



US FDA Drug Approval Strategies for Pharmaceutical Industry

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ABSTRACT

In Pharmaceutical Industry, Regulatory Affairs Department makes an interface between the regulatory authorities and pharmaceutical industry. The Regulatory Affairs department is an important part of the organizational structure of pharmaceutical companies. Internally it liaises at the inter phase of drug development, manufacturing, marketing and clinical research. Externally it is the key interface between the company and the regulatory authorities. Regulatory Affairs is involved in the development of new medicinal products from early on, by integrating regulatory principles and by preparing and submitting the relevant regulatory dossiers to health authorities. Regulatory Affairs is actively involved in every stage of development of a new medicine and in the post-marketing activities with authorized medicinal products. This professional can play a key role in guiding drug development strategy in an increasingly global environment and has an important role for submitting the newly discovered drug products approval documents to the US FDA regulatory authorities and to carry out all the practices required for obtaining the drug products approval. This article mainly focuses on the US FDA drug approval strategies. These strategies playing core job in the pharmaceutical industry. These strategies having all the guidelines which are indispensable part of the IND, NDA and ANDA drug approval applications. It plays a significant role in sequence for registration of newly exposed products and also providing the guidelines which is helpful preparing the registration documents to regulatory authorities.

Keywords: Food and Drugs Administration, Pharmaceutical Industry, Regulatory Affairs, IND, NDA, ANDA and CDER.

INTRODUCTION

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to ensure that drugs marketed in this country are safe and effective. CDER does not test drugs, although the Center's Office of Testing and Research does conduct limited research in the areas of drug quality, safety, and effectiveness. It has responsibility for both prescription and nonprescription or over-the-counter (OTC) drugs.

Some companies submit a new drug application (NDA) to introduce a new drug product into the U.S. Market. It is the responsibility of the company seeking to market a drug to test it and submit evidence that it is safe and effective. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the sponsor's NDA containing the data and proposed labeling.

Types of Applications

- Investigational New Drug (IND)
- New Drug Application (NDA)
- Abbreviated New Drug Application (ANDA)
- Over-the-Counter Drugs (OTC)
- Biologic License Application (BLA)¹

Investigational New Drug (IND)

An IND is an Investigational New Drug application is a regulatory document required for submission by the sponsor and clearance by the U.S. Food and Drug

Administration (FDA) in order to use a drug product not previously authorized for marketing in the United States. The IND provisions apply to new drugs, new antibiotics and new biologics etc.

When is an IND required?

An IND is required when an unapproved drug (or biologic) is used in a clinical investigation. An IND is always required prior to initiation of a clinical study of an investigational new drug in the U.S. In addition an IND is required before initiation of a clinical study of the drug approved for some uses.²

There are two IND categories

- Commercial
- Research (non-commercial)

There are following types of IND

- Investigator INDs
- Commercial
- Emergency Use IND
- Treatment IND

Investigator INDs

An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or

an approved product for a new indication or in a new patient population.

Commercial

They are applications that are submitted primarily by companies whose ultimate goal is to obtain marketing approval for a new product. However, there is another class of filings broadly known as "noncommercial" INDs.

Emergency Use IND

This IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR Sec.312.23 or Sec.312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.

Treatment IND

Other name is Expanded Access IND, this IND may be submitted for experimental drugs showing promise in clinical testing of serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place (21 CFR 312.34).

The IND application must contain information in three broad areas

- Animal Pharmacology and Toxicology Studies
- Manufacturing Information
- Clinical Protocols and Investigator Information

Guidance Documents for INDs

Guidance documents to help prepare INDs include

- Guidance for Industry: CGMP's for Phase 1 Investigational Drugs
- Guidance for Industry: Exploratory IND Studies
- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs Including Well Characterized, Therapeutic, Biotechnology-Derived Products.
- Q & A - Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products. This guidance is intended to clarify when sponsors should submit final, quality-assured toxicology reports and/or update the Agency on any changes in findings since submission of non-quality-assured reports or reports based on non-quality-assured data.
- Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations. This guidance should be useful for applicants planning to conduct bioavailability (BA) and bioequivalence (BE) studies during the IND period for an NDA, BE studies intended for submission in an ANDA, and BE studies conducted in the post approval period for certain changes in both NDAs and ANDAs.

- IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer.
- Drug Master Files: A Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- Immunotoxicology Evaluation of Investigational New Drugs. This guidance makes recommendations to sponsors of investigational new drugs (INDs) on (1) the parameters that should be routinely assessed in toxicology studies to determine effects of a drug on immune function

When additional immunotoxicity studies should be conducted, and

When additional mechanistic information could help characterize the significance of a given drug's effect on the immune system.³

Laws, Regulations, Policies and Procedures

Code of Federal Regulations (CFR)

The following regulations apply to the IND application process;

21CFR Part 312	Investigational New Drug Application
21CFR Part 314	INDA and NDA Applications for FDA Approval to Market a New Drug
21CFR Part 316	Orphan Drugs
21CFR Part 58	Good Lab Practice for Nonclinical Laboratory [Animal] Studies
21CFR Part 50	Protection of Human Subjects
21CFR Part 56	Institutional Review Boards
21CFR Part 201	Drug Labeling
21CFR Part 54	Financial Disclosure by Clinical Investigators

Content of an initial IND

1. Cover Sheet (Form FDA 1571)
2. Table of Contents
3. Introductory Statement & General investigational plan
4. Investigator's Brochure
5. Protocols
6. Chemistry, Manufacturing & Control Information
7. Previous Human Experience with the Investigational Drug
8. Additional Information³

NEW DRUG APPLICATION (NDA)

The NDA is the vehicle through which drug sponsors (pharmacy companies) formally propose that the FDA approve a new pharmaceutical for sale and marketing in



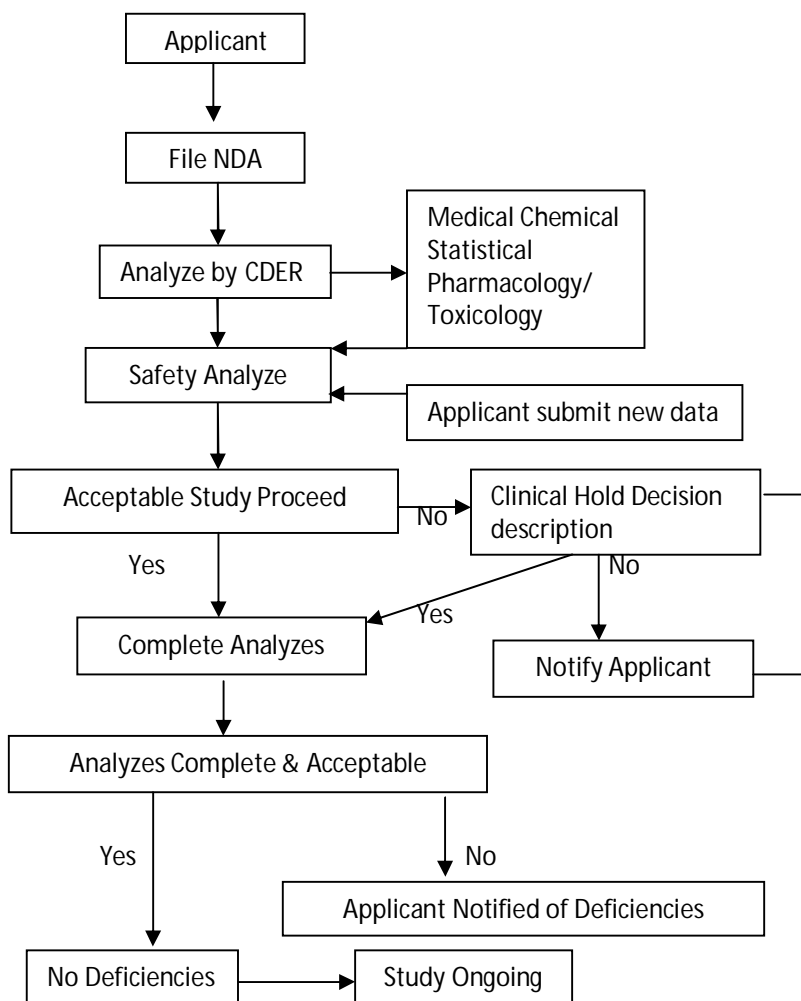
the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

In simple terms “It is an application filed with USFDA to get approval for marketing a new pharmaceutical for sale in the U.S.” Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization.³

