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Analysis of Basic Requirements for Patentability in USA with Relation to Hatch Waxman Act

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ABSTRACT

Worldwide the generic drug market is increasing day by leaps and bounces. This is because of expensive research based drugs which incurs the cost of drugs development, research and marketing of drugs which increases the drug price by many folds. Here the generics are the bioequivalent drugs which does not incurred. These cost that has become the better alternative to the branded drugs. Hatch Waxman act provides the base for the generic manufacturer to enter the markets by various means but it also protects the rights of researchers to get the mileage from using intellectual property. Hatch Waxman act hence now become a very good tool to generics manufactures to enter even in the presence of existing research based products. Also this has become a tool for the Indian drug manufactures to expand their markets.

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INTRODUCTION

The **Food and Drug Administration** (**FDA** or **USFDA**) is a federal agency of the United, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and counter drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary.

A **generic drug** (generic drugs, short: generics) is a drug defined as "a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, quality and performance characteristics, and intended use". It has also been defined as a term referring to any drug marketed under its chemical name without advertising or to the chemical makeup of a drug rather than to the advertised brand name under which the drug is sold.

Hatch Waxman established the abbreviated new drug application (ANDA) process that requires generic manufacturers to demonstrate that the generic is “bioequivalent” to an approved brand drug. Additionally, the generic manufacturer must file a certification regarding patents listed in the Orange. Hatch Waxman also provided brand companies faced with significantly truncated windows of marketing exclusivity and increasing regulatory requirements for drug approval with exclusivities and patent term restoration and established the maximum length and number of exclusivities that can be justified. Although the net effect of Hatch Waxman on pharmaceutical innovation is ambiguous, its effect on generic drug development has been explicit, and the effect on consumers has been beneficial. Hatch Waxman resulted in increased ANDA applications.

Twenty-five years ago, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch Waxman Act1 (hereinafter “Hatch-Waxman”)—the cornerstone for competition between brand and generic pharmaceutical companies. Hatch Waxman amended the Federal Food, Drug and Cosmetic Act (FDCA) and the Patent Act and achieved a sensitive balance between patent protection and encouraging generic entry.

An unexpected consequence resulting from Hatch Waxman, especially over the past 10 years, has been the filing of patent applications by generic companies and increased generic research and development for branded products.[6] Although clearly not a goal of Hatch

Waxman, generics innovate, often obtaining "design around" patents or a more efficient manufacturing process, new formulations, or new forms of the active ingredient.

MATERIALS AND METHODS

1) ANDA

An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD), provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

In simple words "It is an application which is filed with USFDA for generic drug approval of an existing licensed medication or approved drug."

A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use.

I. Important facts about generics and generic drug applications (ANDA)-

Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.

Generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).

Bioequivalence is generally determined by measuring the time taken for generic drug to reach the bloodstream in 24 to 36 healthy, volunteers. This gives the rate of absorption, or bioavailability, of the generic drug, which can be compared to that of the innovator drug.

The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

The basis for approving generic copies of drug products was established by the "**Drug Price Competition and Patent Term Restoration Act of 1984**," also known as the "**Hatch Waxman Act".**

II. Facility and Drug Registration for filing an ANDA-

The facility should be registered with FDA using form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment form).

The product(s)/Drugs to be listed with FDA using form FDA 2657 (Drug listing form).

Note: From June 1, 2009, FDA is accepting only electronic submissions of forms FDA.

Module 1- Administrative and prescribing information

Documents should be organized in the order listed below. Generally, all of the documents in Module 1 can be provided in a single volume. Environmental assessments should be submitted separately.

- and RLD-505(j)(2)(A)
- Request for waiver
- Draft labeling
- Listed drug labeling
- Labeling requirements
- Financial disclosure information
- Waiver requests
- Environmental assessment or request for categorical exclusion
- Statements of claimed exclusivity and associated certifications

B. Prescribing information

All copies of the labels and all labeling for the product should be included. Examples are provided below-

- Container and package labels
- Package inserts
- Draft labeling
- Patient leaflets
- Information sheets
- Medication Guides

1. Overall CTD table of contents

For the first document in this module, a comprehensive table of Contents should be provided listing all of the documents provided in the submission for modules 2 through 5.

2. Introduction to the summary documents

Introduction to the summary should be provided as described in the guidance document M4: Organization of the CTD as a one-page document.

3) ORANGE BOOK REQUIREMENT

The publication **Approved Drug Products with Therapeutic Equivalence Evaluations** (the List, commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act).

Data Descriptions

Products.txt

Ingredient

The active ingredient(s) for the product. Multiple ingredients are in alphabetical order, separated by a semicolon.

Applicant

The firm name holding legal responsibility for the new drug application. The firm name is condensed to a maximum twenty character unique string.

New Drug Application Type

The type of new drug application approval. New Drug Applications (NDA or innovator) are ”N”. Abbreviated New Drug Applications (ANDA or generic).

New Drug Application (NDA) Number

The FDA assigned number to the application.

Product Number

The FDA assigned number to identify the application products. Each strength is a separate product. It may repeat for multiple part products.

Approval Date

The date the product was approved as stated in the FDA approval letter to the applicant. Products approved prior to the January 1, 1982 contain the phrase: "Approved prior to Jan 1, 1982".

Reference Listed Drug (RLD)

The pioneer or innovator of the drug. The RLD identifies the product Abbreviated New Drug Applications (ANDA) uses as a reference. Format is Yes or No.

New Drug Application Type

The type of new drug application approval. New Drug Applications (NDA or innovator) are "N". Abbreviated New Drug Applications (ANDA or generic) are "A".

Product Number

The FDA assigned number to identify the application products. Each strength is a separate product. It may repeat for multiple part products.

Patent Number

Patent numbers as submitted by the applicant holder for patents covered by the statutory provisions. It may repeat for multiple applications and multiple products. Includes pediatric exclusivity granted by the agency.

Patent Expire Date

The date the patent expires as submitted by the applicant holder including applicable extensions. The format is MM, DD, YYYY.

Drug Substance Flag

Patents submitted on FDA Form 3542 and listed after August 18, 2003 may have a drug substance flag indicating the sponsor submitted the patent as claiming the drug substance. Format is Y or null.

Drug Product Flag

Patents submitted on FDA Form 3542 and listed after August 18, 2003 may have a drug product flag indicating the sponsor submitted the patent as claiming the drug product. Format is Y or null.

Patent Use Code

Code to designate a use of patent that covers the approved indication or use of a drug product. It may repeat for multiple applications, multiple products and multiple patents. .

Patent Delist Request Flag

Sponsor has requested patent be delisted. This patent has remained listed because, under Section 505(j)(5)(D)(i) of the Act, a first applicant may retain eligibility for 180-day exclusivity based on a paragraph IV certification to this patent for a certain period. Applicants under Section 505(b)(2) are not required to certify to patents where this flag is set to Y. Format is Y or null.

Product Number

The FDA assigned number to identify the application products. Each strength is a separate product. It may repeat for multiple part products.

RESULTS

The Hatch Waxman Act has given a new dimension to the world generics market and continues to increase in the prescription and market share is evidence for the increasing acceptability of generic drugs and bioavailable but much cheaper alternative for the branded drugs. And challenging patents give a very big 180 days marketing exclusivity award to the generics manufacturers because it gives a way to enter the generic into an open market without any competition. Nowadays they, the generic drug companies are designing their products around the patented brand to bypass the legal hindrance. This requires a deep knowledge and skills to understand the existing products, its claim, design, dosage form, ingredients, route of administration etc. Which are the possible ways of infringement**.**

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