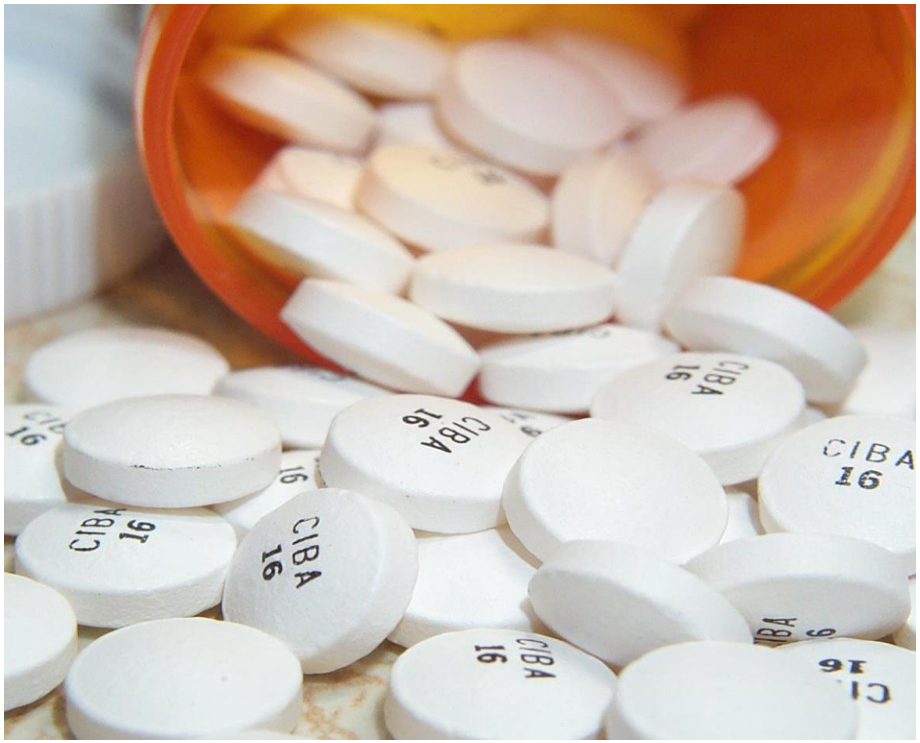
New Drug Application [NDA]

