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# Preliminary requirement for ANDA Filing

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## ABSTRACT

USFDA is very critical regulated agency for submission. This review reveals how to submit an Abbreviated New Drug Application (ANDA) as per FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)).ANDA Submission contains data which when submitted to FDA's CDER, Office of Generic Drugs, 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 public. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

**Keywords:** Orange Book, CDER, ANDA, FDA, Paragraph IV, certifications, clauses, RTR

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## 1. Introduction

An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references (1).

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. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) (2).

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 performs in the same manner as the innovator drug. One way applicants demonstrate that a generic product performs in the same way as the innovator drug is to measure the time it takes the generic drug to reach the bloodstream in healthy volunteers. This demonstration of "bioequivalence" gives the rate of absorption, or bioavailability, of the generic drug, which can then be compared to that of the innovator drug. To be approved by FDA, 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 (3).

The "Drug Price Competition and Patent Term Restoration Act of 1984," also known as the Hatch-Waxman Amendments, established bioequivalence as the basis for approving generic copies of drug products. These Amendments permit FDA to approve applications to market generic versions of brand-name drugs without repeating costly and duplicative clinical trials to establish safety and efficacy. Under the Hatch-Waxman Amendments, brand-name companies gained patent term extension to account for the time the patented product is under review by FDA and also gained certain periods of marketing exclusivity. In addition to the ANDA approval pathway, generic drug companies gained the ability to challenge patents in court prior to marketing as well as 180-day generic drug exclusivity (4).

## 2. Generic Drugs Approval

### *History*

- In 1970 FDA established the ANDA as a mechanism for the review and approval of generic versions.

- Before 1978, generic product applicants were required to submit complete safety and efficacy through clinical trials.
- Post 1978, applicants were required to submit published reports of such trials documenting safety and efficacy.

Neither of these approaches was considered satisfactory and so originated Hatch Waxman Act on 1984 (5).

***Indispensability Grounds for Generics***

- Contain the same active ingredients as the innovator drug (inactive ingredients may vary).
- Must be identical in strength, dosage form, and route of administration.
- Must have same use/indications.
- Must be bioequivalent.
- Must have same batch requirements for Identity, Safety & Purity.
- Must follow strict standards of FDA's GMPs (6).

***Hatch-Waxman Act***

- Commonly known as "Drug Price Competition & Patent Term Restoration Act" of 1984.
- "The Hatch-Waxman Act is an act dealing with the approval of generic drugs and associated conditions for getting their approval from FDA, market exclusivity, rights of exclusivity, patent term extension and Orange Book Listing" (7)

Necessitated by:

1. Absence of Generic drug manufacturing.
2. Cumbersome regulatory procedures.
3. Patients were denied the option of cheaper drugs (7)

***General Provisions of the Act***

1. Maintaining list of patents which would be infringed.
2. Only Bioavailability studies and not clinical trials needed for approval.
3. Para I, II, III and IV certifications
4. Data exclusivity period for New Molecular Entities.
5. Extension of the original patent term.
6. The "Bolar" Provision (7)

***Recent additions to the Hatch-Waxman Act***

Under the "Medicare Prescription Drug and Modernization Act", 2003:

1. Non-extension of the 30-month period.
2. Time limit for informing patent owner.
3. Provision for allowing declaratory judgment.
4. Benefit of exclusivity for several ANDAs filed on same day allowed (8)

***ANDA certification clauses***

Submission is for the company which is seeking to copy branded drug before expiration of patents to get benefit over it, a generic applicant must provide in its application a "certification" that a patent submitted to FDA by the brand-name drug's sponsor and listed in FDA's Approved Drug Products (9).

