

MINISTRY OF HEALTH AND FAMILY WELFARE**(Department of Health)****NOTIFICATION**

New Delhi, the 19th May, 2010

G.S.R. 426(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), at pages 6 to 11 of the Gazette of India Extraordinary, Part II, Section 3, Sub-Section (i) dated the 2nd February 2007, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number GSR 63(E) dated the 2nd February 2007 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 copies of the Official Gazette containing the said notification were made available to the public;

And, whereas copies of the said official Gazette were made available to the public on the 6.2.2007;

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 sections 12 and 33 of the said Act, 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 (4th Amendment) Rules, 2010.
- (2) They shall come into force with effect from 1st day of April 2011.

2. 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.
3. In the said rules, for rule 129, the following rules shall be substituted, namely:-

"129. Registration of cosmetic products imported into the country.-

No cosmetic shall be imported into India unless the product is registered under the rules by the licensing authority appointed by the Central Government under rule 21 or by any person to whom such powers 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 or importer in India or by the subsidiary in India authorised by the manufacturer 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) along with the information and undertaking as specified in Schedule D (III) duly signed by or on behalf of the manufacturer or by his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer.

(2) An authorisation 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.

(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-FESS AND FINES" and the original copy of the treasury challan shall be submitted alongwith 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-FESS 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 testing fees directly to a testing laboratory approved by the Central Government, as may be, required for examination, tests and analysis of cosmetics.

(5) 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.

129 B. 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.

129 C. 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, if satisfied, issue a Registration Certificate in form 43 subject to the conditions of the registration certificates 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 within six months before the expiry of the said certificate, the existing Registration Certificate shall be deemed to continue to remain 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 therefor, 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 of being heard pass orders 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 prescribed under Schedule S and Schedule Q or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case the cosmetic is not included under Schedule S, it shall meet with specifications under the rules and standards applicable to it in the country of origin.

129H. Labeling and Packing of Cosmetics.- No cosmetic shall be imported unless it is packed and labeled in conformity with the rules in Parts XV. Further the label of imported cosmetics shall bear registration certificate number of the product and the name and address of the registration certificate holder for marketing the said product in India".

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. Names of cosmetics along with their brand name and pack size(s) and variants for registration.

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

2. I/We* enclose herewith the information and undertaking 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 number .2 above has been credited to the

Central 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 authorized agent in India.

(Note:- In case the applicant is an authorized agent of the manufacturer 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(s) and variants which may be imported under this Registration Certificate.

(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 agent or importer in India or by the subsidiary in India authorised by the manufacturer, namely:- M/s (name and full address) _____ who shall 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 Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time in this regard.

Place: _____

Date: _____

LICENSING AUTHORITY

Seal/Stamp

Conditions of the Registration Certificate

1. The Registration Certificate shall be produced by the authorised importer/distributor/agent as and when required by the licensing authority/regulatory authority.
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 namely, 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 or subsidiary in India shall inform the licensing authority within 30 days, in writing, in the event of additional variant/additional cosmetic category/additional manufacturing location or any change in labeling or in testing, or in documentation of any of the cosmetic pertaining to this Registration Certificate.

In such cases, where there shall be any additional variant/additional cosmetic category/additional manufacturing location, as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent/importer/distributor/subsidiary in India shall apply for 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 meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises."

5. In the said rules, after SCHEDULE D (II) the following Schedule shall be inserted, namely:-

"SCHEDULE D (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.

1. PARTICULARS OF THE MANUFACTURER AND MANUFACTURING PREMISES.-

- (a) Name and address of the manufacturer and manufacturing premises to be registered along with telephone numbers, Fax numbers and e-mail address.
- (b) Name(s) and address of the Partners/Directors.
- (c) Name and address of the authorised importer / distributor / agent in India, responsible for the business of the manufacturer.
- (d) 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.-

- (a) Names of cosmetics along with their brands name, category, pack sizes and variants to be registered and meant for import into and use in India.
- (b) particulars of the manufacturing licenses/ registration/ marketing authorizations (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses/marketing authorization/registration issued by the Regulatory Authority of that country.
- (c) List of countries where marketing authorization or import permission for the said cosmetic has been granted.

3. CHEMICAL INFORMATION OF COSMETICS.-

- (a) Name(s) of ingredients in the nomenclature of standard references, along with percentages contained in the cosmetic.
- (b) Specification and testing method for testing of the cosmetic(s).
- (c) Manner of labelling as per Drugs and Cosmetics Rules, 1945.
- (d) Package insert (if any).

4. UNDERTAKING TO DECLARE THAT.-

- (a) 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.
- (b) 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.

(c) We shall comply with the provisions of Part XIII of the Drugs and Cosmetics Rules, 1945.

(d) Every cosmetic manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time.

(e) We shall inform to the licensing authority, within 30 days in the event of any change in variants or in category or in manufacturing location or in labelling or in documentation of any of the cosmetic pertaining to the certificate to be granted to us.

(f) 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.

(g) 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.

(h) 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 or
his authorized agent
Seal/Stamp"

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

VINEET CHAUDHRY, Jt. Secy.

Foot Note : The Principal rules were published in the Gazette of India *vide* Notification No. F. 28-10/45-H(I) dated 21st December, 1945 and last amended *vide* notification number G.S.R. 376(E) dated the 3rd May, 2010.