US Module 1 for a Marketing Application in eCTD Format

Module 1 is unique for each region and contains region-specific administrative and prescribing information. US Module 1 is critical in guiding the FDA's review process. It provides a comprehensive overview of the application, ensuring that all regulatory, legal, and scientific requirements specific to the U.S. are addressed.

Cover Letter: An introductory letter with a summary of the submission, including the type of submission, its purpose, and any important highlights or requests.

Form FDA 356h: An application to market a new drug or biologic for human use in the U.S. It provides essential details about the applicant, product, and manufacturing facilities.

Labeling: Includes proposed labeling text, encompassing prescribing information, patient package inserts, and medication guides.

Reviewers Guide: Serves as a navigational tool, providing a clear, concise overview of the submission and highlighting key information and data.

Ad Promo Materials: Materials prepared by the sponsor to market and promote its products to healthcare professionals, patients, or the general public.

Application Forms: Any additional forms required by the FDA, such as financial disclosure forms, pediatric study plans, patent information forms, etc.

Correspondence: Important correspondence relevant to the application, including pre-submission meeting minutes, responses to previous FDA requests, or other relevant communications.

Environmental Assessment or Claim for Categorical Exclusion: Documentation related to environmental impact assessments, if applicable.

Risk Evaluation and Mitigation Strategies (REMS): If required, this section includes strategies to mitigate risks associated with the drug, such as medication guides, communication plans, and elements to assure safe use.

Other Regional Specific Information: This may include specific studies relevant to the U.S. population, U.S. specific regulatory requirements, or other pertinent information requested by the FDA.

Patent Certification and Exclusivity Statement: If applicable, information regarding patent certification and any data exclusivity claims.