Dr. Shashi Kiran Misra
Assistant Professor
School of Pharmaceutical Science

CONTENTS

INTRODUCTION

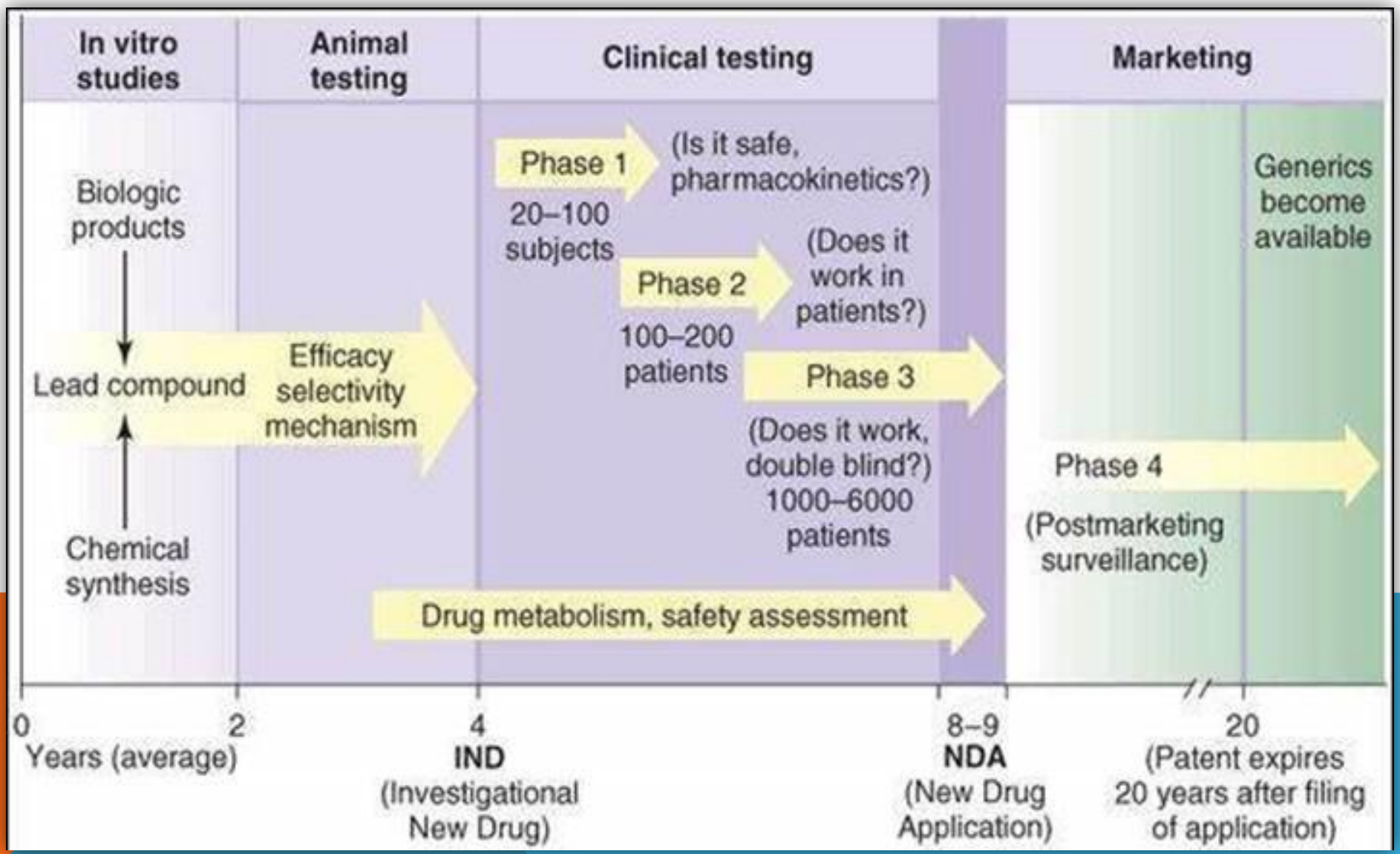
- Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization
- The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.
- The data gathered during the animal studies and human clinical trial of an Investigational New Drug (IND) become part of the NDA



