

REVIEW OF ABBREVIATED NEW DRUG APPLICATION (ANDA) DRUG DEVELOPMENT PROCESS

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Received: 15 July 2022/ Accepted in revised form: 20 July 2022 / Published online: 30 July 2022

ABSTRACT:

The Abbreviated New Drug Application (ANDA) drug development process is an important part of the pharmaceutical industry. It's a streamlined process for getting generic drugs approved in the United States. It doesn't require clinical trials or extensive safety studies, making it faster and cheaper than traditional drug approval processes. ANDAs are submitted to the FDA in order to market a generic version of a drug that has already been approved. The ANDA process can take anywhere from 6 months to 2 years. Generic drugs must be bioequivalent to the innovator drug, and they may not be able to make significant changes to the formulation or manufacturing process. There is always the possibility that patent litigation could delay or prevent generic entry into the market.

Key words: Drug Development, ANDA, FDA, Bioequivalent

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INTRODUCTION:

The ANDA drug development process is an important part of the pharmaceutical industry [1]. It stands for Abbreviated New Drug Application, and it's a streamlined process for getting generic drugs approved in the United States. It doesn't require clinical trials or extensive safety studies, making it much faster and cheaper than traditional drug approval processes [1]. In this article, the authors have reviewed the ANDA drug development process from start to finish, discussing each step along the way. The authors also explore what makes ANDAs different from regular new drug applications, and look at how they can benefit both consumers and pharmaceutical companies.

WHAT IS AN ANDA?

An ANDA is an Abbreviated New Drug Application. It is a type of regulatory submission made to the FDA in order to request approval to market a generic version of a drug that has already been approved [2].

An ANDA contains data that shows that the generic product is equivalent to the existing approved product. In order for an ANDA to be approved, the FDA must determine that the generic product is bioequivalent to the existing approved product [3]. The FDA also assesses the manufacturing process of the generic product to ensure that it meets quality standards.

Once an ANDA is approved, the generic drug company can begin marketing its product [2].

THE DIFFERENT STEPS IN THE ANDA PROCESS:

The different steps in the ANDA process are [4]:

1. Investigational New Drug Application (IND) submission
2. Clinical trials
3. FDA review and approval of ANDA
4. Commercialization

PROS AND CONS OF THE ANDA PROCESS:

The Abbreviated New Drug Application (ANDA) process is the pathway for generic drug approval in the United States. It is a cheaper and faster process than developing a new drug from scratch. The ANDA process was created by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments [4,5].

There are several key benefits of the ANDA process. First, it is less expensive to develop a generic drug using this pathway than to develop a new drug from scratch. Second, the FDA has streamlined the review process for ANDAs, which makes it faster than the review process for new drugs. Third, ANDA holders can rely on FDA-approved data from the innovator drug, which saves time and money on clinical trials [1,2].

There are also some drawbacks to consider with the ANDA process. One downside is that because generic drugs must be shown to be bioequivalent to the innovator drug, they may not be able to make significant changes to the formulation or manufacturing process. Additionally, there is always the possibility that patent litigation could delay or prevent generic entry into the market [3].

HOW LONG DOES THE ANDA PROCESS TAKE?

The ANDA process can take anywhere from 6 months to 2 years. The timeline depends on a number of factors, including the complexity of the drug, the availability of data, and the review team's workload [2].

In general, a simple ANDA with no new chemistry or manufacturing processes can be filed and reviewed in 6 months. A more complex ANDA, with new chemistry or manufacturing processes, can take up to 2 years to file and review [3].

CONCLUSION:

Overall, the ANDA drug development process is complex and requires a significant amount of time and effort to ensure that the necessary steps are taken to bring a product to market. However, with the right team in place and thorough testing throughout each phase of the process, ANDAs can be successfully developed into safe and effective drugs for patients across the United States. This review has provided an overview of what companies should bear in mind when planning their ANDA drug development strategy.

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