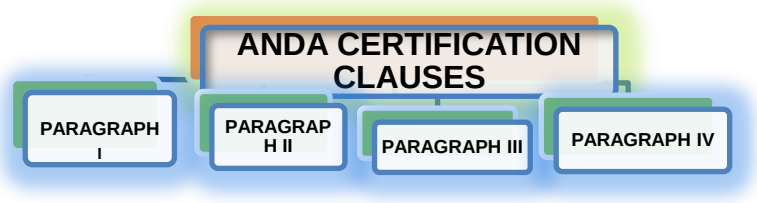


**Figure 1** show parameters for Innovator drug vs generic drugs (9)

**Table 2** Show the selection criteria for application of product in respective clause (9)

| Certification clause | Selection criteria |
|---|---|
| PARA I | • Required patent information has not been filed.<br>• FDA may approve generics immediately; one or more applicants may enter. |
| PARA II | • Patent has expired<br>• FDA may approve generics immediately, one or more applicants may enter |
| PARA III | • Patent not expired, will be expired on a specific date.<br>• FDA may approved ANDA effective on the date of expiration, one or more applicant may enter |
| PARA IV | • Patent is invalid or non- infringed by generic applicant.<br>• Generic applicant file notice to patent holder |

***Modules in CTD***

MODULE I: Administrative and Prescribing Information

MODULE II: Summaries and Overviews

MODULE III: Information on product quality

MODULE IV: Non Clinical Study Reports (not required for ANDA filing)

MODULE V: Clinical Study Reports

Recommendations for e-CTD

1. PDF Files with version 3.0 of Acrobat Reader
2. Use of Embedded fonts in the Portable Document Format
3. A Print area of 8.5 inches by 11 inches and margin of 1 inches is ensured on sides.
4. Scanned Documents should be avoided as Source Documents.
5. Hypertexts can be indicated by Blue-Texts or by rectangles using thin lines.
6. Numbering on the PDF and Documents should be included as same.
7. Security or Passwords should not be included.
8. Full Indexes should be included.
9. Electronic Signatures may be added, Procedures are being employed for archival of the same (10).

**3. ANDA submission review Process**

- Applicant will select the generic product and innovator for ANDA submission along with certification clause.
- Submission requirement shall be followed as per requirement of respective clause selected for product.
- Applicant shall ensure the Hatch-Waxman Act for generic drug vs innovator as per Drug Price Competition and Patent Term Restoration Act of 1984 considering recent addition to act also.
- Applicant shall compile the dossier as per e CTD modules considering the guidance for ANDA format.
- After Fee payment as per GDUFA, Applicant shall apply complete set of dossier along with all required submission forms as listed in next section.
- Once applied by Applicant, Agency reviewer team will review as per their standard guidelines and norms.
- Upon finding of discrepancies/queries, Agency will issue IR (information request), CR (complete response letter),
- DRL (Discipline review letter) based on criticality of observation and Applicant has to respond the same within stipulated timeline to have successful submission and approval.
- If USFDA Agency will feel any critical observation under RTR, they will refuse the application and can issue Warning letter too and again Applicant has to respond the same within stipulated timeline to have successful submission and approval (11).

