



FDA ELECTRONIC SUBMISSIONS GATEWAY

ESG

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to FDA. The ESG does not open or review submissions. It receives submissions, acknowledges receipt, routes them to the proper FDA center or office, and notifies that center or office of delivery.

Submission types

The FDA ESG supports the receipt of guidance-compliant electronic regulatory submissions to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). The FDA ESG also supports the receipt of reports and attachments for many other FDA offices and centers. FDA is continually expanding the list of electronic regulatory submissions that can be received by the ESG.

Submission requirements

As of **May 5, 2017**, many submissions to CBER and CDER are required to use the Electronic Common Technical Document (eCTD) format. (For commercial Investigational New Drugs [INDs] and Master Files, the requirement takes effect on May 5, 2018.)

Submissions that fall under the eCTD requirement and are 10 GB or less in size must be submitted via the FDA ESG as of the applicable date. For more information on these requirements, see www.fda.gov/ectd.

Submission options

FDA ESG options include the following:

- An AS2 Gateway-to-Gateway Connection
- WebTrader software installed on submitter's computer

Getting started

The first step to submitting electronically through ESG is to request a test account. Refer to the [FDA ESG User Guide](http://www.fda.gov/esg), available 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, please visit www.fda.gov/ectd.

If you have questions for CBER, please contact **CBER Electronic Submissions (ESUB)** at esubprep@fda.hhs.gov.

If you have questions for CDER, please contact **CDER ESUB** at esub@fda.hhs.gov.

If you have questions for the ESG Help Desk, please contact esghelpdesk@fda.hhs.gov.

The eCTD is CBER and CDER's standard format for electronic regulatory submissions.

As of **May 5, 2017**, the following submission types must be submitted in eCTD format: **New Drug Application (NDA), Abbreviated NDAs (ANDAs), and Biologics License Applications (BLAs)** (with some exceptions), along with amendments, supplements, and reports for these submission types.

Commercial IND and Master File submissions must be submitted in eCTD format beginning **May 5, 2018**.

Submissions that do not adhere to the requirements stated in the eCTD Guidance will not be filed or received.