G.S.R. 311 (E) - Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), at pages 3 and 4 in Part II, Section 3, Sub-section (i), of the Gazette of India, Extraordinary, dated the 19th October, 2001, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 785 (E), dated the 19th October, 2001 inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public; And whereas copies of the said Gazette were made available to the public on 20th October, 2001. And whereas objections or suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

These rules may be called the Drugs and Cosmetics (3rd Amendment) Rules, 2002.
They shall come into force on the date of their publication in the Official Gazette.

In the Drugs and Cosmetics Rules, 1945 (herein after referred to as the said rules), in rule 69, after sub-rule (5), the following sub-rule should be inserted, namely:-

"(6) Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drugs as defined in rule 122-E, such application shall also be accompanied with approval, in writing, in favour of the applicant, from the licensing authority as defined in clause (b) of rule 21.".

In rule 71 of the said rules, in sub-rule (6), after clause (iv), the following clause shall be inserted, namely:-

"(v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in rule 122-E, from the licensing authority as defined in clause (b) of rule 21.".

in rule 75 of the said rules, in sub-rule (5), the following sub-rule shall be inserted, namely:-

"(6) Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing, in favour of the applicant, from the licensing authority as defined in clause (b) of rule 21.".

In rule 76 of the said rules, in sub-rule (7), after clause (iv), the following clause shall be inserted, namely:-

"(v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in rule 122-E, from the licensing authority as defined in clause (b) of rule 21.".

[No. X-11014/4/2000-DMS &PFA]

DEEPAK GUPTA, Jt. Secy.