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Global regulatory requirements for transdermal drug delivery system

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With the advent of new era of pharmaceutical dosage forms, transdermal drug delivery system (TDDS) established itself as an integral part of novel drug delivery systems. Transdermal patches are polymeric formulations which when applied to skin deliver the drug at a predetermined rate across dermis to achieve systemic effects and from past 30 years there were several advancements in its development process and latest technologies are available in the market. The demand for globally acceptable transdermal products heightens the imperative for harmonization of regulatory requirements to lend efficiency and cost effectiveness to the process of product development, manufacturing and expediency to global access, and where generic companies are playing a crucial role to make them affordable. Hence review process by the regulatory authorities acts a vital role for approval of generics and the process is also being very stringent in various countries such as United States, Europe, Canada, Australia, and Japan includes standard skin irritation, sensitization and adhesion studies with the patch itself in animals/humans. The production of transdermal drug delivery system medications has increased, because these sorts of systems have proved more effective in many situations at directly sending drugs into the body.

Biography

Ch. Teja is currently pursuing her 2nd year M. Pharmacy in Pharmaceutical Regulatory Affairs from JSS University, Mysore. She has done her graduation from the same college i.e. JSS College of Pharmacy, Mysore, Karnataka. She published 2 articles in reputed journals titled "Comparative Study of In- Process and Finished Products Quality Control Tests of Indian Pharmacopoeia, British Pharmacopoeia & United States Pharmacopoeia for Capsules and Liquid Orals" and "New Era in US Prescription Drug Labeling" Which was also published as a poster 63rd IPC. And also attended Indo-American Pharmaceutical Regulatory Symposium- 2011 and presented a poster on "Indian Regulations on Cosmetics".

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A new animal drug is defined, in part as any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including the animal feed, the composition of which is such that the drug is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of the drug.

There are three different types of new drug applications. Form FDA 356v is used to submit an application.

1. NADAs and supplements

2. ANADAs and supplements

3. CNADAs

USER FEES

The Animal drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) authorize FDA to collect fees for animal drug applications. These fees provide funding for increased review staff, training and development for staff members, and for refining business processes and developing policies targeted at more efficient review.

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