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Is the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Is the drug's proposed labeling (package insert) is appropriate, and what it should contain?
- Are the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.⁴

IND Review Flow Chart³



Chemical type classification codes for NDA⁵

Number	Meaning
1	New molecular entity (NME)
2	New ester, new salt, or other non-covalent derivative
3	New formulation
4	New combination
5	New manufacturer
6	New indication
7	Drug already marketed, but without an approved NDA
8	OTC (over-the-counter) switch

Guidance documents to help prepare NDAs include

- Bioavailability and Bioequivalence studies for orally administered drug products.
- Container closure systems for packaging human drugs and biologics.
- Format and content of the chemistry, manufacturing and controls section of an application.
- Format and content of the clinical and statistical sections of an applications.
- Format and content of the summary for new drug and antibiotic applications.



- Formatting, assembling and submitting new drug and antibiotic applications.
- Supporting documentation in drug applications for the manufacturing of drug substances.
- Documentation for the stability of human drugs and biologics.
- Samples and analytical data for methods validation.
- Supporting Documentation in drug applications for the manufacture of drug products.
- NDAs: Impurities in drug substances.
- Format and content of the human pharmacokinetics and bioavailability section of an application.
- Clinical evidence of effectiveness for human drug and biological products.
- Drug master file: A drug master file (DMF) is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- Required specifications for FDA's IND, NDA, and ANDA drug master file binders.
- Qualifying for pediatric exclusivity. Certain applications may be able to obtain an additional six months of patent exclusivity.
- PET drug applications.
- Refusal to file. (Clarifies CDER's decisions to refuse to file an incomplete application).

Code of Federal Regulations (CFR)

The regulations document all actions of all drug sponsors that are required under Federal law.

- 21CFR Part 314 - Applications for FDA Approval to Market a New Drug or an Antibiotic Drug.

CDER's Manual of Policies and Procedures (MaPPs)

MaPPs of particular interest to NDA applicants include:

- 5015-6 Review of the Same Supplemental Change to More than One NDA or ANDA in More than One Review Division
- 6010.5 NDAs: Filing Review Issues 6020.8. Action Packages for NDAs and Efficacy Supplements.
- 6050.1. Refusal to Accept Application for Filing From Applicants in Arrears
- 7211.1. Drug Application Approval 501(b) Policy
- 7600.6. Requesting and Accepting Non-Archivable Electronic Records for New Drug Applications.

Fundamentals of NDA Submission

As outlined in Form FDA-356h, Application to Market a New Drug for Human Use or as an Antibiotic Drug for Human Use, NDAs can consist of as many as 15 different sections:

- Index
- Summary
- Chemistry, Manufacturing, and Control;
- Samples, Method Validation Package, and Labeling
- Nonclinical Pharmacology and Toxicology
- Human Pharmacokinetics and Bioavailability
- Microbiology (for anti-microbial drugs only);
- Clinical Data;
- Safety Update Report (typically submitted 120 days after the NDA's submission);
- Statistical;
- Case Report Tabulations;
- Case Report Forms;
- Patent Information;
- Patent Certification; and
- Other Information.

Number of Copies of NDA

The regulation requires Archival, Review, and Field copies of NDAs.

General Requirements for filing an NDA

The new (present) NDA regulations require that an application be submitted in two copies:

- A. An archival copy that serves as a permanent record of the submission, and
- B. A review copy.

A. Archival Copy

The archival copy is a complete copy of an application submission and must be bound in a **BLUE** cover jacket.

The archival copy should include a cover letter to:

- (i) confirm any agreements or understanding between the FDA and the applicant;
- (ii) Identify a contact person regarding the application;
- (iii) Identify the reviewing division of the FDA and include HFD number; and
- (iv) Convey any other important information about the application.

B. A review copy

- The review copy is made up of a number of separate technical volumes, each tailored to the needs of the disciplines involved in the review.
- Both the archival and review copies are submitted in hard copy, the regulations permit an application to submit the archival copy as microfiche.

The NDA application form (FORM NDA 356 h) consists of: Twelve items (including index) deals with the safety and efficacy features of drug product, two are concerned with patent information.

