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Role of regulatory affairs for new drug approval procedure in India

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ABSTRACT

Regulatory affairs is a comparatively new profession which developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. Regulatory affairs (RA) professionals play critical roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global regulators but is also differentiated from the competition in some way and also is to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities

Keywords: Regulatory Affairs, IND-Investigational New Drug, DCGI-Drug Controller General of India, CDSCO-Centre for Drug Standards Control organization.

INTRODUCTION

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods) most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals [1-5].

Procedure for new drug approval in India

The Drug and Cosmetic Act 1940 and Rules 1945 were passed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its leader, the Drugs Controller General (India) [DCGI] were established [6-8].

In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure. The changes includes, establishing definitions for Phase I–IV trials and clear responsibilities for investigators and sponsors [9, 10].

The clinical trials were further divided into two categories in 2006. In one category (category A) clinical trials can be conducted in other markets with competent and major regulatory systems whereas the remaining ones fall in to another category (category B) Other than A [11].

Clinical trials of category A (approved in the U.S., Britain, Switzerland, Australia, Canada, Germany, South Africa, Japan and European Union) are eligible for fast tracking in India, and are likely to be approved within eight weeks. The clinical trials of category B are under more scrutiny, and approve within 16 to 18 weeks [12].

An application to conduct clinical trials in India should be submitted along with the data of chemistry, manufacturing, control and animal studies to DCGI. The data regarding the trial protocol, investigator's brochures, and informed consent documents should also be attached. A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only after approval of DCGI and ethical committee. To determine the maximum tolerated dose in humans, adverse reactions, etc [13].

On healthy human volunteers, Phase I clinical trials are conducted. The therapeutic uses and effective dose ranges are determined in Phase II trials in 10-12 patients at each dose level. The confirmatory trials (Phase III) are conducted to generate data regarding the efficacy and safety of the drug in ~ 100 patients (in 3- 4 centers) to confirm efficacy and safety claims. Phase III trials should be conducted on a minimum of 500 patients spread across 10-15 centers, if the new drug substance is not marketed in any other country.

The new drug registration (using form # 44 along with full pre-clinical and clinical testing information) is applied after the completion of clinical trials. The comprehensive information on the marketing status of the drug in other countries is also required other than the information on safety and efficacy. The information regarding the prescription, samples and testing protocols, product monograph, labels, and cartons must also be submitted.

The application can be reviewed in a range of about 12-18 months. Figure 10 represents the new drug approval process of India. After the NDA approval, when a company is allowed to distribute and market the product, it is considered to be in Phase IV trials, in which new uses or new populations, long-term effects, etc. are explored.

The drug approval process varies from one country to another. In some countries, only a single body regulates the drugs and responsible for all regulatory task such as approval of new drugs, providing license for manufacturing and inspection of manufacturing plants e.g. in USA, FDA performs all the functions. However in some counties all tasks are not performed by a single regulatory authority, such as in India, this responsibility is divided on Centralized and State authorities. Other issues where the difference appears are, time taken for the approval of a CTA application, time taken in evaluation of marketing authorization application, registration fee, registration process and marketing exclusivity.

Some counties have two review processes as normal review process and accelerated review process as in USA, China etc. and some countries have only a single review process as in India. Similarly, the format used for the presentation of dossier submitted for approval of drug is also different. In some countries like as in USA, EU, and Japan, it is mandatory that the dossier prepared in CTD format, however, in some countries it is optional such as in India.

CTD guideline in India

The CTD is only a format for submission of information to CDSCO. It does not define the content.

Difference in organization of data in each application has made reviewing more difficult and can also lead to omission of critical data or analysis so unnecessary delay in approval. Thus common format of submission will help. Through the ICH process, CTD guidance developed for Japan, EU & US. CDSCO also adopted the CTD.

Guidelines for preparation of CTD

CTD: Over view

Module 1: general information

This module should contain documents specific to India; for example, Form 44, Treasury challan fee or the proposed label for use in India.

