FDA eCTD Glossary

Biologic License Application (BLA): The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680. A BLA is submitted by any legal person or entity engaged in manufacture or an applicant for a license who takes responsibility for compliance with product and establishment standards. Form 356h specifies the requirements for a BLA. This includes:

- Applicant information
- Product/Manufacturing information
- Pre-clinical studies
- Clinical studies
- Labeling

CDER: The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

eCTD: The electronic Common Technical Document (eCTD) is an interface for the transfer of regulatory information. eCTD is the preferred format for submitting applications to CDER. It provides support for all application types, including:

- Investigational New Drug Application (IND)
- New Drug Application (NDA)
- Biologics License Application (BLA)
- Abbreviated New Drug Application (ANDA)
- Drug Master File (DMF)

eCTD Triangle: The eCTD is commonly represented as a triangle that has five modules:

1. Administrative Information and Prescribing Information
2. Common Technical Document Summaries
3. Quality
4. Nonclinical Study Reports
5. Clinical Study Reports

Electronic Submissions Gateway (ESG): The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory information for review.

The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach their final destination. It does not open or review submissions; it automatically routes them to the proper FDA Center or Office.

Investigational New Drug Application (IND): Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

New Drug Application (NDA): The New Drug Application (NDA) is the vehicle in the United States through which drug sponsors formally propose that the Food and Drug Administration (FDA) approve a new pharmaceutical for sale and marketing. The goals of the NDA are to provide enough information to permit FDA reviewers to establish the following:

- Is the drug safe and effective in its proposed use(s) when used as directed, and do the benefits of the drug outweigh the risks?
- Is the drug's proposed labeling (package insert) appropriate, and what should it contain?
- Are the methods used in manufacturing the drug and the controls used to maintain the drug's quality adequate to preserve the drug's identity, strength, quality, and purity?

Pre-Assigned Application Number: A pre-assigned application number is a unique six-digit number, e.g., 012345, assigned to sponsors to enable them to identify their application.

Sample Application

Sample eCTDs are evaluated by the Electronic Submissions staff for compliance with eCTD specifications, display, organization, navigation, and reviewability of the documents. You need to provide some bookmarks, proper placement of files, proper use of attributes, use of valid values, and descriptive leaf titles in your sample.

You may have to wait up to 30 days to receive feedback on your sample, but frequently you can expect an answer sooner than that. After you have received and implemented the feedback, you should be technically ready to submit to the Agency in eCTD format.

To submit a sample:

1. Obtain a Sample Application Number by emailing esub@fda.hhs.gov.
2. Submit a sample in advance. This generally has a 30-day turnaround time.

3. The sample is reviewed by the ESUB staff, and not by a reviewer. ESUB staff looks for, among others, include: compliance with specifications, eCTD validation and display, organization, navigation, and reviewability of the submission.
4. When providing the sample, refer to recommended contents of the sample submission.
5. There is no need for real data in the eCTD sample. Fake data are perfectly acceptable.
6. You should send sample via physical media. The sample should not be sent via the test gateway.
7. Refer to Sample Submission Process and recommended contents of the sample submission Web pages, which can be found in the Resources tab.
8. Contact the FDA at ESUB@fda.hhs.gov for additional information.

Sponsor: A sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Validation Check: FDA performs validation checks for both eCTD and non-eCTD submissions to ensure that submissions are processed and routed accurately and in a timely fashion. FDA uses a commercial, off-the-shelf product to validate eCTD submissions.

WebTrader: WebTrader is an applet that is downloaded on to your PC, when you log on to the FDA ESG Web page. It is part of the Axway COTS product suite that is used at FDA. WebTrader copies and packages your submission on your desktop in a secure fashion, transmits the submission in a fully encrypted message to the FDA, and then removes any traces of its presence from your PC.