

FAQs

Question	Answer
ANDA pre-assigned numbers expire after 60 days. Can I file an ANDA to CDER OGD after 60 days?	Yes. However, we recommend that sponsors always check first to make sure the pre-assigned number is active prior to submitting.
Are there any exceptions to the paper submission?	Yes. Exceptions include briefing documents, as well as the paper copy of the cover letter and form, when submitting on physical media, just in case the CD or tape proves unreadable.
Can FDA refuse to file an ANDA submission for expired pre-assigned numbers?	No, this would not happen. The number is just a placeholder to identify applications. It is not part of the regulatory review process.
Can I submit PDF files by themselves?	No. Currently, the only acceptable electronic format for submitting applications to CDER is eCTD structure, which is submitted with an XML backbone.
Do I need to submit previously submitted documents when transitioning to eCTD?	No, you don't need to resubmit any previously submitted information when you convert to eCTD. That is, unless you are instructed to by the division. In that case, you can use eCTD section 1.4.4 to provide a PDF of the application's paper table of contents or other cross-reference information.
Do we always have to code the first transitioning submission as original application even if my first transition submission is an Annual Report?	No. You can code any first-level submission type for your transitioning submission depending on what you are submitting. For example, if your transitioning submission is an amendment to an Annual Report, then you can code the submission as an "Annual Report". If it's an amendment to a CMC Supplement, then you can code the submission as a "CMC Supplement". For more information, click here .

<p>FDA recommends we submit a successful eCTD sample prior to submitting an actual eCTD submission. Is that mandatory?</p>	<p>No, it is not mandatory. However, FDA recommends that sponsors submit a successful eCTD sample prior to submitting an actual eCTD submission to ensure sponsors understand the eCTD specifications and to avoid their initial eCTD submission being rejected.</p>
<p>Should we code the us-regional.xml as an amendment since it is not the original application?</p>	<p>Identify your first eCTD sequence as a general correspondence submission in the cover letter and FDA Form. State that the application will be submitted in eCTD format from this date forward and then intentionally code the us-regional.xml as the original application.</p>
<p>When transitioning to eCTD, what should the first eCTD sequence be coded as? Do I have to use sequence 0000 when I transition to eCTD or can I use any other sequence number?</p>	<p>You can use sequence 0000 or any other sequence number when transitioning to eCTD.</p>
<p>What is the procedure for reactivations of expired pre-assigned numbers after 60 days?</p>	<p>After 60 days, the applicant needs to send an email to the CDERAPPNUMREQUEST account and inquire about the validity of the number.</p>
<p>When did FDA start requesting eCTDs?</p>	<p>As of January 1, 2008, eCTD became the standard for electronic submission for CDER and the Center for Biologics Evaluation and Research (CBER).</p>

<p>Will the reviewers know when I transition to eCTD or, do I have to state on the form or cover letter?</p>	<p>The FDA form should list the submission type as General Correspondence or Other. The bold print on the top of the cover letter should say the correct submission type, General Correspondence or Amendment.</p> <p>In the body or at the end of the cover letter, you could state something similar to the following:</p> <p>"As per the advice received from Office of Business Informatics, this eCTD submission sequence is intentionally being coded as an original application in the us-regional.xml and serves as a first-level submission type in the electronic common technical document format. This eCTD sequence is intentionally being submitted as the original application to establish the eCTD hierarchal structure and will allow second-level submission types such as amendments and resubmissions to be related to it."</p>
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