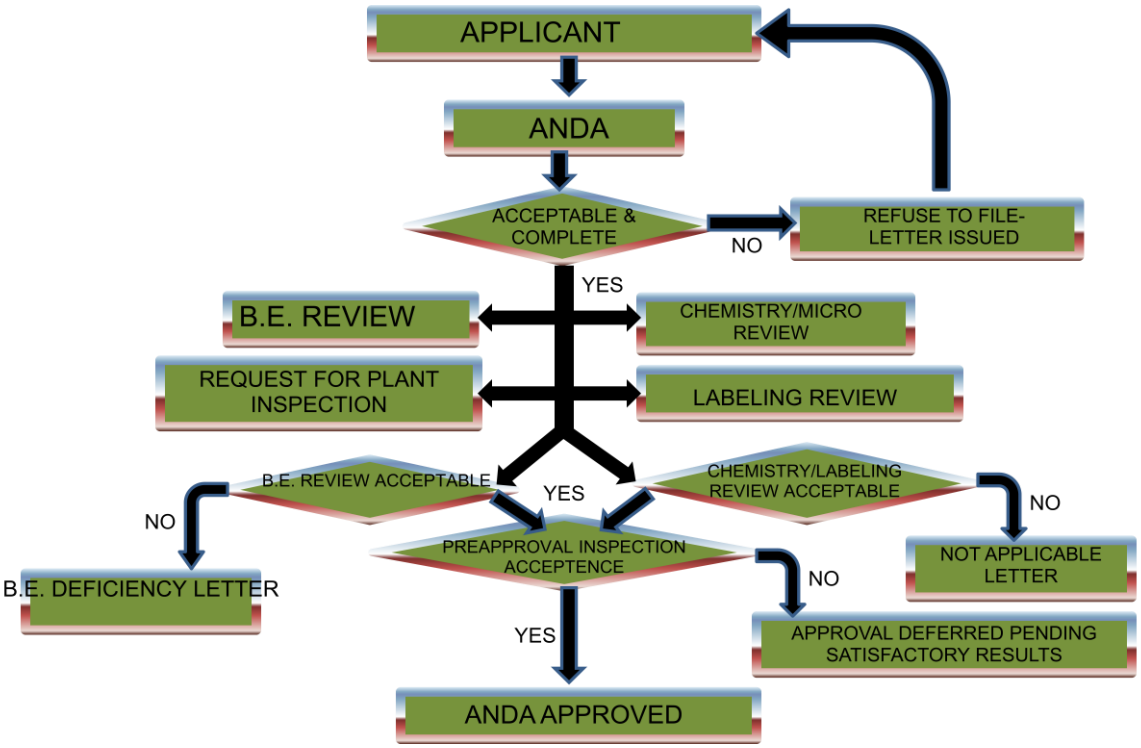


**Figure 2** Flowchart image for ANDA submission review Process (11)

**4. Abbreviated New Drug Application (ANDA) filing requirements and checklist of documents**

Abbreviated New Drug Application (ANDA) Forms and Submission Requirements

***ANDA Forms***

Applicant shall prepare and fill following forms in order to complete ANDA application. All forms are available at fda.gov/..

- New of ANDAs MAPP including filing checklist
- Form FDA-356h: Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use
- Instructions for using Form FDA-356h
- Form FDA-3794: GDUFA Cover Sheet
- Instructions for creating a GDUFA Cover Sheet
- Form FDA-3674: Certification of Compliance
- Instructions for completion of Form FDA-3674
- Generic Drug User Fee Payment Information
- Drug Master Files (DMFs)

***Requesting a Pre-Assigned ANDA Number***

- Applicable when submitting a new ANDA
- While converting to e CTD must use the original ANDA application number. For further guidance, please View Requesting a Pre-Assigned ANDA Number or email:

  CDERAPPNUMREQUEST@fda.hhs.gov.

***Electronic Submissions***

- Paper ANDA submissions are not acceptable.
- All ANDA submissions MUST be in eCTD format
- eCTD submission sizes 10 GB or less must use the FDA Electronic Submission Gateway (ESG).
- If it is greater than 10 GB, shall be submitted via physical media (DVD/USB Drive) to the CDER Document Room or via ESG
- The guidance for industry "Transmitting Electronic Submissions Using eCTD specifications
- For the submission of Form FDA 3500A reports (15-day Alert Reports and Periodic Adverse Drug Experience Reports) to ANDAs, continue to send these to the following address:
- Central Document Room, 5901-B Ammendale Road, Beltsville MD 20705-1266

***Summary Tables***

- Following summary tables shall be utilized for ANDA application as a standard, concise and consistent format with current recommendations.
- Bioequivalence Summary Tables for In Vitro Feeding Tube Testing
- Clinical Endpoint Summary Tables
- Common Technical Document (CTD) Modules/Sections Corresponding to Summary Data Tables
- Bioequivalence Submissions to ANDAs
- Model Bioequivalence Data Summary Tables
- Summary Tables for the Listing and Characterization of Impurities and Justification of Limits in Drug Substance and Drug Products (consistent with the recommendations delineated in the Guidance for Industry.
- ANDAs: Impurities in Drug Substances and ANDAs: Impurities in Drug Products)
- Model Bioequivalence Data Summary Tables A detailed content and format information resource for generic drug applicants submitting ANDAs to FDA.
- BCS-Based Study Summary and Formulation Tables
- Pharmacy Bulk Package Sterility Assurance Table

***Generic Drug Regulatory Resources***

Following resources shall be referred to achieve fruitful ANDA submission.