1. Covering letters & compressive table of contents (module 1 to 5)
2. Administrative information
   Brief introduction about the applicant company
   Duly filled and signed application form 44 and treasury challan
3. Legal and critical documents
4. Coordinates related to the application
5. General information of the drug product
6. Summary of the testing protocol(s) for quality control testing
7. Regulatory status in other countries
8. Domestic price of the drug followed in the countries of origin.
9. Brief profile of manufacturer's company & business activity
10. Information regarding involvement of expert if any Samples of drug product Promotional material

Module 2: CTD summaries

This module should begin with a general introduction to the pharmaceutical, including its pharmacologic class, mode of action, and proposed clinical use, not exceeding one page. Module 2 should contain 7 sections in the following order:

1. CTD table of contents
2. CTD introduction
3. Quality overall summary
4. Nonclinical overview
5. Clinical overview
6. Nonclinical written and tabulated summaries
7. Clinical summary

In this module following information is required

1. Table of content of module
2. Introduction
3. Quality overall summary
4. In this section not provide the entire information it is presented in module 3. It is not more than 40 pages.
5. Summary of drug substance & drug product.
6. Nonclinical overview
7. Clinical over view

Module: 3 quality

In this module following information is required

1. Table of contents of module 3
2. Drug substances
3. Manufacture of drug substances
4. Characterization of drug substances
5. Quality control of drug substances
6. Reference standards and material
7. Container closer system
8. Stability of drug substance
9. Drug product and manufacture of drug product
10. Control of drug product and excipient

Module: 4 non clinical study report

Table of contents in this module should be provided that lists all of the nonclinical study reports and gives the location of the each study reports in CTD.

It contains following data

1. Study reports
   Pharmacology
   Pharmacokinetic
   Toxicology
2. Literature references

Module: 5 Clinical study report

It contains tabular listing of all clinical studies.

Following data are required.

Clinical study report

- Reports of biopharmaceutical studies
- Reports of studies pertinent to pharmacokinetic use in human biomaterials.
- Reports of human pharmacokinetic studies
- Reports of human pharmacodynamic studies
- Reports of efficacy and safety study
- Reports of post marketing experience
- Case report form and individual patient listing
- Literature references [CDSCO Guideline]

Documents to be submitted for grant of permission to conduct bioequivalence studies for export purpose

A large number of applications are being filed to the office of DCG (I) at CDSCO (HQ) by Pharmaceutical companies, both manufacturers and importers as well as CRO's on behalf of them, requesting for the approval to carry out BE studies

with various pharmaceutical dosage formulations on Indian subjects.

In light of the above, for easy processing of such applications and to bring uniformity in decision making all stake holders of the above mentioned activities are hereby advised to submit their applications with following documents. All applications should accompany the documents with proper index & page number.

New drugs – developed in India as an IND and not marketed anywhere in world.

1. Form 44
2. Treasury Challan of INR 50,000.
3. Source of bulk drugs /raw materials.

Requirements for BE study of a new molecule not approved in India but approved in the other countries

1. Application in Form-44 duly signed, by the competent authority with name and designation.
2. Treasury Challan of Rs. 50000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval granted to the BE study centre by CDSCO.
5. Sponsor's Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. The study synopsis
8. Pre-clinical single dose data and repeated dose toxicity data.
9. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers/patients data published in reputed journals.
10. Regulatory status of the drug
11. Names of the countries where the drug is currently being marketed (to be mentioned in the Covering letter also).
12. Package literature on the international product
13. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
14. In the case of multiple doses BE study adequate supporting safety data should be submitted.
15. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
16. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

1. Application in Form-44 duly signed, by the competent authority with name and designation

New drugs approved in India within period of 1 year

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers data published in reputed journals.
8. Package literature on the international product.
9. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
10. In the case of multiple doses BE study adequate supporting safety data should be submitted.
11. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
12. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

