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REGULATIONS PERTAINING TO THE REGISTRATION OF GENERIC DRUGS IN UNITED STATES

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ABSTRACT

Generic and name-brand medications have similar risks as well as benefits. They also have the same active ingredients. The **Abbreviated New Drug Application** is used in the United States to approve generic drugs. The outcomes of bioavailability and bioequivalence studies are essential to the approval of generic drugs. From proof-of-concept to commercialization, developing a novel healthcare product (a drug) requires resources and time. It is the result of several years of development and study. Product development should adhere to all applicable regulatory standards to cut down on the amount of time and money needed to bring items to market. By adhering to these guidelines, you may maintain development efforts enduring while guaranteeing that the product you produce meets the stringent safety and effectiveness requirements of the country or countries you are considering. The goal of the study is to understand the regulations, approval process & also provide enough drug information to ensure **safety and efficacy** in humans.

Keywords: Generic Drugs, ANDA, FDA, Healthcare Product, Name-Brand Medications

INTRODUCTION

Developing a novel healthcare product, such as a medicine takes time and resources from proof-of-concept to commercialization. It is the outcome of many years of research and development.

- Product development operations must be carried out in compliance with the national regulatory frameworks of each nation.

- Across the world, many countries are setting up Drug Regulatory Authorities.
- Every country has an organization responsible with enforcing laws and developing regulations regarding to drug research, licensing, registration, manufacture, marketing, and labelling of medical products.
- As well as the suitability and reliability of the publically available medication information.

A generic drug is developed to be identical to its name-brand equivalent that is currently available on the market in terms of dosage form, safety, strength, delivery method, quality, performance characteristics, and intended purpose **[1]**.

Both name-brand and generic medications have similar advantages and disadvantages. They also have the same active ingredients. The FDA Generic Drugs Program monitors drug safety once a generic medication has been approved and released to the market, as well as performs extensive evaluations and inspections of manufacturing facilities to make sure that generic pharmaceuticals meet these standards.

The generic medication enters to the market when the FDA approves it, the patent expires, or the patent holder gives up his rights. The development of generic medications has increased market competition. In general, generic drugs are significantly less expensive than name-brand equivalents. It is not required to disclose clinical data about the safety and efficacy of generic pharmaceuticals as this information has already been supplied for name-brand products **[2]**.

A generic medication could change somewhat from a brand-name medicine in a few key areas, such as the inactive ingredients. There will always be some expected variability, just as there is fluctuation between batches of name-brand products and batches of drugs, but it won't have a major impact on health. Whether a drug is made under a name brand or a generic label, these kinds of variations are likely to occur. Very little differences in purity, size, strength, and other factors are acceptable when a medication, whether brand-name or generic, is manufactured. The appropriate level of variation is limited by the FDA **[10]**.

In the United States, drug registration is primarily divided into two categories of applications:

1. New Drug Application (NDA) and
2. Abbreviated New Drug Application (ANDA) **[3]**.

The sponsor doesn't need to duplicate the clinical trials conducted for the original, name-brand product. Rather Manufacturers of generic medications must prove that their

product is identical to and bioequivalent to a brand-name product that has already received approval **[4]**.

US FOOD AND DRUG ADMINISTRATION (USFDA)

Table 1: Regulatory Factsheet

Country	USA
Capital	Washington, D.C.
Currency	United States Dollar ($)
Language	English
Regulatory authority	US Food and Drug Administration (USFDA)
Division	Centre for Drug Evaluation & Research (CDER)

To protect public health, the Food and Drug Administration directs guaranteeing the efficacy, safety, and security of medications, medical supplies, and biological products meant for use in people and animals. It also guarantees the safety of our nation's food supply, cosmetics, and products that release radiation.

In addition to providing the public with reliable and accurate information about how to use foods and medications to maintain and improve their health, the FDA is responsible for advancing public health by accelerating technological advancements that improve the efficacy, accessibility, and safety of medical products **[5]**.