- Product-Specific Guidance's for Generic Drug Development
- Generic Drugs Guidances
- Biopharmaceutics Guidances
- Laws Enforced by the FDA
- Generic Drug User Fee Amendments (GDUFA)
- Code of Federal Regulations(CFR)
- Federal Register (FR)
- CDER FOIA Electronic Reading Room

***Contact FDA***

- Applicant can contact the FDA Generic Drugs Program with questions at any point in their development and ANDA
- Preparation processes
- Applicant can inquire related to ANDAs pending filing review and the status of pending suitability petitions, via email ANDAFiling@fda.hhs.gov.
- If Applicant has specific questions regarding the development of a generic drug product which are not yet submitted in an abbreviated new drug application (ANDA), Applicant can submit a controlled correspondence by email to genericdrugs@fda.hhs.gov.
- Applicant can contact for any general question about generic drugs, by email on druginfo@fda.hhs.gov.
- If Applicant have a question regarding an ANDA for which you are the applicant or authorized representative, please contact the regulatory project manager assigned to the application.

***Office of Generic Drugs***
10903 New Hampshire Avenue
Silver Spring, MD 20993

240-402-7920
301-595-1147 Fax (12)

**Abbreviated New Drug Application (ANDA) filing checklist for documents**

Following documents are prime requirement for Application as per E- CTD Modules:

***Module –I – Administrative***

**a.** Form 356 h, b. Form FDA 3674 , cover letter c. field copy certification , debartment certification , financial certification , patent information

**b.** Module –II, III, IV: Quality overall summary (QOS) (documents related to drug substance and Drug product) and clinical documents.

***Drug substance related documents***

- Drug substance approved vendor documents with approved DMF including all required declarations /certifications from drug substance manufacturer as listed below.
    - cGMP Certificate, Genotoxicity certificate. TSE/BSE Certificate, GMO Certificate, Metal Catalyst Declaration, Melamine Certificate, Residual Solvent Declaration, Access on CEP, Debarment Certificate, CEP Attestation, Elemental Impurity Assessment.
- Approved Drug substance specification
- Certificates of analysis for both drug substance and drug product manufacturer with complete sets of chromatograms/histograms /difractograms.

***Drug Product related documents***

- Executed BMRs and BPR for all strengths to be applied.
- Intended BMRs and BPRs for all strengths to be applied.
- Specifications/ Standard testing procedures :
    - Excipients specifications
    - Packing material specifications
    - In-process specifications
    - Finished product specifications
    - Stability specifications
- Certificates for analysis for Drug substance manufacturer and Drug product manufacturer
    - Excipient COA
    - Packing material COAs
    - Purified water COAs used for batch execution
    - In-process COAs
    - Finished product COAs with complete sets of chromatograms
- Packaging Material IR, Drawing, Vendor qualification data/ Technical data Sheet, component specification& Test data and Food Grade Certificate (for new vendor) with all required certificates as listed below
    - Declaration/Certificate FP
    - cGMP Certificate
    - Debarment Certificate
    - Reconciliation Summary Sheet-Strength wise
    - Sample Availability statement for drug product
    - Comparative list of equipment's (Exhibit Vs. Intended)
    - Reprocessing Statement
    - Post approval Stability Commitment
    - Conviction statement
    - Environmental Impact Analysis Certificates

***Validation requirements***

- *Manufacturing Process*

Process validation protocol and reports for exhibit batch and also for intended commercial (proposed)

- *Analytical process*
    - API verifications for applicable parameters as per specifications
    - Drug product validation for applicable parameters as per specifications
    - Hold time protocols and reports
- *Stability Study*
    - Pre-approval Stability protocols /photo stability protocols
    - Stability summary for pre-approval, post approval ,photo stability (ACC, long term and photo stability)
    - Post approval stability commitment
- *Reference/Working Standard*
    - Reference/Working Standard (used in verification/ validation and analysis of drug substance and drug product as listed below:
    - Reference Standard - Certificate of Analysis
    - Working Standard - Certificate of Analysis, Characterization / qualification data
    - Impurity Standard - Certificate of Analysis, Characterization / qualification data
    - Reference standard and Working Standard Individual Spectra/Chromatogram
    - Reference standard and Working Standard - Overlapping Spectra/Chromatogram
- Comparative Multimedia Dissolution Profiling for generic drugs vs. innovator drug
- Moisture vapor transmission report for packing components

- Uniformity of dosage unit by content uniformity using Stratified sampling if Applicable
- Microbial limits validation study for Drug substance and drug product
- Transport study protocol if applicable

***Clinical study documents***

Bio-equivalence study report for selected pivotal batch for IP (investigational drug product) and Reference listed product (13).

