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Perspective

Overview of Abbreviated New Drug Application (ANDA) Process

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DESCRIPTION

A type of application submitted to the US Food and Drug Administration (FDA) for the approval of generic medications is known as an "Abbreviated New Drug Application" (ANDA). The Hatch-Waxman Act, often known as the Drug Price Competition and Patent Term Restoration Act of 1984, established the ANDA procedure. The Hatch-Waxman Act was created to promote competition in the pharmaceutical sector by making it simpler for producers of generic medications to bring their goods to market.

Generic medication producers can submit an application through the ANDA procedure to show that their product is bioequivalent to a Reference Listed Drug (RLD) that has already received approval. The RLD is often a name-brand medication that has already received FDA approval. The manufacturer of the generic medication must show that the dosage form, strength, administration method, quality, and intended use of their product are identical to those of the RLD. Additionally, the producer must show that their product is bioequivalent to the RLD. The term "bioequivalence" refers to the fact that the generic medicine is absorbed into the bloodstream at a rate and to the same extent as the RLD and shares the same active ingredients, dosage form, strength, method of administration, and intended purpose as the RLD.

The New Drug Application (NDA) process is distinct from the ANDA process. New medications that have not yet received FDA approval go through the NDA process. To prove safety and efficacy, the NDA procedure calls for thorough preclinical and clinical testing. Preclinical and clinical testing is not necessary for the ANDA process because the RLD's efficacy and safety have already been shown. A generic drug product's data is included in an ANDA, which is submitted to the FDA for assessment and possible approval. After receiving approval, an application can produce and sell the generic drug product so that the general public has access to a secure, efficient, and affordable substitute.

The FDA's Office of Generic Drugs (OGD) oversees the ANDA review procedure, which involves a review of the chemistry, manufacturing procedures, labeling, and bioequivalence of the proposed generic medicine. Compared to the NDA process, the ANDA approach has a number of benefits. The NDA process does not necessitate preclinical or clinical testing, thus it is cheaper and faster than that. Second, it enables generic medication producers to launch their goods faster than they could if they had to go through the NDA procedure. Thirdly, it encourages competition in the pharmaceutical sector by making it simpler for producers of generic medications to get their goods on the market.

Generic medication producers can submit an application through the ANDA procedure to show that their product is bioequivalent to a RLD that has already received approval. Compared to the NDA process, the ANDA process has a number of advantages. Due to the lack of preclinical or clinical testing, it is less expensive and time-consuming than the NDA process. It enables producers of generic medications to launch their goods more quickly than they could if they were to go through the NDA procedure. By facilitating the commercialization of generic medication makers' goods, it fosters competition in the pharmaceutical sector.

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