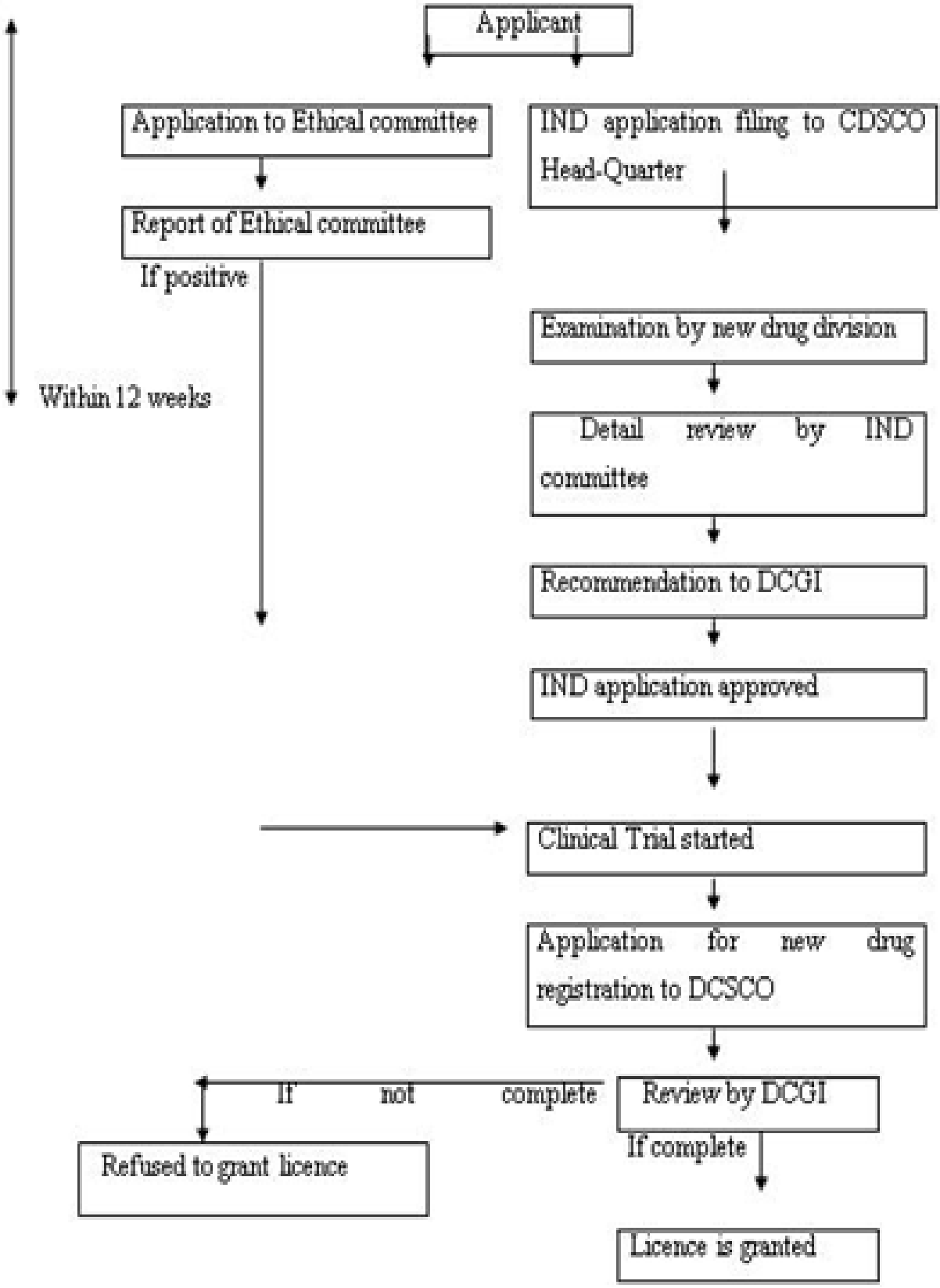
New drugs approved within period of more than 1 year & less than 4 years

2. Treasury Challan of Rs. 15000/- as per Drugs & Cosmetic Rules.

3. Undertaking by the Principal Investigator (PI)
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed on their letterhead by the competent authority.
6. The study protocols.
7. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
8. In the case of multiple doses BE study adequate supporting safety data should be submitted.
9. In the case of Inject able preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
10. Depending on the nature of the drug like cytoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

BE NOC for all the drug products in modified release form irrespective of their approval status

1. Application in Form-44 duly signed, by the competent authority with name and designation as per appendix VII of schedule "Y" of Drugs.
2. Treasury Challan of Rs. 15000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed on their letterhead by the competent authority.
6. The study protocols.
7. Complete Certificate of Analysis of same Batches (both test & reference formulations) to be used in the BE study.
8. In the case of multiple doses BE study adequate supporting safety data should be submitted.
9. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
10. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.