The review copy is divided into six technical sections (“review sections”) and should be submitted with each review section separately bound in a specific color: (i) Chemistry, Manufacturing and Controls (CMC) – **RED**; (ii) Nonclinical Pharmacology and Toxicology – **YELLOW**; (iii) Human Pharmacokinetics and Bioavailability – **ORANGE**; (iv) Microbiology (if required) – **WHITE**; (v) Clinical Data – **LIGHT BROWN**; (vi) Statistical – **GREEN**.³

Facility and Drug Registration for filing an NDA: Within 5 days of filing the NDA-

- 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).⁶

NDA Forms and Electronic Submissions:

- Form FDA-356h. Application to Market a New Drug, Biologic, or An Antibiotic Drug For Human Use
- Form FDA-3397. User Fee Cover Sheet
- Form FDA-3331. New Drug Application Field Report.^[7]

NDA REGULATIONS**Review Time Frames (21 CFR 314.100)**

This time frame includes:

- Within 180 days of receipt of an application, the FDA will review and issue an approval, approvable, or not approvable letter. This 180-day period is called the „review-clock“
- During the review period an applicant may withdraw an application (21 CFR 314-65) and later resubmit it.
- The time period may be extended by mutual agreement between the FDA and the applicant or as the result of submission of a major amendment (21 CFR 314.60)

Filing Time Frames (21 CFR 314.101)

- Within 60 days after the FDA receives an application, a determination will be made whether the application may be filed.
- This will determine whether sufficient information is provided to proceed with an in-depth review of application.
- If FDA files the application, the applicant will be notified in written. The date of filing will be the date 60 days after the FDA received the application.
- The date of filing begins the 180-days period of the review. If FDA refuses to file the application, the sponsor will be given the opportunity to meet with FDA to discuss the reasons why the application is not file able.

NDA Pre-Approval and Post- Approval Safety Reports

These safety reports must be submitted as follows:

- Four months after the initial submission
- Following receipt of an approvable letter
- At other times as requested by FDA

Computer Assisted New Drug Application (CANDA)

- Concept: it is designed to shorten FDA review time by submitting data to FDA in a form ready for manipulation by a computer.
- Importance is given on the clinical sections of the NDA, as they require the maximum time to review and often require manipulation of the data by FDA.
- In a September 15, 1988 Federal Register Notice, FDA stated to increase the use of computers in field of improving efficiency of the drug review process. FDA had not provided exact blue print on how to best organize / submit a CANDA, but two basis computer systems have been developed so far:
 - Involves keeping the data on a mainframe computer that is operated either by the sponsor / by the computer company assisting it with FDA able to access the information via a telephone connection.
 - Putting the data on a floppy disk, laser disc, etc. for use by FDA via desktop computers that are provided by the sponsor.
- One possible concern of CANDAs is the possibility of „data dredging“ by FDA reviewers that is pursuing tangential rather than central issues because the computer makes it easy to do so, but this has not been observed routinely.³

Format and content of NDA

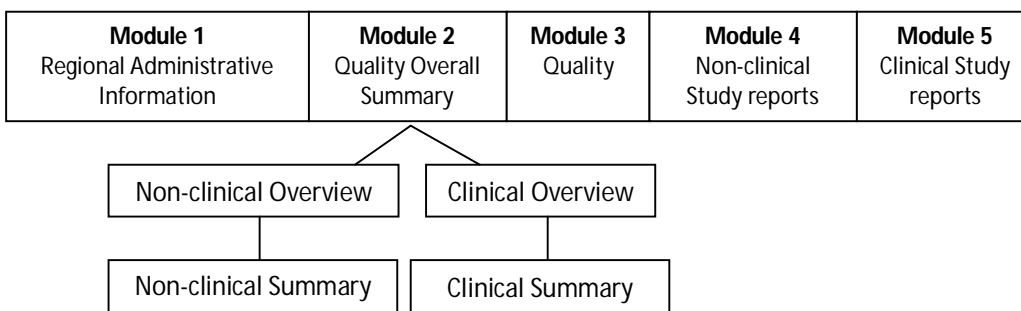
The FDA recommends ICH's CTD for filing the NDA.

