[1][FORM 45

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

Permission to import Finished Formulation of a New Drug

Number of the permission and date of issue……..
M/s ..... of…….
(address) is hereby permitted to import the following new drug formulation under rule 122 A /122 D/122 DA of the Drugs and Cosmetics Rules, 1945.

(1) Name of the New Drug :
(2) Dosage form :
(3) Composition :
(4) Indications :

Dated:.....
Signature.....

Name and designation of Licensing Authority

Conditions for Grant of Approval / Permission.

(1) The formulation shall conform to the specifications approved by the Licensing Authority.

(2) The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.

(3) The label of the innermost container of the drug and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and without disturbing the other conditions printed on the label to depict it as prescription drug.

(4) The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

"WARNING : To be sold by retail on the prescription of a ..... Only."

[2][(5) Post marketing surveillance study shall be conducted during initial period of two years of marketing of the new drug formulation, after getting the protocol and the names of the investigator duly approved by the Licensing Authority.]

(6) All reported adverse reactions related to the drug shall be intimated to the Drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be complied with.

(7) No claims except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.

(8) Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drugs is marketed.

(9) Each consignment of imported drug shall be accompanied by a test/analysis report.

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1. Ins. by No.G.S.R. 900 (E), dt. 12.12.2001.
2. Subs by G.S.R. 101(E), dt. 18.2.2011.