Difference Between Brand Name & Generic Drug

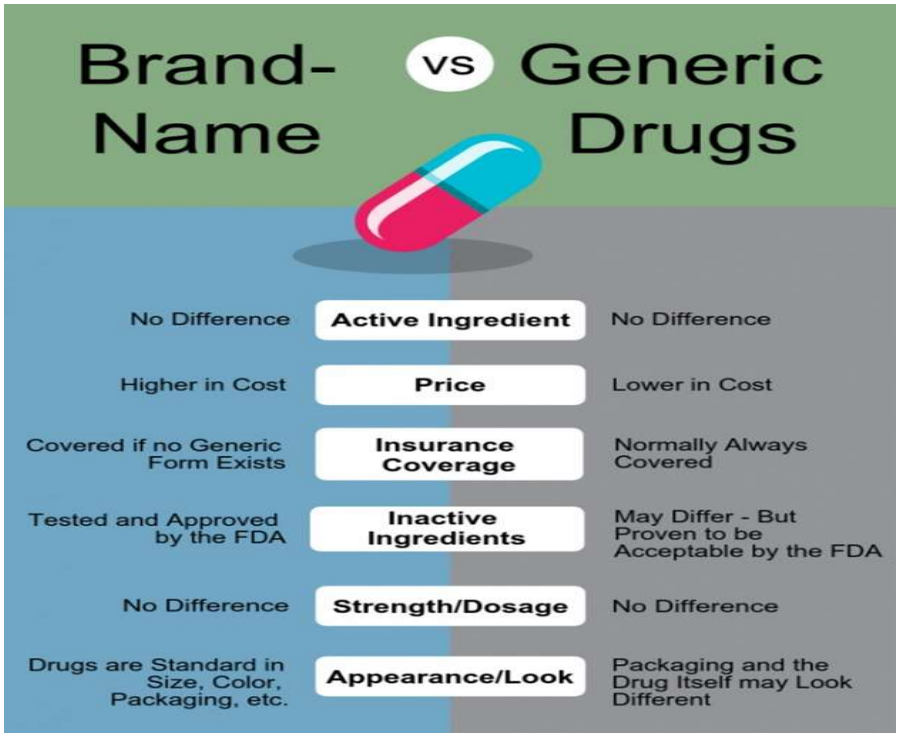

Figure 1: Difference Between Brand Name & Generic Drugs

Objectives:

1. To provide in detailed overview of Generics in the US
2. To understand the Registration requirements for Generics in US
3. To comprehend the Approval Process & Timeline for Generic Drugs in the US

RESULTS & DISCUSSIONS

Abbreviated New Drug Application

Data of an abbreviated new drug application (ANDA) is sent to the FDA so they can review and potentially approve a generic medication. After approval, a candidate may produce and distribute the generic medication to serve as an affordable, safe substitute for the name-brand medication. It takes at least 18 months for the FDA to finally approve an ANDA **[2]**.

It is referred to as "abbreviated" because it usually does not require preclinical (animal) or clinical (human) proof to establish safety and efficacy in applications utilizing generic pharmaceuticals **[6]**.

Hatch-Waxman Act

The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic (FD&C Act) Act were initially known as the Drug Price Competition and Patent Term Restoration Act of 1984, is regarded as one of the most effective pieces of legislation ever written and is credited with creating the generic drug business. According to this act, the FDA had to start publishing the patent listings in "Approved Drug Products with Therapeutic Equivalency - Orange Book". This book lists all approved products, both innovator and generic **[7]**.

ANDA Review Process

When a candidate applies to the Centre for Drug Evaluation and Research (CDER) or the Office of Generic Drugs (OGD), the ANDA process gets started. Personnel in the document room process the ANDA; they also number and stamp the cover letter with the date of receipt. After receiving the ANDA, a consumer safety technician checks the first five elements on the checklist provided. When evaluating the filed ANDA, consideration is given to the medicine's chemistry, microbiology, and bioequivalence as well as its labelling. An application is reviewed during the first sixty days following submission of an ANDA. A simplified flowchart of the ANDA review process by the USFDA is shown in **Figure 2**.

