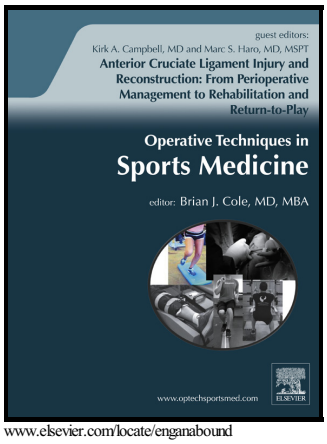

Getting Products to Market: Understanding and Navigating the Regulatory Pathway

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ABSTRACT

Orthobiologics are products that include growth factors, stem cells, and matricies, that are designed to alleviate symptoms and improve function in the setting of musculoskeletal injury. In the United States, biologics are regulated by the FDA's Center for Biologics Evaluation and Research (CBER). In 1997, the CBER established a tiered regulatory framework for management human cells, tissues, cellular, and tissue-based products (HCT/Ps) based on perceived risk. Products are separated into those exempted from regulation, those seen as low risk (section 361 products), and those seen as higher risk (section 351 products). The distinctions between section 361 and 351 products are primarily based upon the extent to which they are manipulated, used for a non-homologous purpose, combined with other products, and elicit a systemic effect. Higher risk products require more concrete data supporting product safety and efficacy derived from an investigational new drug (IND) application or independent device exemption (IDE). Under current regulations, blood products, including PRP, are exempt and