GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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Ref. WHO TRS, NO. 858, 1995, ANNEX-1

Date: 14/05/2018

The Guideline on Regulation and Licensing of Biological Products

In Bangladesh DGDA is functioning as National Regulatory Authority.
As a competent medicine regulatory authority it gives marketing authorization of a new biological product for the purpose of marketing or distribution after evaluation of its safety, efficacy and quality.

In General Biological products are distinguished from other drugs by being derived from living organisms (ranging from normal or genetically modified microorganisms to humans), and frequently have a complex molecular structure.
They require special quality considerations because of the biological nature of a) the starting material, and/or
b) the manufacturing process, and/or
c) the test methods needed to characterize batch to batches of the product.

So guidelines are needed to review the submitted documents/ dossier of Biological product properly and effectively.

In these purpose WHO TRS, No. 858, 1995 Annex-1, on "Regulation and Licensing of Biological Products in Countries with Newly Developing Regulatory Authorities" is very extensive guidelines which covered all the aspect and issues of reviewing application and documentation of marketing authorization.

So this guidelines (page: 21-35) is adopted for the purpose of review in DGDA from the date give below and valid up to next office order.

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