COMMON TECHNICAL DOCUMENT (CTD)

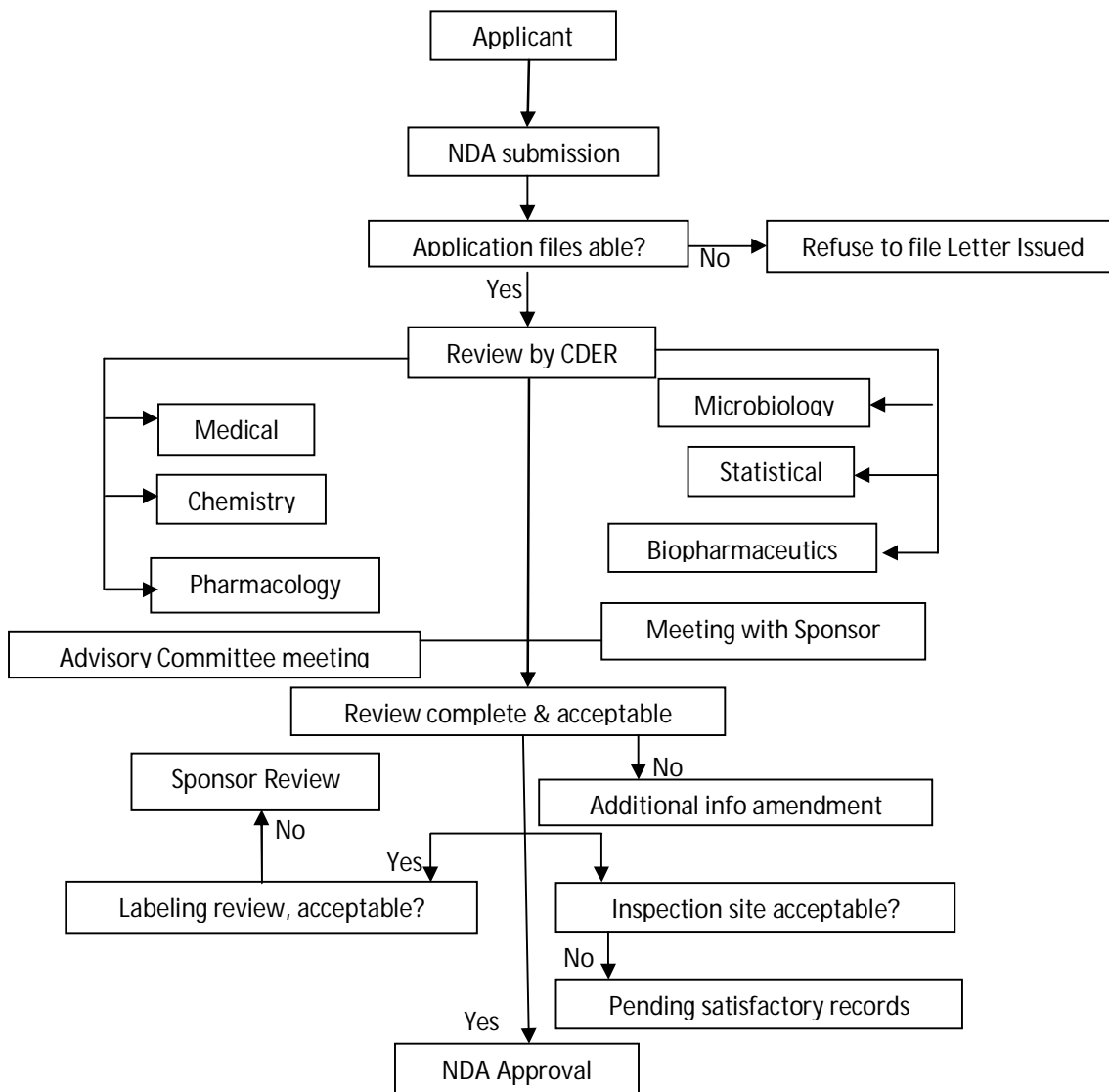
The Common Technical Document (CTD) is a set of specification for application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States. It is an internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in

participating countries. It was developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, U.S.) and the Ministry of Health, Labour and Welfare (Japan). The CTD is maintained by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).⁸

