Clinical Evaluation of Biologics

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vaccines, blood products, biotechnology derived products, human stem cell therapies, gene therapies, allergenic materials and anti-toxins.

Biologics, in contrast to drugs that are chemically synthesized, are derived from living sources (such as humans, animals, and microorganisms). Most biologics are complex mixtures that are not easily identified or characterized, and many biologics are manufactured using biotechnology. Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.

A sponsor shall submit an IND to KFDA if the sponsor intends to conduct a clinical investigation with investigational biologics. Our primary objectives in reviewing an IND are, in all phases of investigation, to assure the safety and right of subjects, and, in phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of biologics' effectiveness and safety. Therefore, although our review of phase 1 submissions will focus on assessing the safety of phase 1 investigations, our review of phase 2 and 3 submissions will also include assessment of scientific quality of clinical investigations and likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval. Current regulation, Guidance on IND application(Korea FDA regulation 2004-51, 2004.7.19), contains the general requirements for IND's content and format. In case of biologics, the amount and depth of CMC information depends on the phase of the investigation. All the clinical investigations should be complied with Enforcement provision 29 and Good Clinical Practice(KFDA regulation 1999-67, 2000.1.4).