[1][FORM 44]

(*See* rules 122A, 122B, 122D 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 is given below :

1. Particulars of new drug *:*

(1) Name of the drug.

(2) Dosage form.

(3) Composition of the formulation :

(4) Test specification. (i) active ingredients. (ii) inactive ingredients.

(5) Pharmacological classification of the drug.

(6) Indications for which proposed to be used.

(7) Manufacturer of the raw material (bulk drug substances).

(8) Patent status of the drug.

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

A. 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 licence.

B. Subsequent approval / permission for manufacture of already approved new drug :

(a) 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.

(b) Raw material (bulk drug substances):

(1) Manufacturing method.

(2) Quality control parameters and/or analytical specification, stability report.

(3) Animal toxicity data.

C. Approval / Permission for fixed dose combination:

(1) Therapeutic Justification.

(authentic literature in pre-reviewed journals/text books)

(2) Data on pharmacokinetics/pharmacodynamics combination.

(3) Any other data generated by the applicant on the safety and efficacy of the combination.

D. 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).

Dated :.....

Signature…….....

Designation…….

Note: *Delete whichever is not applicable.

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1. Forms 44 to 46 A ins. by No.G.S.R. 900 (E), dt. 12.12.2001.