OBJECTIVES

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

When will we go for NDA

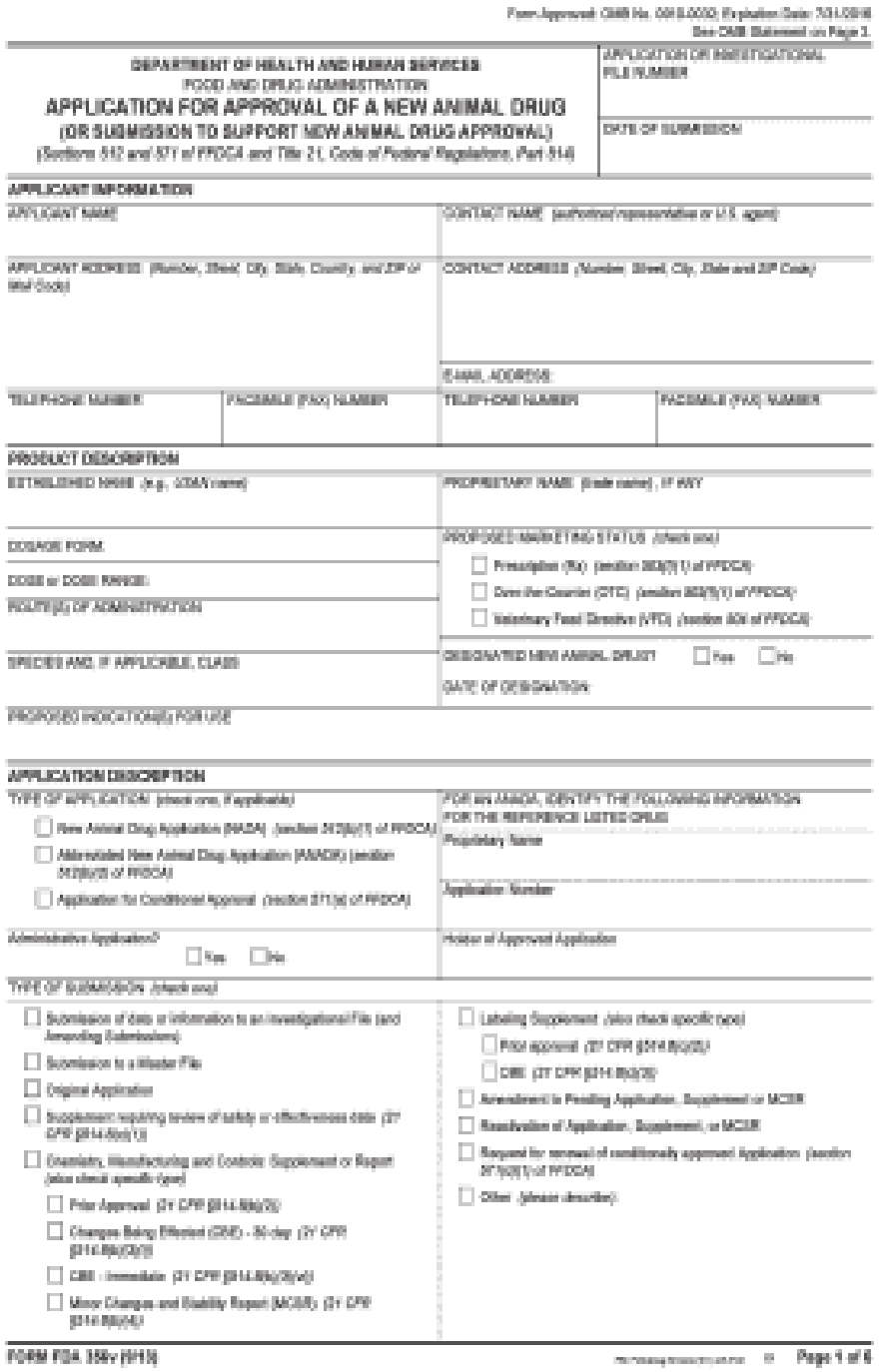


NDA CONTENTS

1. Introduction
   - Brief description of the drug and the therapeutic class to which it belongs
2. Chemical and pharmaceutical information
3. Animal Pharmacology
4. Animal Toxicology
5. Human/Clinical Pharmacology phase I
6. Therapeutic exploratory trials (Phase II)
7. Therapeutic confirmatory trials (Phase III)
8. Special Studies
   - Geriatrics, pediatrics, pregnant or nursing women
9. Regulatory status in other countries
10. Prescribing information
11. Samples and Testing Protocol/s

NDA FORM

- ✓ Form FDA-356h. Application to market a new drug, biological or an antibiotic drug for human use.
- ✓ Form FDA 3397. User fee cover sheet.
- ✓ Form FDA 3331. New drug application field report.
- ✓ Impurity in drug substance.
- ✓ Required specification for FDAs IND, and ANDA drug master file binders.
- ✓ Refusal to file.