***Checkpoints for review of documents before submission to avoid RTR***

The following type of deficiencies that FDA considers to be major or minor deficiencies:

***Form FDA 356h (356h)***

An ANDA must contain a completed application form (i.e., Form FDA 356h). If this form is not included, or is not signed, which indicates that the applicant is not attesting to the material contained in the application, FDA will RTR the ANDA?

***Submission, Format, and Organization***

The ANDA should be formatted according to the eCTD format, and it should be submitted electronically for GDUFA metric goals to apply to the ANDA.

21 Under Section 745A(a) of the FD&C Act, electronic submissions of applications to FDA will be required at least 24 months after the issuance of the final guidance for industry, Providing Regulatory Submissions in Electronic Format-Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (the eCTD guidance e), which published on May 22.

***Non-Payment of GDUFA Obligations***

FDA will RTR an ANDA in certain cases if there are outstanding user fee obligations

- If an applicant fails to pay the GDUFA ANDA or PAS fee within 20 calendar days of submitting the application 24
- If an ANDA references a Type II active pharmaceutical ingredient (API) Drug Master File (DMF) that is not on the public available for reference list because of non-payment of the GDUFA DMF fee
- If an ANDA references a facility that is on the facility arrears list for failure to pay the GDUFA facility fee(s)
- If the applicant is the owner of or is affiliated with the owner of a facility on the facility arrears list
- If the applicant is listed on the backlog arrears list
- If the applicant is affiliated with an applicant on the backlog arrears list.

In all of these cases, FDA will RTR an ANDA for nonpayment of GDUFA user fee obligations. Upon satisfaction of all applicable user fee obligations, CDER's Office of Management will issue a formal correspondence to the applicant Indicating the adjusted receipt date (i.e., the date on which all outstanding user fee obligations were satisfied in full) for which the ANDA is eligible.

Lack FDA wills RTR an ANDA in certain cases if there are outstanding user fee obligations:

- If an applicant fails to pay the GDUFA ANDA or PAS fee within 20 calendar days of submitting the application
- If an ANDA references a Type II active pharmaceutical ingredient (API) Drug Master File (DMF) that is not on the public available for reference list because of non-payment of the GDUFA DMF fee
- If an ANDA references a facility that is on the facility arrears list for failure to pay the GDUFA facility fee(s)
- If the applicant is the owner of or is affiliated with the owner of a facility on the facility arrears list
- If the applicant is listed on the backlog arrears list
- If the applicant is affiliated with an applicant on the backlog arrears list. In all of these cases, FDA will RTR an ANDA for nonpayment of GDUFA user fee obligations. Upon satisfaction of all applicable user fee obligations, CDER's Office of Management will issue a formal correspondence to the applicant indicating the adjusted receipt date (i.e., the date on which all outstanding user fee obligations were satisfied in full) for which the ANDA is eligible.

Lack accordance with 21 CFR 314.93 and 10.30, and the suitability petition is approved by FDA. The changes (from the RLD) that can be requested in a suitability petition are:

- Change in route of administration
- Change in dosage form
- Change in strength

One active ingredient is substituted for one of the active ingredients in a listed combination drug An applicant who wishes to rely on an approved suitability petition as the basis of submission for an ANDA can do so by identifying the listed drug cited in the approved petition as the basis for the ANDA, subject to the limitation described in 21 CFR 314.93(f)(2).

In addition, the docket number and a copy of FDA's correspondence approving the petition must be included in the ANDA submission.

***Generic Product vs RLD***

The generic product shall be identical to the RLD in "active ingredient(s), dosage form, strength, and route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted.

Applicants generally should not submit new pharmacy bulk package strength or fill volume in an amendment.

Documents like the environmental assessment, the environmental impact statement, or the claim of categorical

Exclusion and the justification for the exclusion should be provided.

***A claim of categorical exclusion must***

(1) "include a statement of compliance with the categorical exclusion criteria" and

(2) "state that to the applicant's knowledge, no extraordinary circumstances exist."

