MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th August, 2014

G.S.R. 570(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), *vide* the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R. 748(E), dated the 5th October, 2012, 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 the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the Gazette in which the said notification was published were made available to the public on the 5th October, 2012;

And whereas, the Drugs Technical Advisory Board has been consulted in the matter;

And whereas, the objections and suggestions received from the public on the said draft rules were considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), 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:—

1. (1) These rules may be called the Drugs and Cosmetics (3rd Amendment) Rules, 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

(3) Notwithstanding anything contained in sub-rule (2), the licensees who are manufacturing single active ingredient drug formulation on the commencement of these rules shall make application for grant of licence for the drug formulation containing single active ingredient in proper name within one year of the commencement of these rules.

2. In the Drugs and Cosmetics Rules, 1945,—

(a) in rule 71, after sub-rule (7), the following sub-rule shall be inserted, namely:—

"(8) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient only in proper name.";

(b) in rule 71A, after sub-rule (3), and before the proviso, the following sub-rule shall be inserted, namely:—

"(4) The application for grant of licence for a drug formulation containing single active ingredient shall be made only in proper name.";

(c) in rule 71B, after clause (iv), the following proviso shall be inserted, namely:—

"Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made only in proper name.";

(d) in rule 76, after sub-rule (8), the following sub-rule shall be inserted, namely:—

"(9) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient only in proper name.";

(e) in rule 76A, the following proviso shall be inserted, namely:—

"Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made only in proper name."

[F. No. X.-11014/5/2011-DFQC]

K. L. SHARMA, Jt. Secy.

Note : The principal rules were published in the Gazette of India, *vide* notification No. F. 28-10/45-H (1), dated the 21st December, 1945 and last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), *vide* number G.S.R. 346(E), dated the 21st May, 2014.