

## An update on regulatory approval pathway of bio-similar products

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**B**io-similar or follow-on biologics are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. Unlike the more common small-molecules drugs, biologics generally exhibit high molecular complexity, and may be quite sensitive to changes in manufacturing processes. Follow-on manufacturers do not have access to the originator's molecular clone and original cell bank, nor to the exact fermentation and purification process, nor to the active drug substance. They do have access to the commercialized innovator product. Differences in impurities and/or breakdown products can have serious health implications. This has created a concern that copies of biologics might perform differently than the original branded version of the product. Consequently only a few subsequent versions of biologics have been authorized in the US through the simplified procedures allowed for small molecule generics, namely Menotropins (January 1997) and Enoxaparin (July 2010).

**Approval processes:** The European regulatory authorities led with a specially adapted approval procedure to authorize subsequent versions of previously approved biologics, termed "similar biological medicinal products" - often called biosimilars for short. This procedure is based on a thorough demonstration of "comparability" of the "similar" product to an existing approved product.

In the US the FOOD AND DRUG ADMINISTRATION (FDA) held that new legislation was required to enable them to approve biosimilars to those biologics originally approved through the Public Health Service Act pathway. Additional Congressional hearings have been held, on March 17, 2009, the Pathway for Biosimilars Act was introduced in the House.

The FDA gained the authority to approve biosimilars (including interchangeable that are substitutable with their reference product) as part of the Patient Protection and Affordable Care Act signed by President Obama on March 23, 2010 - none have yet been approved. The FDA has previously approved biologic products using comparability, for example, Omnitrope in May 2006, but this like Enoxaparin was also to a reference product, Genotropin, originally.

### Biography

Sruthi Konangi is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. She has completed his B Pharm from JSS College of Pharmacy, Mysore during the year 2011. Presently she is pursuing M Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. She has attended various National and International Conferences. Her current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, GMP Auditing and analytical method development of novel drugs.

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## Ethosomes as a novel drug delivery system

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**E**thosomes are noninvasive drug delivery carriers that enable drugs to reach the deep skin layers and/ or the systemic circulation. Although ethosomal systems are conceptually sophisticated, they are characterized by simplicity in their preparation, safety and efficacy. Ethosomes are soft, malleable vesicles tailored for enhanced delivery of active agents. This article reviews, the work carried out both in vitro, in vivo, animal models with various ethosomal systems incorporating a wide range of drugs. Because of their unique structure, ethosomes are able to encapsulate and deliver through the skin highly lipophilic molecules such as cannabinoids, testosterone, minoxidil, as well as cationic drugs such as propranolol and trihexyphenidil. Results obtained in a double-blind randomized study showed that treatment with the ethosomal acyclovir formulation significantly improved all the evaluated parameters. Preliminary studies with plasmids and insulin revealed that the ethosomal carrier may be used for enhanced delivery of these agents. In future, the ethosomal technology was broadened to introduce agents into cultured cells and microorganisms. Enhanced delivery of bioactive molecules through the skin and cellular membranes by means of an ethosomal carrier opens numerous challenges for the research and future development of novel improved therapies.

### Biography

I am studying M.pharmacy first year, belongs to department of pharmaceuticals.