



DRUGS & COSMETICS

Shakun Sl.No.2

-COPY OF- NOTIFICATION

Dated 2nd February, 2007



FS - 94454
ISO 9001:2000 Certified
British Standards Institution

The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, after consultation with the Drugs Technical Advisory Board, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said sections, of the said Act, for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of forty five days from the date on which the copies of the Official Gazette in which this notification is published, are made available to the public;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi-110011;

Any objection or suggestion which may be received from any person with respect to the said draft rules, before the expiry of the period as specified above, will be taken into consideration by the Central Government.

DRAFT RULES

1. (1) These rules may be called the **Drugs and Cosmetics (Amendment) Rules, 2007**.
- (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 referred to as the said rules), in rule 2, clause (j) shall be omitted.
3. In rule 75 A of the said rules, in sub-rule (1),-
 - (a) in the Explanation, for the word and figures "Form 28" occurring at the end, the words, figures and letter "Form 28 and Form 28 D" shall be substituted;
 - (b) after sub-rule (2), the following proviso shall be inserted, namely :-

"Provided that if an item is a notified drug under rule 68 A, the manufacturing unit undertaking manufacture on behalf of the loan licensee shall have a valid manufacturing licence approved by the Central Licence Approving Authority and its manufacture on loan licence shall not affect the quality of the drug."
4. In rule 78 A of the said rules, in sub-rule (1), for the word and figures "Form 28" occurring after the words "owned by the licensee in", the words, figures and letter "Form 28 and Form 28 D" shall be substituted.
5. In rule 94 of the said rules, in sub-rule (1), -
 - (a) in the proviso, for the words "blood products, Narcotic and Psychotropic Substances" the following words shall be substituted, namely:-

"or blood products defined under rule 122 EA";
 - (b) after the proviso, the following proviso shall be inserted, namely:-

"Provided further that where a drug classified as Narcotic Drug or Psychotropic Substance is to be exported under a code number, the same may be permitted by the licensing authority defined under clause (b) of rule 21 on the following conditions, namely:-

 - (i) each consignment of export shall be accompanied with requisite import licence from the importing country;
 - (ii) the applicant shall obtain a no objection certificate from the Drugs Controller, India for manufacture of such formulations to be exported with code number against each export order alongwith certificate from the regulatory authority of the Importing country controlling Narcotics drugs and Psychotropic Substances that they do not have any objection for the import of the drug with code number;

- (iii) the State Licensing Authority shall issue the manufacturing licence for these formulations on each export order on the basis of a no objection certificate from Drugs Controller, India;
- (iv) a no objection certificate shall be obtained from the Drugs Controller, India for export of each consignment; and
- (v) a no objection certificate shall be obtained from the Narcotic Commissioner of India, Gwalior for export of each consignment of the drug."

6. In rule 96 of the said rules, in sub-rule (1),-

- (a) in clause (viii), the words 'and (c) where such drugs are imported, also the number of licence under which the drug is imported, preceded by the words "Import Licence",' shall be omitted;
- (b) after clause (xi), the following clause shall be inserted, namely :-

'(xii) Drugs and their preparations including combinations with other drugs imported into the country shall also bear on the label, the licence number under which the drug is imported, preceded by the words "Import Licence" and the name and address of the importer.'

7. In the said rules, in Schedule A,-

- (a) in Form 17 A, in the opening paragraph, for the figures "19", occurring in the first line after the words "day of", the figures "20", shall be substituted;
- (b) in Form 35, for the entries under the heading "Form 35", the following entries shall be substituted, namely:-

[see rules 65, 67 G, 74, 74 A, 74 B, 78, 78 A, 85 H, 122 P, 142, 142 B, 150 E, 158 and 158 A]"

8. In the said rules, in Schedule K,-

- (i) in item number 5, under the column 'Extent and conditions of Exemption', after entry number (3), the following shall be inserted, namely:-

"(4) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.";

- (ii) in item number 5A, under the column 'Extent and conditions of Exemption', after entry number (4), the following shall be inserted, namely:-

"(5) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.";

- (iii) in item number 31,-

(A) in sub-item (b), for the words and figures "in 15 gm. Tube", the words and figures "in 25 gm. Tube" shall be substituted;

(B) after sub-item (d), the following sub-item shall be inserted namely:-

"(e) All Biochemic combinations (1 to 28), in tablet forms, in sealed original packing of the manufacture."

9. In the said rules, in Schedule S, under the heading 'STANDARDS FOR COSMETICS', after item number 28 and the entry relating thereto, the following item and entry shall be inserted, namely:-

"29. Bathing Bars IS: 13498: 1997".

Sd/-
(Amarjeet Sinha)
Joint Secretary to the Govt. of India

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