CTD Diagram: Module 1 is not the part of CTD Module 2,3,4,5 is the part of CTD



Review Process of NDA⁵



Documents in each Module ⁹

Module	Information
1	Administrative and prescribing information (region specific): a. FDA form 356h b. Comprehensive table of contents (as per 21 CFR 314.50) c. Administrative documents: d. Prescribing information e. Annotated labeling text:
2	Summaries and overview a. Common technical document table of contents (Modules 2–5) b. CTD introduction c. Quality overall summary d. Nonclinical overview e. Clinical overview f. Nonclinical written and tabulated summaries Pharmacology, Pharmacokinetics, Toxicology g. Clinical summary Biopharmaceutics studies and associated analytical methods, Clinical pharmacology studies, Clinical efficacy, Literature references
3	Information on product quality a. Table of contents b. Body of data c. Literature References
4	Nonclinical study reports a. Table of contents b. Study reports and related information c. Literature References
5	Clinical study reports a. Table of contents b. Study reports and related information c. Literature References

ABBREVIATED NEW DRUG APPLICATION (ANDA)

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

A generic drug product is the one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

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. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).¹⁰

Hatch-Waxman Act

Hatch-Waxman Act formally known as the Drug Price Competition and Patent Term Restoration Act of 1984. Hatch-Waxman allowed generic manufacturers to file an Abbreviated New Drug Application (ANDA). The ANDA requires the generic company to demonstrate that its product is "bioequivalent" to a referenced NDA's brand name product. Proof of bio-equivalence for a drug is much easier to establish than the requirements for an NDA: i.e., the active (not inactive) ingredients must be proven "bioequivalent".

Generic manufacturer must file one of four alternative certifications provided for under Hatch-Waxman

- "Paragraph I Certification" - No patent in the NDA.
- "Paragraph II Certification" - Term of patent(s) in NDA has expired.
- "Paragraph III Certification" - Patent(s) in NDA remains extant.
- "Paragraph IV Certification" - Patent in NDA is alleged to be invalid or the generic equivalent product does not infringe.¹¹

Hatch-Waxman Amendments-1984

- Increased availability of generics.
- Legislative benefits both brand and generics.
- Generics can rely on findings of safety and efficacy of branded drug after expiration of patents and exclusivities (do not have to repeat expensive clinical and pre-clinical trials).
- Allowed patent extensions and exclusivities to brands.
- The act attempts to strike a balance between the interests of the party seeking approval of an ANDA and the owner of a drug patent.

ANDA litigation basics under the Hatch-Waxman Act and Medicare Prescription Drug, Improvement and Modernization Act of 2003.¹²

Guidance Documents for ANDAs**Generics**

- Generics (Draft - Distributed for comment purposes only).
- Procedural Draft: Applications Covered by Section 505(b)(2). This provision permits FDA to rely, for approval of an NDA, on data not developed by the applicant.



Biopharmaceutics

- Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations. This guidance should be useful for applicants planning to conduct bioavailability (BA) and bioequivalence (BE) studies during the IND period for an NDA, BE studies intended for submission in an ANDA, and BE studies conducted in the postapproval period for certain changes in both NDAs and ANDAs.
- Drug Master Files. A Drug Master File (DMF) is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- Required Specifications for FDA's IND, NDA, and ANDA Drug Master File Binders.
- Guidance for Industry: Changes to an Approved NDA or ANDA.
- Refusal to Receive: Clarifies CDER's decisions to refuse to receive an incomplete application.
- Inactive Ingredient Database. This database contains all inactive ingredients present in approved drug products or conditionally approved drug products currently marketed for human use.

Laws, Regulations, Policies and Procedures

Code of Federal Regulations (CFR)

Code of Federal Regulations (CFR). The FDA's portion of the *CFR* interprets the *Federal Food, Drug and Cosmetic Act* and related statutes. Section 21 of the *CFR* contains