Applicant
Application to Ethical committee
IND application filing to CDSCO Head-Quarter
Report of Ethical committee
If positive
Within 12 weeks
Examination by new drug division
Detail review by IND committee
Recommendation to DCGI
IND application approved
Clinical Trial started
Application for new drug registration to DCSCO
Review by DCGI
If not complete
If complete
Refused to grant licence
Licence is granted

APPLICATION FORM FORMAT

Form 44 (India)

(See rules 122 A, 122 B, 122 D, and 122 DA)

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

*****

I/we_____ of
M/s._____ (address)

Hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information / data are given below:

Particulars of New Drugs

1. Name of the drug:
2. Dosage Form:
3. Composition of the formulation:
4. Test specification:
5. Active ingredients:
6. Inactive ingredients:
7. Pharmacological classification of the drug:
8. Indications for which proposed to be used:
9. Manufacturer of the raw material (bulk drug substances):
10. Patent status of the drug:

Data submitted along with the application (as per Schedule Y with indexing and page nos.)

Permission to market a new drug

1. Chemical and Pharmaceutical information
2. Animal Pharmacology
3. Animal Toxicology
4. Human/Clinical Pharmacology (Phase I)
5. Exploratory Clinical Trials (Phase II)
6. Confirmatory Clinical Trials (Phase III) (including published review articles)
7. Bio-availability, dissolution and stability study Data
8. Regulatory status in other countries
9. Marketing information:
    a. Proposed product monograph
    b. Drafts of labels and cartons
10. Application for test license

Subsequent approval / permission for manufacture of already approved new drug

Formulation

1. Bio-availability/ bio-equivalence protocol
2. Name of the investigator/center
3. Source of raw material (bulk drug substances) and stability study data.

Raw material (bulk drug substances)

1. Manufacturing method
2. Quality control parameters and/or analytical specification, stability report.
3. Animal toxicity data

Approval / permission for fixed dose combination

1. Therapeutic Justification (authentic literature in pre-reviewed journals/text books)

2. Data on pharmacokinetics/pharmacodynamic combination
3. Any other data generated by the applicant on the safety and efficacy of the combination.

Subsequent approval or approval for new indication – new dosage form

1. Number and date of Approval/permission already granted.
2. Therapeutic Justification for new claim / modified dosage form.
3. Data generated on safety, efficacy and quality parameters.

A total fee of rupees_____ (in words)._____) has been credited to the Government under the Head of Account_____ (Photocopy of receipt is enclosed).

Date_____
Signature_____
Designation_____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0014.
Expiration Date: May 31, 2009
See OMB Statement on Reverse.

INVESTIGATIONAL NEW DRUG APPLICATION (IND)

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).

1. NAME OF SPONSOR

2. DATE OF SUBMISSION

3. ADDRESS (Number, Street, City, State and Zip Code)

4. TELEPHONE NUMBER (Include Area Code)

5. NAME(S) OF DRUG (Include all available names: Trade, Generic, Chemical, Code)

6. IND NUMBER (If previously assigned)

7. INDICATION(S) (Covered by this submission)

8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED: ☐ PHASE 1 ☐ PHASE 2 ☐ PHASE 3 ☐ OTHER (Specify)

9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), DRUG MASTER FILES (21 CFR Part 314.420), AND PRODUCT LICENSE APPLICATIONS (21 CFR Part 601) REFERRED TO IN THIS APPLICATION.

10. ***IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.***

SERIAL NUMBER

11. THIS SUBMISSION CONTAINS THE FOLLOWING: *(Check all that apply)*

☐ INITIAL INVESTIGATIONAL NEW DRUG APPLICATION (IND)
☐ RESPONSE TO CLINICAL HOLD

PROTOCOL AMENDMENT(S):
☐ NEW PROTOCOL
☐ CHANGE IN PROTOCOL
☐ NEW INVESTIGATOR

INFORMATION AMENDMENT(S):
☐ CHEMISTRY/MICROBIOLOGY
☐ PHARMACOLOGY/TOXICOLOGY
☐ CLINICAL

IND SAFETY REPORT(S):
☐ INITIAL WRITTEN REPORT
☐ FOLLOW-UP TO A WRITTEN REPORT

☐ RESPONSE TO FDA REQUEST FOR INFORMATION
☐ ANNUAL REPORT
☐ GENERAL CORRESPONDENCE
☐ REQUEST FOR REINSTATEMENT OF IND THAT IS WITHDRAWN, INACTIVATED, TERMINATED OR DISCONTINUED
☐ OTHER (Specify)

CHECK ONLY IF APPLICABLE

JUSTIFICATION STATEMENT MUST BE SUBMITTED WITH APPLICATION FOR ANY CHECKED BELOW. REFER TO THE CITED CFR SECTION FOR FURTHER INFORMATION.

