स्वास्थ्य एवं परिवार कल्याण मंत्रालय
(स्वास्थ्य एवं परिवार कल्याण विभाग)
बाधितवाचन
नई दिल्ली, 24 जून, 2019

सा.का.नि. 447(अ)—सरकार और प्रसाधन सामग्री नियम, 1945 का और संशोधन करने के लिए, क़रीबी निम्नांकनों के निर्देशित प्रारूप, जिनमें केंद्रीय सरकार की अधिकतनीक सहायता जेबों के परामर्श से औपचारिक और प्रसाधन सामग्री अधिनियम, 1940 (23 के 1940) की धारा 12 की उप-धारा (1) और धारा 33 की उप-धारा (1) द्वारा प्रवेश शक्तियों का प्रयोग करने हुए, इसके द्वारा प्रभावित होने की संभावना वाले सभी व्यक्तियों की मानकारी के लिए प्रकाशित किया जाता है और एकदम द्वारा सूचना दी जाती है कि उक्त प्रारूप निम्नांकन पर उस तारीख से तीस दिनों की अवधि समाप्त होने पर या उसके
बाद विवाद किया जाएगा जिस तारीख की इन प्रारूप निम्नांकन वाले भारत के राज्य की प्रत्येक जनता को उपलब्ध कराई जाएगी;

केंद्रीय सरकार द्वारा उपर्युक्त निर्दिष्ट अवधि के भीतर किसी भी व्यक्ति ने प्राप्त होने वाले आपत्तियां और मुद्दाओं पर
विवाद किया जाएगा;

आपत्तियां और मुद्दाओं को चाहे जाँच के लिए (औपचारिक), स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत
सरकार, कमरा सं. 414ए, डी विंग, निर्माण भवन, नई दिल्ली - 110011 को अंतर्निष्ठ किया जाए और द्वारा drugsdiv-
mohfw@gov.in पर ई-मेल किया जाए।

प्रारूप नियम

1. (1) इन निम्नांकनों की औपचारिक और प्रसाधन सामग्री (………………..संशोधन) नियम, 2019 कहा जाएगा।
   (2) ये नियम आधिकारिक राज्य में इसके अंतिम प्रकाशन की तारीख को प्रभावी होंगे।
2. The Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs which the Central Government proposes to make in exercise of the powers conferred by sub-section (1) of section 12 and G.S.R. 447(E).—

(i) The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, drugsdiv-mohfw@gov.in.

(ii) The Family Welfare, Government of India, Room No. 414A, D Wing, Nirman Bhavan, New Delhi - 110011 or email at Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

3. The draft in the Gazette of India: Extraordinary (2) They shall come into force on the date of their final publication in the Official Gazette.

4. The draft in the Gazette of India: Extraordinary (1) of the Exercise (xii) of the draft publication in the Official Gazette.

(xiii) (k) The MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th June, 2019

G.S.R. 447(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make in exercise of the powers conferred by sub-section(1) of section 12 and sub-section(1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414A, D Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (……….. Amendment) Rules, 2019.

(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter to be referred as said rules) in rule 2,-

   (i) after clause (e), the following clause shall be inserted, namely:—

   "(ea) 'Marketer' means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution."

   (ii) after clause (ea) the following existing clauses (ea) and (eb) shall be renumbered as (eb) and (ec), respectively.

3. In the said rules, after rule 84D, the following rule shall be inserted, namely:—

   "84E. Responsibility of marketer of the drugs: Any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules."

4. In the said rules, in rule 96, after sub clause (xii) of clause (1), the following sub-clause shall be inserted, namely:—

   "(xiii) (a) the name of the marketer of the drug and its address, in case the drug is marketed by a marketer:

   Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown."

[F. No. X.11014/22/2018 -DR]

Dr. MANDEEP K. BHANDARI, 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. ..........(E) dated.............