रजिस्ट्री सं० डी० एल०-33004/99

REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप खण्ड (i)

PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 684] नई दिल्ली, सोमवार, दिसम्बर, 22, 2014/पौष 1, 1936

No. 684] NEW DELHI, MONDAY, DECEMBER 22, 2014/PAUSHA 1, 1936

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 22 दिसम्बर, 2014

सा.का.नि. 908 (अ).—ओषधि और प्रसाधन सामग्री नियम, 1945 का और संशोधन करने के लिए कतिपय नियमों का प्रारूप, जिसे ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 33 के साथ पठित धारा 12 द्वारा यथापेक्षित भारत सरकार के स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य और परिवार कल्याण विभाग) की अधिसूचना सं. सा.का.नि. 312(अ), तारीख 5 मई, 2014 को, भारत के राजपत्र, असाधारण, भाग II, खंड 3, उपखंड (i), तारीख 5 मई, 2014 में प्रकाशित किया गया था और उन सभी व्यक्तियों से, जिनके उससे प्रभावित होने की संभावना थी, उस तारीख से, जिसको उक्त अधिसूचना वाले राजपत्र की प्रतियां जनता को उपलब्ध करा दी गई थीं, पैंतालीस दिन की अवधि की समाप्ति से पूर्व आक्षेप और सुझाव मांगे गए थे ;

और राजपत्र की प्रतियां, 12 मई, 2014 को जनता को उपलब्ध करा दी गई थीं ;

और उक्त नियमों के बारे में, जनता से कोई आक्षेप और सुझाव प्राप्त नहीं हुए थे ;

अतः, अब, केंद्रीय सरकार, ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 33 के साथ पठित धारा 12 के अधीन प्रदत्त शक्तियों का प्रयोग करते हुए, ओषधि तकनीकी सलाहकार बोर्ड से परामर्श करने के पश्चात् ओषधि और प्रसाधन सामग्री नियम, 1945 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात् :—

5049 GI/2014

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 22nd December, 2014

G.S.R. 908 (E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with 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. 312(E), dated the 5th May, 2014, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 5th May, 2014, 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 of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 12th May, 2014;

And whereas, no objections and suggestions were received from the public on the said rules;

Now, therefore, in exercise of the powers conferred under section 12 read with 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 (7th Amendment) Rules, 2014.

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

2. In the Drugs and Cosmetics Rules, 1945, in rule 3A, for sub-rule (8), the following sub-rule shall be substituted, namely:—

   "(8) (a) The functions of the Laboratory in respect of the following kits or class of drugs shall be carried out at the National Institute of Biologicals, Noida and the functions of the Director in respect of the said drugs or class of drugs shall be exercised by the Director of the said institute.

   (b) The kits or class of drugs referred to in clause (a) are-

   (1) Blood grouping reagents.
   (2) Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus.
   (3) Blood products-
      (a) Human Albumin;
      (b) Human Normal Immunoglobulin (intramuscular and intravenous);
      (c) Human Coagulation Factor VIII;
      (d) Human Coagulation Factor IX;
      (e) Plasma Protein Fractionation;
      (f) Fibrin Sealant Kit;
      (g) Anti Inhibitor Coagulation complex.
   (4) Recombinant products such as-
      (a) Recombinant Insulin and Insulin analogues;
      (b) r-erythropoietin (EPO);
      (c) r-Granulocyte Colony Stimulating Factor (G-CSF).
   (5) Biochemical kits-
      (a) Glucose Test Strips;
      (b) Fully automated analyser based glucose reagents.".

[F. No. A.11018/6/2011-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 vide notification number G.S.R. (E), dated the 12th December, 2014

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054