☐ **TREATMENT IND 21 CFR 312.35(b)** ☐ **TREATMENT PROTOCOL 21 CFR 312.35(a)** ☐ **CHARGE REQUEST/NOTIFICATION 21 CFR312.7(d)**

FOR FDA USE ONLY

CDR/CBER/CDER RECEIPT STAMP	CDR RECEIPT STAMP	DIVISION ASSIGNMENT
		IND NUMBER ASSIGNED

FORM FDA 1571 (4/06) PREVIOUS EDITION IS OBSOLETE **PAGE 1 OF 2**

12. **CONTENTS OF APPLICATION**

This application contains the following items: *(Check all that apply)*

- ☐ 1. Form FDA 1571 *[21 CFR 312.23(a)(1)]*
- ☐ 2. Table of Contents *[21 CFR 312.23(a)(2)]*
- ☐ 3. Introductory statement *[21 CFR 312.23(a)(3)]*
- ☐ 4. General Investigational plan *[21 CFR 312.23(a)(3)]*
- ☐ 5. Investigator's brochure *[21 CFR 312.23(a)(5)]*
- ☐ 6. Protocol(s) *[21 CFR 312.23(a)(6)]*
  - ☐ a. Study protocol(s) *[21 CFR 312.23(a)(6)]*
  - ☐ b. Investigator data *[21 CFR 312.23(a)(6)(ii)(b)]* or completed Form(s) FDA 1572
  - ☐ c. Facilities data *[21 CFR 312.23(a)(6)(ii)(b)]* or completed Form(s) FDA 1572
  - ☐ d. Institutional Review Board data *[21 CFR 312.23(a)(6)(iii)(b)]* or completed Form(s) FDA 1572
- ☐ 7. Chemistry, manufacturing, and control data *[21 CFR 312.23(a)(7)]*
  - ☐ Environmental assessment or claim for exclusion *[21 CFR 312.23(a)(7)(iv)(e)]*
- ☐ 8. Pharmacology and toxicology data *[21 CFR 312.23(a)(8)]*
- ☐ 9. Previous human experience *[21 CFR 312.23(a)(9)]*
- ☐ 10. Additional information *[21 CFR 312.23(a)(10)]*

13. IS ANY PART OF THE CLINICAL STUDY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION? ☐ YES ☐ NO

IF YES, WILL ANY SPONSOR OBLIGATIONS BE TRANSFERRED TO THE CONTRACT RESEARCH ORGANIZATION? ☐ YES ☐ NO

IF YES, ATTACH A STATEMENT CONTAINING THE NAME AND ADDRESS OF THE CONTRACT RESEARCH ORGANIZATION, IDENTIFICATION OF THE CLINICAL STUDY, AND A LISTING OF THE OBLIGATIONS TRANSFERRED.

14. NAME AND TITLE OF THE PERSON RESPONSIBLE FOR MONITORING THE CONDUCT AND PROGRESS OF THE CLINICAL INVESTIGATIONS

15. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF INFORMATION RELEVANT TO THE SAFETY OF THE DRUG

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set fourth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

16. NAME OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE — Sign

18. ADDRESS *(Number, Street, City, State and Zip Code)*

19. TELEPHONE NUMBER *(Include Area Code)*

20. DATE

(**WARNING**: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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1401 Rockville Pike
Rockville, MD 20852-1448

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Please DO NOT RETURN this application to this address.

FORM FDA 1571 (4/06) **PAGE 2 OF 2**

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CONCLUSION

Generally, the drug approval process comprised mainly the two steps, application to conduct clinical trial and application to the regulatory authority for marketing authorization of drug. The new drug approval process of various countries is similar in some of the aspects whereas it differs in some aspects. In most of the counties, sponsor firstly files an application to conduct clinical trial, and only after the approval by the regulatory authority, the applicant conducts the clinical studies and further submits an application to the regulatory authority for marketing authorization of drug. In all countries, information submitted to regulatory authorities regarding the quality, safety and efficacy of drug is similar; however, the time, fee and review process of clinical trials and marketing authorization application differs.

For the purpose of harmonization, the International Conference on Harmonization (ICH) has taken major steps for recommendations in the uniform interpretation and application of technical guidelines and requirements. This step will ultimately reduce the need to duplicate work carried out during the research and development of new drugs. Therefore, harmonization of drug approval processes either by ICH or WHO may be initiated at global level.

REFFERENCES

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