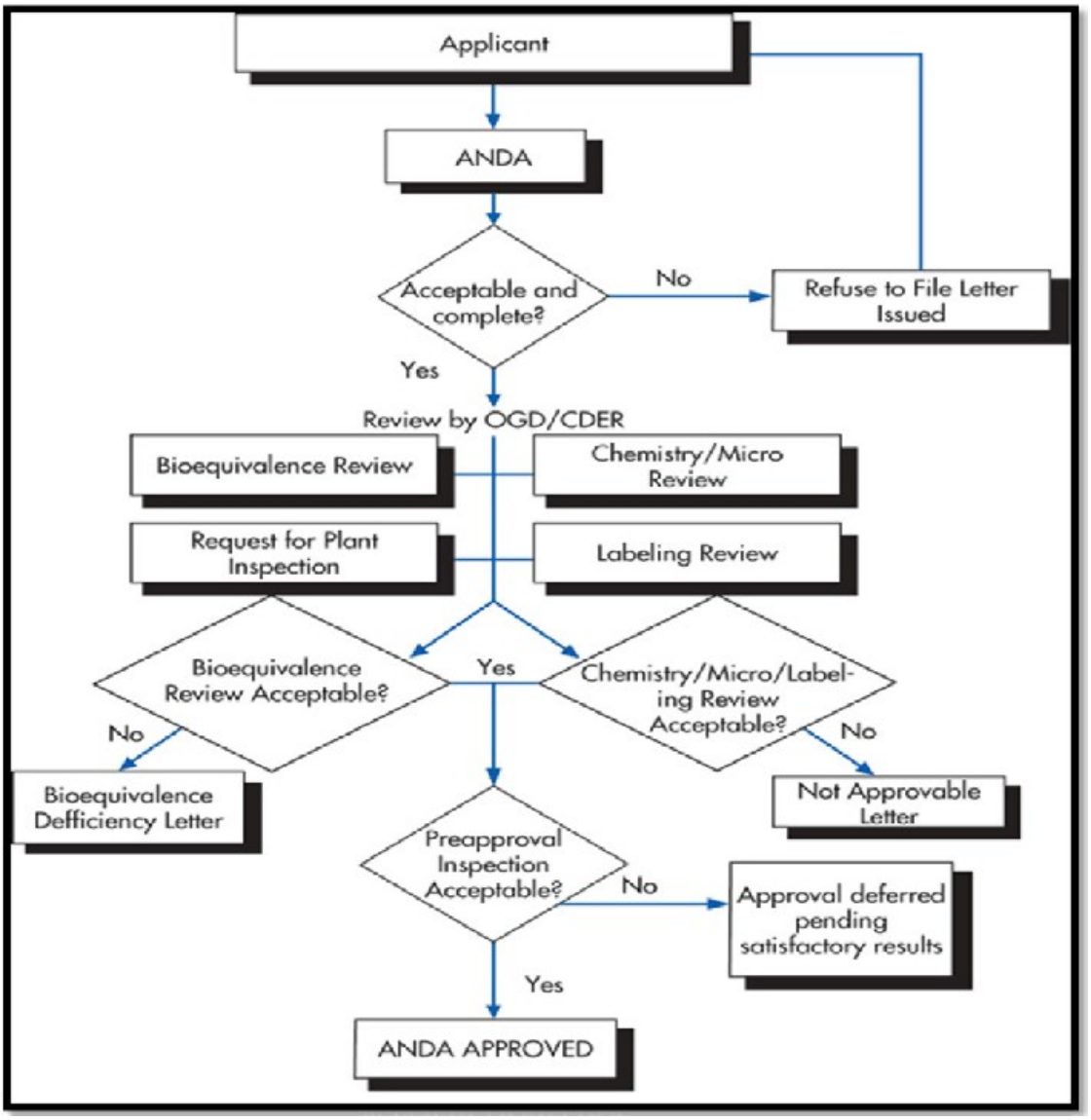

Figure 2: ANDA Review process

Types Of Certifications

Four types of submissions are accepted by ANDA (Section 505(j)(2)(A)(vii); 21 CFR 314.95). On the list, they are:

