

1. (1) इन नियमों का संक्षिप्त नाम औषधि और प्रसाधन सामग्री (पहला संशोधन) नियम, 2018 है।
(2) ये नियम 13 सितंबर, 2018 की तारीख को प्रवृत्त होंगे।
2. औषधि और प्रसाधन सामग्री नियम, 1945 के नियम 96 में, उपनियम (1) में, खंड (i) में, उप-खंड (क) में, "इस उद्देश्य के लिए" शब्दों से आरंभ होने वाले और "नाम और होगा" शब्दों के साथ समाप्त होने वाले भाग के लिए, "इस प्रयोजन के लिए, औषधि का उचित नाम अथवा विटामिन के निर्धारित खुराक संयोजन के अलावा निर्धारित खुराक संयोजन औषधि संयोजन तथा तीन या इससे अधिक औषधि वाले अन्य निर्धारित खुराक संयोजनों को साफ अक्षरों में मुद्रित किया जाएगा अथवा लिखा जाएगा, जो समान फॉन्ट में होगा लेकिन ब्रांड नाम अथवा व्यापारनाम, यदि कोई हो, से आकार में कम से कम दो फॉन्ट बड़ा होगा, तथा अन्य मामलों में ब्रांड नाम या ट्रेड नाम, यदि कोई हो, नीचे कोष्ठकों में या उचित नाम के बाद लिखा जाएगा" शब्द रखे जाएंगे।

[फा. सं. X.11014/5/2017-डीआरएस]

सुनील शर्मा, संयुक्त सचिव

टिप्पण: मूलनियम अधिसूचना संख्या एफ.28-10/45-एच(1), तारीख 21 दिसम्बर, 1945 में प्रकाशित किये गए थे और सा.का.नि. 1380(अ.), तारीख 10 नवम्बर, 2017 अधिसूचना द्वारा संशोधित किये गए।

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 13th March, 2018.

G.S.R. 222 (E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (I) of sections 12 and sub-section (I) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare, number G.S.R. 302 (E), dated the 30th March, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from 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 copies of the Gazette were made available to the public on 30th March, 2017;

And whereas, objections and 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 the section 12 and section 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 (First Amendment) Rules, 2018.
(2) They shall come into force on the 13th day of September, 2018.
2. In the Drugs and Cosmetics Rules, 1945, in rule 96, in sub-rule (1), in clause (i), in sub-clause (A), for the portion beginning with the words "For this purpose" and ending with the words "name and shall be", the words "For this purpose, the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name and shall be" shall be substituted.

[F. No. X.11014/5/2017-DRS]

SUNIL SHARMA, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification No.F.28-10/45-H (1), dated 21st December, 1945 and last amended vide notification number G.S.R. 1380(E), dated the 10th November, 2017.