



## **DRUGS & COSMETICS**

Shakun Sl.No.3

### **-COPY OF- NOTIFICATION**

**Dated 2<sup>nd</sup> 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) 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.
- In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules), in Part XIII, for the heading "IMPORT OF COSMETICS", the heading "IMPORT AND REGISTRATION OF COSMETICS" shall be substituted.
- For rule 129 of the said rules, the following rules shall be substituted, namely:-

**"129. Registration of cosmetic products imported into the country.**-No cosmetic shall be imported into the country unless the product is registered under rule 129D by the licensing authority appointed by the Central Government under rule 21 to perform the duties of licensing authority under these rules or by any person to whom such powers of the licensing authority may be delegated under rule 22.

**129A. Form and manner of application for Registration Certificate.**-(1) An application for issue of a Registration Certificate for cosmetics intended to be imported into India shall be made in Form 42 either by the manufacturer himself or by his authorised agent in India or by the importer and shall be accompanied by a fee of two hundred and fifty US dollars or its equivalent to Indian rupees for each brand of cosmetic. The application shall be accompanied by a treasury challan as specified in sub-rule (3) and the information and undertaking specified in Schedule D (III) duly signed by or on behalf of the manufacturer.

- (2) An authorization by the manufacturer to his agent in India shall be duly authenticated either in India before a First Class Magistrate or in the country of origin before such an equivalent authority and duly attested by the Indian Embassy in that country where the manufacturing is located.
- (3) The fees shall be paid through a challan in the designated branches of Bank of Baroda either in US dollars or in equivalent Indian rupees under Head of Account "0210-MEDICAL AND PUBLIC HEALTH, 04-PUBLIC HEALTH, 104-FEES AND FINES" and the original copy of the treasury challan shall be submitted along with the application for product registration:

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210- MEDICAL AND PUBLIC HEALTH, 04 PUBLIC HEALTH, 104-FEES AND FINES" and the original receipt of the said transfer shall be treated as an equivalent to the bank challan subject to the approval by the Bank of Baroda that they have received the payment.

- (4) The applicant shall be liable for the payment of a fee of five thousand US dollars for expenditure as may be required for inspection or visit of the manufacturing premises of the cosmetic manufacturer by the licensing authority or by any other person to whom power has been delegated in this behalf by the licensing authority under rule 22.
- (5) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of cosmetic.
- (6) A fee of one hundred US dollars or its equivalent shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

**129B. Registration Certificate for the import of cosmetics manufactured by one manufacturer.-** A single application may be made and a single Registration Certificate in Form 43 may be issued in respect of import of one or more than one cosmetics manufactured by the same manufacturer:

Provided that the cosmetics are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit.

**129C. Grant of Registration Certificate.-** (1) On receipt of an application for Registration Certificate in the Form and manner specified in rule 129A, the licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 43:

Provided that if the application is complete in all respects and information specified in Schedule-D III is in order. the licensing authority shall, within six months from the date of receipt of an application, issue such Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months, as the licensing authority may deem fit.

- (2) If the applicant does not receive the Registration Certificate within the period as specified above, he may appeal to the Central Government and the Central Government may after such enquiry into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.

**129D. Duration of Registration Certificate.-** A Registration Certificate, unless it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue:

Provided that if application for a fresh Registration Certificate is made six months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.

**129E. Suspension and cancellation of Registration Certificate.-** If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons therefore, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly or in respect of some of the cosmetics to which it relates:

Provided that a person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government and the Central Government may after such enquiry into the matter as it considers necessary and after giving the said appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.

**129F. Prohibition of import of certain cosmetic.-** No cosmetic, the manufacture, sale or distribution of which is prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis.

**129G. Standard for imported cosmetics.-** No cosmetic shall be imported unless it complies with the specifications as prescribed under Schedule-S or any other standards of quality and safety, applicable to it, and other provisions under the rules.

**129H. Labelling and Packing of Cosmetics.-** No cosmetic shall be imported unless it is packed and labelled in conformity with the rules in Parts XV."

4. In Schedule A to the said rules, after Form 41, the following Forms shall be inserted namely:-

**"Form 42  
(See rule 129 A)**

Application for issue of Registration Certificate for import of cosmetics into India under the Drugs and Cosmetics Rules, 1945.

I/We\* .....  
(Name and full address) hereby apply for the grant of Registration Certificate to the manufacturer, M/s..... (full address with telephone, fax and e-mail address of the foreign manufacturer) for his manufactured cosmetics meant for import into India.

1. Name of cosmetics along with their brand name and pack size for registration.

- |     |     |
|-----|-----|
| (1) | (4) |
| (2) | (5) |
| (3) | (6) |

2. I We\* enclose herewith the informations and undertakings specified in Schedule-D III duly signed by the manufacturer for grant of Registration Certificate for the premises stated below:

3. A fee of ..... for registration of cosmetics for import as specified at Serial No. 2 above has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central" vide Challan No.....dated.....(attached in original).

4. Particulars of premises to be registered where manufacture is carried on :

Address(es) .....

Telephone .....

Fax .....

E- mail .....

I/we undertake to comply with all the terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place: .....

Date: .....

Signature.....

Name.....

Designation.....

Seal/Stamp of manufacturer or his authorised agent in India

(Note:- In case the applicant is an authorised agent of the manufae<sup>r</sup> -er in India, the Power of Attorney is to be enclosed)

\*Delete whichever is not applicable.