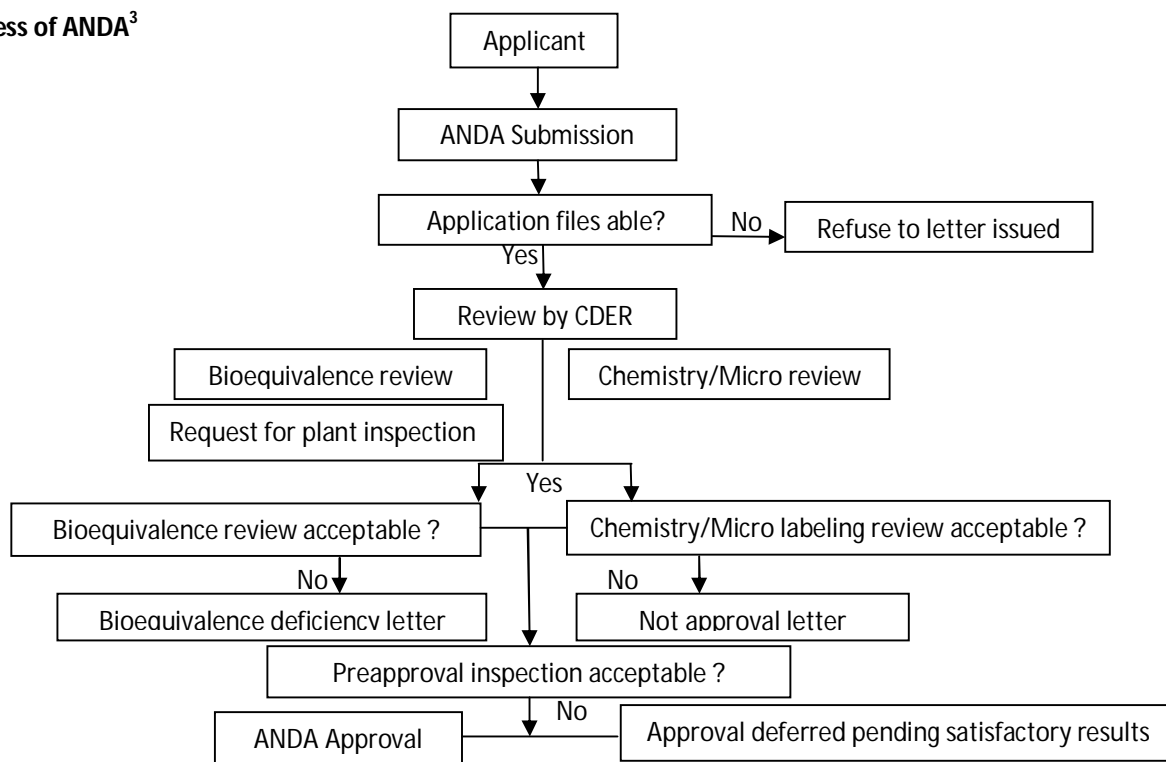
most of the regulations pertaining to food and drugs. The regulations document most actions of all drug sponsors that are required under Federal law. The following regulations apply to the ANDA process:

- 21CFR Part 314 Applications for FDA Approval to Market a New Drug or an Antibiotic Drug
- 21CFR Part 320 Bioavailability and Bioequivalence Requirements.
- 21CFR Part 310 New Drugs

ANDA Forms and Electronic Submissions

- ANDA Checklist for Completeness and Acceptability. The Office of Generic Drugs has revised the regulatory filing checklist for 2011 to enhance the ANDA review process. The regulatory filing checklist will be reviewed on a quarterly basis (calendar year) and updated on an as needed basis.
- FDA Form 356h. Application to Market a New Drug for Human Use/Antibiotic Drug for Human Use
- The CDER Office of Generic Drugs has developed a guidance document entitled *Providing Regulatory Submissions in Electronic Format — ANDAs* to assist applicants making regulatory submissions in electronic format of abbreviated new drug applications. This guidance should be used in conjunction with the following guidance:
 - Guidance for Industry: Providing Regulatory Submissions in Electronic Format - General Considerations.
 - Regulatory Submissions in Electronic Format; New Drug Applications.¹³

Review Process of ANDA³



OVER-THE-COUNTER DRUGS (OTC)

Over-the-counter (nonprescription) drug products play an increasingly vital role in America's health care system. OTC drugs are defined as drugs that are safe and effective for use by the general public without seeking treatment by a health professional. FDA's review of OTC drugs is primarily handled by CDER's Office of Drug Evaluation IV.^[14] Over-the-counter (OTC) medications—drugs available to consumers without a prescription—play an increasingly vital role in our healthcare system and are the most prevalent means of treating the majority of common health problems in the United States. There are over 80 therapeutic categories of OTC drugs which can be grouped in 12 broad therapeutic classes. [1, 2] (See below Table)