Form Approved: OMB No. 0910-0032; Expiration Date: 7/31/2018
See OMB Statement on Page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION FOR APPROVAL OF A NEW ANIMAL DRUG
(OR SUBMISSION TO SUPPORT NEW ANIMAL DRUG APPROVAL)
(Sections 512 and 571 of FFDCA and Title 21, Code of Federal Regulations, Part 514)

APPLICATION OR INVESTIGATIONAL FILE NUMBER

DATE OF SUBMISSION

APPLICANT INFORMATION

APPLICANT NAME

CONTACT NAME (authorized representative or U.S. agent)

APPLICANT ADDRESS (Number, Street, City, State, Country, and ZIP or Mail Code)

CONTACT ADDRESS (Number, Street, City, State and ZIP Code)

E-MAIL ADDRESS

TELEPHONE NUMBER | FACSIMILE (FAX) NUMBER | TELEPHONE NUMBER | FACSIMILE (FAX) NUMBER

PRODUCT DESCRIPTION

ESTABLISHED NAME (e.g., USAN name)

PROPRIETARY NAME (trade name), IF ANY

DOSAGE FORM

PROPOSED MARKETING STATUS (check one)
- Prescription (Rx) (section 353(b)(1) of FFDCA)
- Over-the-Counter (OTC) (section 353(b)(1) of FFDCA)
- Veterinary Feed Directive (VFD) (section 504 of FFDCA)

DOSE or DOSE RANGE

ROUTE(S) OF ADMINISTRATION

SPECIES AND, IF APPLICABLE, CLASS

DESIGNATED NEW ANIMAL DRUG? ☐ Yes ☐ No

DATE OF DESIGNATION

PROPOSED INDICATION(S) FOR USE

APPLICATION DESCRIPTION

TYPE OF APPLICATION (check one, if applicable)
- New Animal Drug Application (NADA) (section 512(b)(1) of FFDCA)
- Abbreviated New Animal Drug Application (ANADA) (section 512(b)(2) of FFDCA)
- Application for Conditional Approval (section 571(a) of FFDCA)

FOR AN ANADA, IDENTIFY THE FOLLOWING INFORMATION FOR THE REFERENCE LISTED DRUG:
Proprietary Name

Application Number

Administrative Application? ☐ Yes ☐ No

Holder of Approved Application

TYPE OF SUBMISSION (check one)
- Submission of data or information to an investigational File (and Amending Submissions)
- Submission to a Master File
- Original Application
- Supplement requiring review of safety or effectiveness data (21 CFR 514.8(a)(1))
- Chemistry, Manufacturing and Controls Supplement or Report (also check specific type)
  - Prior Approval (21 CFR 514.8(b)(2))
  - Changes Being Effected (CBE) - 30-day (21 CFR 514.8(b)(2)(i))
  - CBE - Immediate (21 CFR 514.8(b)(2)(ii))
  - Minor Changes and Stability Report (MCSR) (21 CFR 514.8(b)(4))
- Labeling Supplement (also check specific type)
  - Prior approval (21 CFR 514.8(b)(2))
  - CBE (21 CFR 514.8(b)(3))
- Amendment to Pending Application, Supplement or MCSR
- Resubmission of Application, Supplement, or MCSR
- Request for removal of conditionally approved Application (section 571(c)(1) of FFDCA)
- Other (please describe)

FORM FDA 356v (9/15) Page 1 of 6

REQUIREMENT :

A) No. of copies – Before 1985-3 copies & now only 2copies

1 -Archival copy

2-Review copy

1) **Archival copy:**

Archival copy is a complete copy of an application subission.

-Reference copy for FDA (i.e. retained by FDA)

-Locate information not contained in review copy.

