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Overview Biological License Application

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Abstract: Biological products are highly evolving products its respects years. Thus biological products needs to be regulated. In USA biological products are approved and regulated by food and drug administration (FDA). To get approval of biologicals in USA, biologics license application is used BLA ensures that safe and effective products are approved in the market. Bio-similar are the product which differ from original FDA approved biological drug while still being very close to it.

The BLA application can either be full BLA (351 a) or it can be used for the bio-similar i.e. (351 k). In USA the biologics and bio-similar are included in the public health service act which has certain rules and regulations for approval of biologics. Thus review collectively gives us the idea about biologic license application and also its requirements and forms which are needed while approval of products.

Keywords: Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Public Health Service, Public Health Service, Food and Drug Administration, Common Technical Document, New Drug Application