## Form 43

(See rule 129 C)

## Registration Certificate

**Registration Certificate to be issued for import of cosmetics into India under Drugs and Cosmetics Rules, 1945.**

Registration Certificate No..... Date.....

M/s .....(Name and full Address of registered office)  
 ..... having factory premises at.....(full address) has been  
 registered under rule 129 C as a manufacturer and is hereby issued this Registration Certificate.

2. Name(s) of cosmetics, along with their brand names and pack size which may be imported under this Registration Certificate.

(1)

(2)

(3)

3. This Registration Certificate shall be in force from ..... to ..... unless it is sooner suspended or cancelled under the Rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorised importer/distributor/agent in India M/s (name and full address) .....who will be responsible for the business activities of the manufacturer, in India in all respects.

5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Act and the rules, from time to time.

Place: .....

Date: .....

LICENSING AUTHORITY  
 Seal/Stamp

**Conditions of the Registration Certificate**

- (1) The Registration Certificate shall be displayed at a prominent place by the authorised importer/distributor/agent.
- (2) The manufacturer or his authorised importer/distributor/agent in India shall inform the licensing authority forthwith in the event of any administrative action taken viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any cosmetic pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed/sold or distributed.

The dispatch and marketing of the cosmetic in such cases shall be stopped and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of cosmetic shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.

- (3) The manufacturer or his authorised agent/importer/distributor in India shall inform the licensing authority within 30 days, in writing, in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the cosmetic pertaining to this Registration Certificate.

In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent/importer/distributor in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee.

- (4) The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing, in the event, of any change in the constitution of the firm and/or address of the registered office/factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless in the mean time, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the first and/or changed address of the registered office or factory premises."
5. After Schedule D (II) to the said rules, the following Schedule shall be inserted, namely:

**"SCHEDULED (III)**

(See rule 129 A)

**INFORMATION AND UNDERTAKING REQUIRED TO BE SUBMITTED BY THE MANUFACTURER OR HIS AUTHORISED IMPORTER/DISTRIBUTOR/AGENT WITH THE APPLICATION FORM FOR A REGISTRATION CERTIFICATE. THE FORMAT SHALL BE PROPERLY FILLED IN FOR EACH APPLICATION IN FORM 42 AND FURNISHED**

**1. PARTICULARS OF THE MANUFACTURER AND MANUFACTURING PREMISES**

- 1.1 Name and address of the manufacturing premises (telephone No., Fax No. e-mail address) to be registered.
- 1.2 Name(s) and address(es) of the Partners/Directors,
- 1.3 Name and address of the authorised importer/distributor/agent in India, responsible for the business of the manufacturer.
- 1.4 A brief profile of the manufacturer's business activity, in domestic as well as global market.

**2. PARTICULARS OF THE COSMETICS TO BE REGISTERED UNDER REGISTRATION CERTIFICATE.**

- 2.1 Names of cosmetics along with their brands name and pack size to be registered meant for import into and use in India.
- 2.2 Particulars of the manufacturing licences/registration/marketing authorisations (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licences/marketing authorisation/registration issued by the Regulatory Authority of that country.
- 2.3 List of countries where marketing authorisation or import permission for the said cosmetic is granted with date.

**3. CHEMICAL INFORMATION OF COSMETIC**

- 3.1 Name(s) of chemicals used in the manufacture of cosmetic.
- 3.2 Specification and testing method for testing of the cosmetics.
- 3.3 Manner of labelling as per the rules of the Drugs and Cosmetics Rules, 1945.
- 3.4 Package insert (if any).

**4. UNDERTAKING TO DECLARE THAT**

- 4.1 We shall comply with all the conditions imposed on the Registration Certificate for the import of cosmetics as required under the provisions of Drugs and Cosmetics Rules, 1945.
- 4.2 We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.
- 4.3 We shall comply with the provisions of Part XIII of the Drugs and Cosmetics Rules, 1945.
- 4.4 Every cosmetic manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs and Cosmetics Rules, 1945 as amended from time to time.
- 4.5 We shall from time to time report for any change or manufacturing process, or in packaging, or in labelling, or in testing, or in documentation of any of the cosmetics, pertaining to the Registration Certificate to be granted to us. Where any change in respect of any of the cosmetics under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the licensing authority, in writing, within 30 days from the date of such changes.
- 4.6 We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawals regulatory restriction, or cancellation of authorisation and/or "not of standard quality report" of any cosmetic pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the cosmetic is marketed/sold or distributed. The despatch and marketing of the cosmetic in such cases, shall be stopped and the licensing authority shall be informed immediately.
- 4.7 We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made thereunder.
- 4.8 We shall allow the licensing authority and/ or any person authorised by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any cosmetic manufactured by us for which the application for Registration Certificate has been made. We further undertake that the applicant may be required to deposit inspection fee as stipulated under Rule 129A (4) to enable the inspection of manufacturing site by the officials authorised for this purpose. Non-compliance to this condition as and when so directed would result in cancellation of Registration Certification.
- 4.9 We shall allow the licensing authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the licensing authority.

The information submitted above is true to the best of my/our knowledge and belief.

Place:

Date:

Signature of the Manufacturer  
Seal/Stamp"

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

G.S.R.63(E)

F.No.X-11014/4/2006-DMS & PFA

Issued by:

Ministry of Health and Family Welfare

(Department of Health)

New Delhi

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