2) **Review copy:**

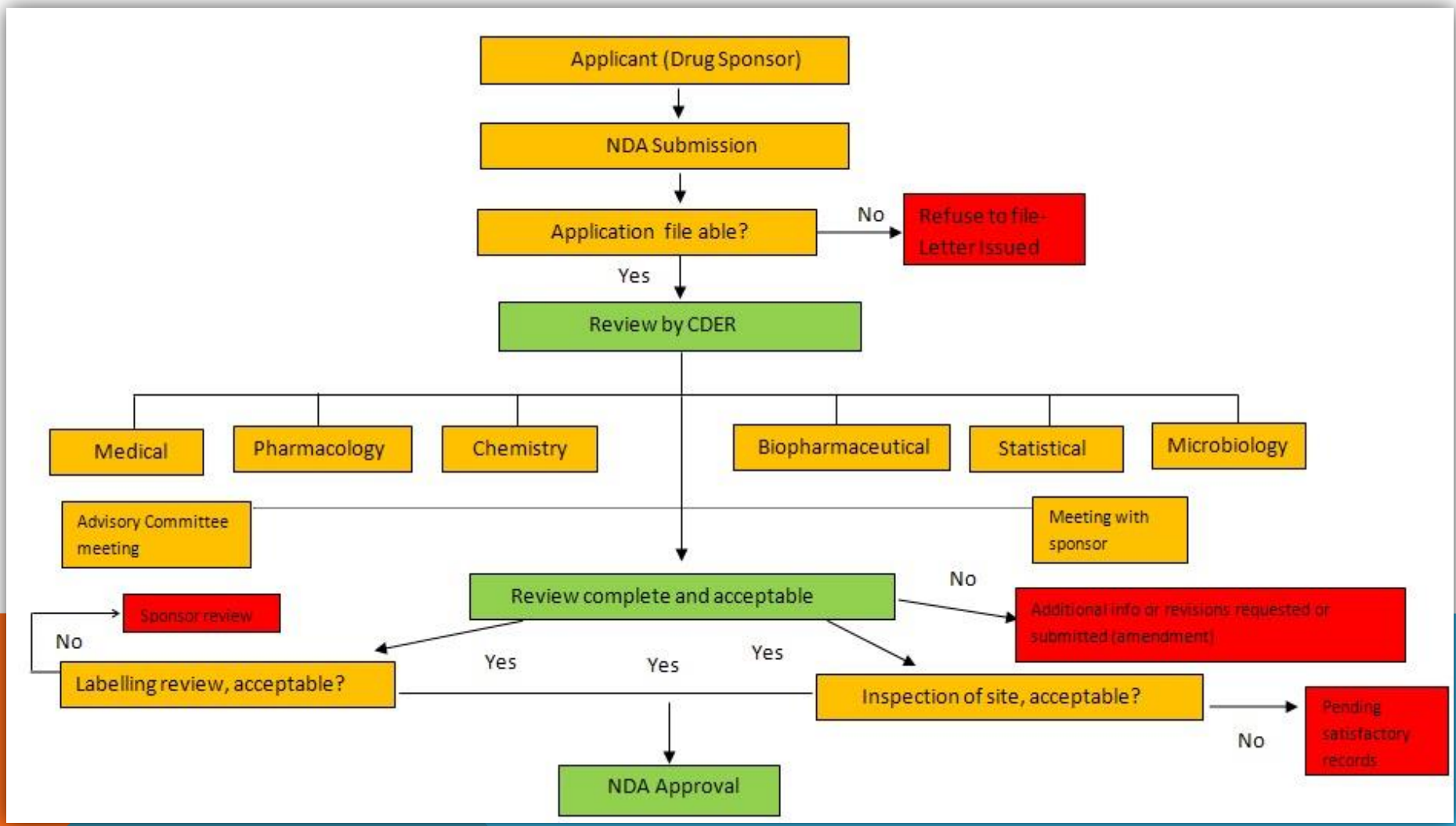
- Review copy of an application is divided into 5 or 6 containing technical and scientific information separately bound.

- It contains copy of cover letter, application form, overall summary ,index ,specific review section.

1) A copy of the FDA cover letter.
2) A copy of the application form.
3) A copy of index to the entire application
4) A copy of the overall summary ,
5) A copy of a reference or authorisation letter to access NDAs , DMFs , etc

DOCUMENTS	FOLDER COLOUR	FORM NUMBER
Archival copy	Light blue	FD 2626
Chemistry,manufacturing, and controls section	Red	FD 2626a
Non-Clinical pharmacology and toxicology section	Yellow	Fd 2626b
Human pharmacokinetics and bioavailability section	Orange	FD 2626c
Microbiology section	White	Fd 2626d
Clinical data section	Light brown	Fd 2626e
Statistical section	Green	Fd 2626f
Field copy	Maroon	Fd 2626h

REVIEW OF NDA



Thank you