**Table 1** Show parameters for Innovator drug vs generic drugs (7)

| Sr. no. | Parameters | Innovator drug | Generic name |
|---|---|---|---|
| 1 | Active ingredients | Same | Same |
| 2 | Safety and efficacy | Same | Same |
| 3 | Quality and strength | Same | Same |
| 4 | Performance and standards | Same | Same |
| 5 | Cost and prescription | Highly expansible | Less expansible |
| 6 | FDA inspection of manufacturing facility | Yes | Yes |
| 7 | FDA review reports for adverse reaction | Yes | Yes |
| 8 | FDA review of drug labeling | Yes | NO |
| 9 | Extensive research and development investment | Yes | No |
| 10 | Expensing marketing and advertising | Yes | No |
| 11 | Patent protection | Yes | No |
| 12 | FDA review to show active ingredient is equivalent to original | NA | Yes |
| 13 | Product development time | 12 years | 2-4 years |

Contains a request, if applicable, to waive the requirement that applicants submit evidence either measuring in vivo

Bioavailability (BA) or demonstrating in vivo BE of the generic product (known as a biowaiver).

***Container and closure***

- Applicants should ensure that the label and labeling design do not contribute to medication error.
- And confirm whether the container closure is child resistant.
- Contains the annotated draft labeling text, including side-by-side labeling comparison of the generic drug product's container(s) and carton(s) to the RLD's container(s) and carton(s) for each strength (or total drug content and concentration for injections) and for each container closure system.
- All differences should be highlighted and annotated. Applicants should indicate the RLD version (e.g., strength,
- Package size of carton used for the side-by-side comparison
- Contains the prescribing and patient information in text-based PDF, Microsoft Word, and structured product
- Labeling files
- Contains the Pharmacy Bulk Package Sterility Assurance table, if applicable
- Contains the labeling history
- Applicants must submit side-by-side labeling comparison(s) with all differences annotated and explained.
- Applicants should also submit the RLD package insert, FDA has determined that, in general, an ANDA may be approved based on a draft labeling provided that the only
- Medication Guide, one container label, and one outer carton, if applicable, for each strength and package size listed in the application.
- Applicants are reminded to use the most recent RLD labeling available at the Drugs@FDA website.

In addition, applicants should do the following: (1) State that a sufficient number of Medication Guides will be included in each package size (i.e., an amount to ensure that the authorized dispenser is able to provide a Medication Guide to each patient receiving a prescription for the drug product), (2) Confirm that the Medication Guides will be distributed in accordance with 211.14.3.3 Contains the RLD labeling, the Medication Guide, one RLD container label, and one RLD outer carton label for each strength and package size, if applicable.

- Contains a risk management plan (non-REMS) for products that require tools to minimize risks while preserving benefits.
- Contains, for applicants relying on an RLD with a risk evaluation and mitigation strategy (REMS), a REMS for the generic drug product and any REMS supporting documents.
- A REMS for an ANDA must have the same Medication Guide and patient package insert as the RLD.

In addition, if applicable, a REMS for an ANDA must use a single, shared system of elements to assure safe use unless FDA waives the requirement under section 505-1(i)(1)(B) of the FD&C Act (21 U.S.C. 355-1(i)(1)(B) (14).

## 5. Conclusion

Applicant will get successful approval of generic drugs by means of effective implementation of all modules and ANDA filing checklist as well check points to avoid RTR deficiency and it ultimate benefits to Drug product manufacturer those who market the generic drug product

to provide a safe, effective, low cost alternative to the public.

From the study, it was revealed that ANDA submission is very challenging .we have provided this review based on many blogs and websites. ANDA submission is most important for the generic drugs companies for marketing with low cost compared to branded drug.

Submission is for the company which seeks to copy branded drug before expiration of patent to get benefits over it. Also, generic applicant must provide in its application a "certification clause".

**Acknowledgments**

We take this opportunity to express deep sense of gratitude to IJDRA Journal for publishing our Article.

**Conflict of interest**

The authors declare that there are no conflicts of interest, financial or otherwise.

**Abbreviations**

USFDA –Unite states of Food and Drug Administration
CDER- Center for Drug Evaluation and Research
ANDA -Abbreviated New Drug Applications
FD&C Act- Federal Food, Drug, and Cosmetic Act
GDUFA- Generic Drug User Fee Amendments
CFR-Code of Federal Regulations
CBER -Center for Biologics Evaluation and Research
e-CTD- electronic common technical dossier (documents)
RTR - refuse to receive

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