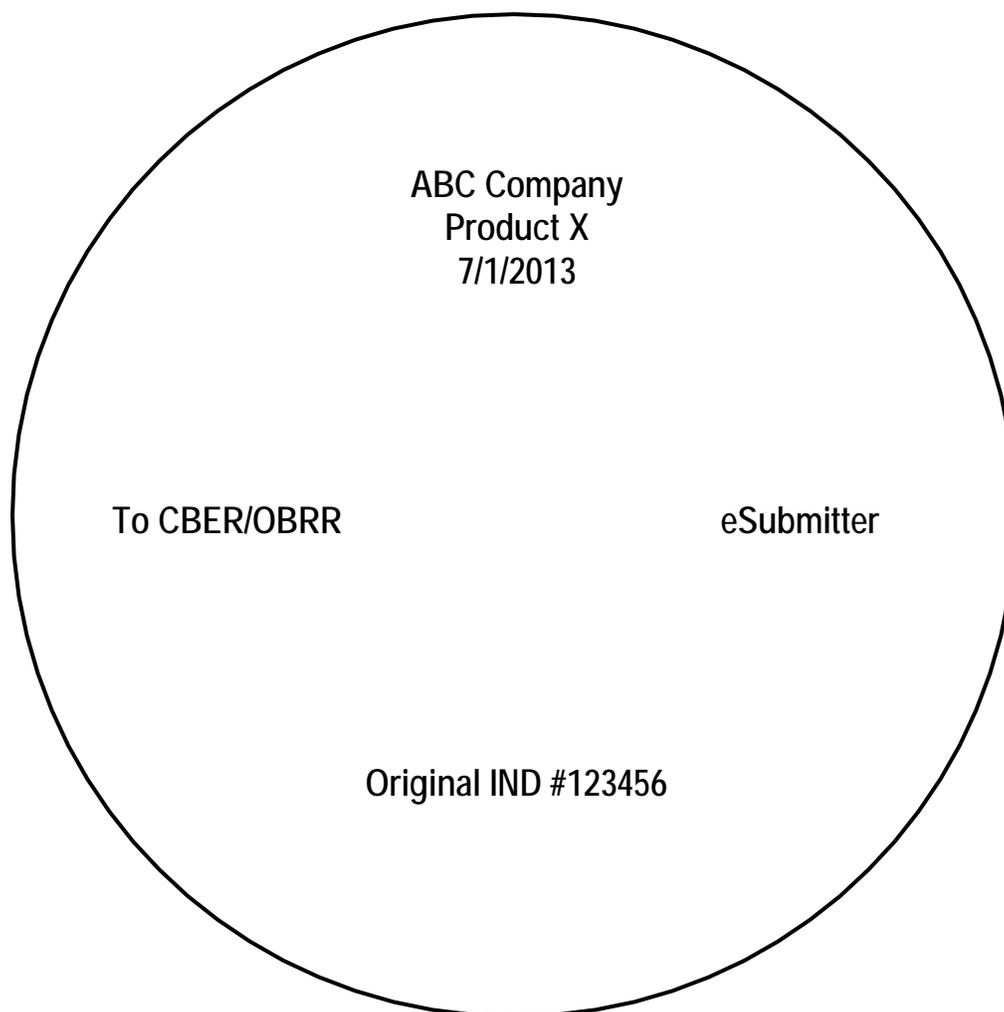


APPENDIX B:

eSubmitter: CD-ROM Labeling Instructions

Please label the CD-ROM clearly with the items listed below. If a paper label is not used, write on the CD-ROM using a felt-tip marker, not a ball point. The label should contain the following items, in the fashion shown on the sample image below:

1. Sponsor Name
2. Product Name
3. Date it is being submitted
4. The application type (e.g., Original, Supplement, Amendment) and FDA-assigned number (if applicable)
5. The word "eSubmitter"
6. To CBER and the appropriate Office (e.g., OBRR)





APPENDIX C:

eSubmitter: Email Notification

Please use the template below for your email notification once you have mailed your eSubmitter submission to the CBER Document Control Center.

To: Janet O'Brien [JanetD.OBrien@fda.hhs.gov]

Subject: eSubmitter Submission Notification

Janet,

An eSubmitter submission has been mailed to the CBER Document Control Center (DCC). The details of the submission are as follows:

- 1) [Company Name]
- 2) [FDA-Assigned Number (if applicable)]
- 3) [Shipping Company]
- 4) [Shipping Date]
- 5) [Shipping Tracking Number]

Thank you,

[Name of Company Representative]

[Title of Company Representative]

[Contact Information of Company Representative]