Table 1: Broad Therapeutic Classes of OTC Medications

<ul style="list-style-type: none"> Analgesics and antipyretics Cold, cough, and allergy products Nighttime sleep-aids Gastrointestinal products Dermatological products Other topical products (including dermal and vaginal antifungals, anorectal medications, head lice products, hair loss products, and otics) 	<ul style="list-style-type: none"> Ophthalmic products Oral health care products Menstrual products Nicotine replacement products Weight loss aids Vaginal contraceptives and emergency contraceptives
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OTC retail sales totaled \$17 billion (excluding Walmart sales) in 2010. Currently, 35% of adult Americans use OTC medications on a regular basis and there is a trend for increasing use as more drugs move from prescription to OTC status.

The Center for Drug Evaluation and Research (CDER) division of the Food and Drug Administration (FDA) regulates OTC medications to ensure that they are properly labeled, their benefits outweigh their risks, their potential for misuse and abuse is low, and that health practitioners are not needed for their safe and effective use.

The benefits of over-the-counter availability include

- Direct, rapid access to effective medicines
- Wide availability
- Decreased healthcare system utilization (fewer physician visits, lower healthcare system costs)
- Allowing individuals to be in charge of their own health¹⁶

BIOLOGIC LICENSE APPLICATION (BLA)

The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680. A BLA is

submitted by any legal person or entity who is engaged in manufacture or an applicant for a license who takes responsibility for compliance with product and establishment standards. Form 356h specifies the requirements for a BLA. This includes:

- Applicant information
- Product/Manufacturing information
- Pre-clinical studies
- Clinical studies
- Labeling¹⁷

Guidance Documents¹⁵

OTC Drug Products for Existing Monographs	21 CFR Part 330 - Over the-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and not Misbranded.
Monograph Changes	21 CFR Part 330.10
MaPPs (Manual of Policies and Procedures)	6020.5R (PDF -107KB) Good Review Practice: OND Review Management of INDs and NDAs for Nonprescription Drug Products.

FDA IND, NDA, ANDA, or Drug Master File Binders¹⁸

FDA NDA/ANDA File Binders

Listed below are FDA New Drug Application /Abbreviated New Drug Application (ANDA) binders identical to sample above. Cover name is **ONLY** difference.

Form	Color	Ink	Cover name
2626	Blue	Black	Archival copy
2626a	Red	Black	NDA Chemistry
2626b	Yellow	Black	NDA Pharmacology
2626c	Orange	Black	NDA Pharmacokinetic
2626d	White	Black	NDA Microbiology
2626e	Tan Black	Black	NDA Clinical Data
2626f	Green	Black	NDA Statistics
2626h	Maroon	White	NDA Field Submission Chemistry

FDA Drug Master File Binders

Form	Color	Ink	Cover name
3316	Red	Black	Drug Master File
3316a	Blue	Black	Drug Master File

FDA IND File Binders

Form	Color	Ink	Cover name
2675	Red	Black	IND Name of Drug
2675a	Green	Black	IND Name of Drug
2675b	Orange	Black	IND Name of Drug



CONCLUSION

The purpose of this article is to describe the U.S. Food and Drug Administration's Drug Approval Strategies for Pharmaceutical Industry and how the pharmaceutical companies communicate about the approval for drug products. It is necessary to understand the various steps for drug approval. Deciding on a suitable regulatory strategy plays a vital role in gaining time on the market authorization of a drug product. This article provides a brief account and an overview of the drug approval process in United States.

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15. "Over-The-Counter Medications: Use In General And Special Populations, Therapeutic Errors, Misuse, Storage And Disposal". <http://cymcdn.com/sites/www.acpm.org/resource/resmgr/timetools-files/otcmedsclinicalreference.pdf>
16. "Biologics License Applications (BLA) Process (CBER)" <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess>.
17. "FDA IND, NDA, ANDA, or Drug Master File Binders" www.fda.gov/drugs/.../drugmasterfilesdmfs/ucm073080.htm.

Source of Support: Nil, **Conflict of Interest:** None.

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Pursuing M.Pharmacy in Pharmaceutical Management and Regulatory Affairs from CT Institute of Pharmaceutical Sciences, Jalandhar, Punjab (INDIA). I have teaching, research and Industrial experience including USFDA Drug applications, Technical Data Package, Drug master filing Procedure in USDMF & Europe.