U.S. FOOD & DRUG ADMINISTRATION

NEW REQUIREMENTS FOR ELECTRONIC SUBMISSIONS OF DMFs

eCTD

The Electronic Common Technical Document (eCTD) is the standard method for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). This includes Drug Master Files (DMFs), Biological Product Files (BPFs), and other master files.

Converting existing DMFs to eCTD format

If you currently hold a DMF in paper form, you are not required to resubmit it in eCTD format. However, you may convert an existing paper DMF into eCTD format if you wish. When submitting your first eCTD submission to a DMF, you will use the existing DMF number. If the existing number is four digits, you will need to add zeros on the left to convert it to a six-digit format. For example, 1234 would become 001234.

If you choose to resubmit a paper DMF in electronic format and there are changes in the content of the DMF, such as new or updated information, you must list the changes in the cover letter for the submission.

Starting **May 5, 2017,** new DMFs, new BPFs, and any submissions to existing DMFs and BPFs (e.g., amendments, annual reports, LOAs) must be submitted using the eCTD 3.2.2 standard. All submissions must be submitted electronically even if the remainder of the master file is on paper. DMF submissions that are not submitted in eCTD format after May 5, 2017, will not be filed or received. The eCTD standard will be updated in the future. The current requirements and supported versions can be found in the FDA Data Standards Catalog at www.fda.gov/eStudyResources.

Submitting DMFs electronically

Implementing electronic DMFs will improve the efficiency of the DMF review process. This will make it easier for FDA to review applications supported by DMFs. The first step to submitting DMFs electronically through FDA Electronic Submissions Gateway (ESG) is to request an ESG test account. Refer to the FDA ESG User Guide, at www.fda.gov/esg, for information on how to submit the registration request. Setting up an ESG account is a multi-step process and should be started well before you intend to make your first electronic submission.

Additional information

For more information on eCTD requirements, please visit www.fda.gov/ectd

If you have **questions about DMFs**, please write to dmfquestion@cder.fda.gov and visit the DMF website at www.fda.gov/DMF

Contact information

If you have questions about **DMFs filed under the Generic Drug User Fee Amendments of 2012**, please write to AskGDUFA@fda.hhs.gov

If you have questions about **electronic submissions to CDER**, please write to esub@fda.hhs.gov

If you have questions about **electronic submissions to CBER**, please write to esubprep@fda.hhs.gov

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES/U.S. FOOD & DRUG ADMINISTRATION
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