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Regulatory Aspects of Cell Therapy Products

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Cell therapy is the prevention or treatment of human disease by administration of cells that have been selected, multiplied and pharmacologically treated or altered outside the body. The aim of cell therapy is to replace, repair or enhance the function of damaged tissues or organs. The cells used can originate from the patient (autologous) or from a donor (allogeneic) or from another species (xenogeneic). The cells used in cell therapy include myoblasts, cardiomyocytes, chondrocytes, dendritic cells, various lymphocytes, fetal neural tissue, fibroblasts, hepatocytes, islet cells, keratinocytes and stem cells. As the cell therapy application grows, regulatory issues become important consideration. Safety•efficacy and quality is an essential consideration of any new therapy and regulatory considerations for cell therapy are those for biological preparations. KFDA concerns a range of cell therapy products, relevant manipulation procedure, and products to be administered is of acceptable quality and standard, and free from contamination. All necessary control measures should be considered in order to ensure appropriate sourcing and control of all materials, minimizing the risks of damage and ensuring integrity, desirable characteristics and function of the therapeutic product, and compliance with high quality and safety standards of establishments and processes involved in the manipulation of cell products. Also, preclinical studies are intended to define the pharmacologic and toxicological effects predictive of the human response. Due to the unique and diverse nature of the products employed in cell therapies, conventional pharmacology and toxicity testing may not always be appropriate to determine the safety and biologic activity of this therapeutics. Available animal models mimicking the disease indication may be useful in obtaining both sufficient safety and efficacy data prior to entry of cell therapy products into clinical trials. It is recommended that plans for preclinical studies be discussed with KFDA (BED) before initiation.