1. Paragraph I
2. Paragraph II
3. Paragraph III
4. Paragraph IV

Table 2: Types of Certifications [8]

Paragraph I	Paragraph II	Paragraph III	Paragraph IV
In cases when a drug candidate's patent is not filed (No Patent in Orange book). The FDA can quickly approve ANDA.	The FDA may promptly approve ANDA when the patent expires.	The FDA may approve an ANDA after the specific date on which the drug patent is set to expire.	This is a little more complicated. The applicant applies for ANDA paragraph IV certification to the FDA. Within 20 days, the applicant must inform the patent holder of this application.

The FDA can approve the ANDA if the generic is certified under paragraph I or II. The FDA may grant approval to a certification submitted in accordance with paragraph III at any time following the patent's expiration. The consequences of a certification are covered in considerably more duration in paragraph IV. A manufacturer of a generic drug must get certification under paragraph IV if they want to release the drug into the market before the original drug's patent expires. Instead, it claims that the drug's early distribution on the market is justified since the pioneer's patent is null and invalid and does not conflict with the drug's registration **[2]**.

Timeline: Within **10 months** after the date of submission, the FDA aims to review and act upon 90% of standard ANDAs **[9]**.

Navigation Pathway – ANDA

Figure 3: USFDA ANDA Navigation Pathway

Pathway Link: https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

Checklist:
https://www.fda.gov/media/144976/download?attachment/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDA/abbreviated-new-drug-application-anda-forms-and-submission-requirements

SUMMARY & CONCLUSION

Before being approved by regulatory authorities, no medications could be sold. The US has the most stringent rules in the pharmaceutical market globally. When it comes to submitting applications for generic drugs, the regulatory body looks over the laws and regulations established by the FDA must be followed by pharmaceutical companies. Ensuring that drugs manufactured by standards to promote patient safety and well-being is the primary objective of the regulations governing medicines in the United States. Different

nations have different regulations for licensing generic medications; However, long timelines and high registration costs are typical. The substantial share of the market of generics in the US might be attributed to this.

In conclusion, the registration of generic drugs is a comprehensive process designed in order to ensure that these medications are equally effective and safe as those marketed under brand names. This process plays a vital role in increasing access to essential medications, promoting public health, and controlling healthcare costs.

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CONFLICT OF INTEREST

The authors declared that there is no conflict of interest.

REFERENCES

[1] Research, C. F. D. E. A. (2021, March 16). *Generic Drugs: Questions & Answers*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers

[2] Rafi N, DS S, Narayanan A. Regulatory requirements and registration procedure for generic drugs in the USA. Indian journal of pharmaceutical education and research. 2018 Oct 1; 52:544-9.

[3] Handoo S, Arora V, Khera D, Nandi PK, Sahu SK. A comprehensive study on regulatory requirements for developing and filing generic drugs globally. International journal of pharmaceutical investigation. 2012 Jul;2(3):99.

[4] Dharani T, Kumar PP, Phanindra DS, Nagabhushanam MV, Bonthagarala B, Ramakrishna G, Sindhu YR, Ch SK. A review on abbreviated new drug application (ANDA).

[5] *What We Do*. (2023, November 21). U.S. Food and Drug Administration. https://www.fda.gov/about-fda/what-we-do

[6] Research, C. F. D. E. A. (2022, December 16). *Abbreviated New Drug Application (ANDA)*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

[7] Rahul R, et al. Comparative Study of Generic Drug Approval in EU, USA and China. Int J Pharm Sci Rev Res. 2017;42(2):67-73

[8] A. (2023, October 14). *Generic Products Approval Pathways (USA): Paragraph Certification I, II, III,*

and IV: - LifeProNow. https://lifepronow.com/2019/12/25/generic-products-approval-pathways-paragraph-certification-i-ii-iii-and-iv/

[9] Research, C. F. D. E. A. (2022, December 16). *Abbreviated New Drug Application (ANDA)*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

[10] Research, C. F. D. E. A. (2021, March 16). *Generic Drugs: Questions & Answers*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers