

F. No. A-11019/53/2011-NMPB
Government of India
Ministry of Health & Family Welfare
Department of (AYUSH)
(NATIONAL MEDICINAL PLANTS BOARD)

Room No. 309, 3rd Floor,
AYUSH Bhawan, B-Block,
GPO Complex, INA Market,
New Delhi - 110 023
E-mail: info-nmpb@nic.in
DATED: NOVEMBER 07, 2013

To,
The Director
Food & Drugs Administration,
Govt. of Goa,
Old IPHB Building, Altinho-403507
(403001 in website of Goa govt.)
Panji- Goa

Subject: Maintenance of records of raw material used by Ayurveda, Siddha and Unani (ASU) Licensed drug Manufacturers.

Sir,

The National Medicinal Plants Board (NMPB), Department of AYUSH has been set-up to coordinate matters related to development of medicinal plants sector and to formulate / implement schemes in this regard. To this end a reliable database of raw material consumed by ASU licensed drug manufacturers is required for formulation of a better implementable policy for development of the sector.

2. As you are aware, Government has amended the Drugs & Cosmetics Rules 1945 requiring the manufacturing units of Ayurveda, Siddha & Unani drugs to maintain and furnish record of the raw material used in the manufacture of their products to the State Drug licensing authorities and to the National Medicinal Plants Board on an annual basis vide notification No. K.11020/2/2006-DCC(AYUSH), dated 09th July, 2008 (copy enclosed).

3. A reference is invited to Rule 157A of the Drugs and Cosmetics Rules, 1945 - reproduced below:-

"157A. Maintaining of records of raw material used by each licensed manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year. Each licensed manufacturing unit of Ayurveda or Siddha or Unani drugs shall be required to keep record of raw material used by each licensed manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year and to submit record in the proforma given in schedule T-1 in respect of all raw materials utilized by that unit in the manufacture of Ayurveda or Siddha or Unani drugs in the preceding financial year, by the 30th day of June of the succeeding financial year with the State Drug Licensing Authority of Ayurveda or Siddha or Unani drugs and National Medicinal Plants Board or any agency nominated by the National Medicinal Plant Board for this purpose.


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4. In this connection, it is hereby informed that NMPB has engaged the services of M/s Centre for Research, Planning and Action (CERPA), New Delhi as the agency for collection and compilation of information on raw material used by industry.

5. In view of the above, you are requested to kindly issue a circular along with a set of enclosed Schedule T Proforma to all manufacturers of Ayurveda or Siddha or Unani drugs and their associations with instructions to furnish the requisite information to your Office and M/s CERPA, New Delhi in respect of the years 2010-11, 2011-12 and 2012-13. Address of M/s CERPA for communication:

**The President,
Centre for Research, Planning and Action (CERPA),
16, Dakshineswar, 10, Hailey Road, New Delhi-110001.
E-mail: nmpb.cerpa@gmail.com, spahuja@nde.vsnl.net.in
Fax: 011-23329216**

6. For any clarification or further information contact may be made either to:
- (1) Manager (Marketing & Trade) – Tel: 24651300 or Assistant Advisor (Botany) – Tel: 24651821 of National Medicinal Plants Board, Department of AYUSH, Room No. 309, 3rd Floor, AYUSH Bhawan, B-Block, GPO Complex, INA Market, New Delhi – 110023.
 - (2) The President or Sh. Rajendra Singh, Director, Centre for Research, Planning and Action (CERPA), 16, Dakshineswar, 10, Hailey Road, New Delhi-110001; Phones: 011-23326955, 23355170, Fax 23329216, Email: nmpb.cerpa@gmail.com, spahuja@nde.vsnl.net.in
7. You are also requested to forward a copy of the above said circular to this office along with a list of the manufacturers of Ayurveda or Siddha or Unani drugs and their associations with complete addresses, phone numbers, Email IDs etc. enabling us to follow up the matter.
8. You are mandated under Rule 157A of the Drugs and Cosmetics Rules 1945, to maintain and regularly update this record at your end and upload the same on your website.


(Meenakshi Negi)
Dy. CEO

Encl. Schedule T Proforma

Copy to: The President, Centre for Research, Planning and Action (CERPA), 16, Dakshineswar, 10, Hailey Road, New Delhi-110001 (Email: nmpb.cerpa@gmail.com)

(28) 12/11/08

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy)

NOTIFICATION

New Delhi, the 9th July, 2008

G.S.R. 512(E).—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, dated the 19th October, 2006, vide Number GSR 651 (E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft will be taken into consideration after 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, the said Gazette was made available to the public on the 18th October, 2006;

And whereas, objections and suggestions received from the public on the said draft rules Drugs & Cosmetics Act, 1940 (23 of 1940) have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 33-N of the Drugs & Cosmetics Act, 1940 (23 of 1940) the Central Government, after consultation with the Ayurveda, Siddha and Unani 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 Drug and Cosmetics (First Amendment) Rules, 2008.
(2) They shall come into force from the date of their publication in the Official Gazette.
2. In the Drug and Cosmetics Rules, 1945 (herein referred to as the said rules), after rule 157, the following rule shall be inserted, namely: -
"157A. Maintaining of records of raw material used by licensed manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year. Each licensed manufacturing unit of Ayurveda or Siddha or Unani drugs shall keep a record of raw material used by each licensed manufacturing unit of Ayurveda, Siddha or Unani drugs the case may be in the performa given in Schedule TA in respect of all raw materials utilized by that unit in the manufacture of Ayurveda or Siddha or Unani drugs in the preceding financial year, and shall submit the same by the 30th day of June of the succeeding financial year to the State Drug Licensing Authority of Ayurveda, Siddha and Unani drugs and to the National Medicinal Plants Board or any agency nominated by the National Medicinal Plant Board for this purpose"
3. In the said rules, after Schedule T, following Schedule shall be inserted, namely: -

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"Schedule TA
(See rule 157 A)

Form for record of utilization of raw material by Ayurveda or Siddha or Unani licensed manufacturing units during the financial year.

Identification Particulars:

Manufacturing License No.....
Issued by.....

Name:

Address:

State: Pin Code:

Telephone: Fax:

Email:

1. Quantity of Medicinal Plants/Extracts/Essential Oils/Metals/Animal By-Products/Minerals Used During 1st April, to 31st March, of the proceeding year (For Productions at the identified facility)

(a). Herbs Used

| Common Name as in AFI/API* | Plant's Botanical Name | Quantity Used/per annum (in Kgs.) | Sources of Supply | | | | Total | Part Used | | | |
|----------------------------|------------------------|-----------------------------------|-----------------------|-------------------|-------------|----------|-------|--------------|------|------|--------|
| | | | Traders/Manufacturers | Forest Collectors | Cultivators | Imported | | Whole plants | Root | Leaf | Others |
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* Ayurvedic Formulary of India/ Ayurvedic Pharmacopoeia of India

(b). Extracts Used

| Name of Extracts | | Quantity Used/ per annum (in Kgs.) | Sources of Supply | | | Total |
|----------------------------|----------------|------------------------------------|-------------------|------------------|----------|-------|
| Common Name as in AFI/API* | Botanical Name | | In-House | Export Suppliers | Imported | |
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* Ayurvedic Formulary of India/ Ayurvedic Pharmacopoeia of India

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(c) Metals/Minerals Used

| Name of Mineral | | Quantity Used / per annum (in Kgs.) | Sources of Supply | | |
|-----------------|---------------|-------------------------------------|---------------------------------|-----------|-------|
| Common Name | Chemical Name | | Manufactures Traders (Domestic) | Importers | Total |
| | | | | | |
| | | | | | |

(d) Animal By-Products Used

| Name of By-Product | | Quantity Used / per annum (in Kgs.) | Sources of Supply | | |
|--------------------|-----------------------------------|-------------------------------------|---------------------------------|-----------|-------|
| Common Name | Biological/Chemical Name (if any) | | Manufactures Traders (Domestic) | Importers | Total |
| | | | | | |
| | | | | | |

2. Shortage of raw material(s)/inputs during the preceeding year.

Yes No

If yes, please indicate name(s) of such raw material(s) by level of importance starting from most important to least important, reason for shortage [availability, quality or any other (please specify)]

| Name of Raw Material | Appro. Qty of shortage (in Kgs.) | Reason |
|---|-----------------------------------|--------|
| Name of the drug and part used as mentioned in official formulary/Pharmacopoeial/Schedule I books | Biological/Chemical Name (if any) | |
| | | |
| | | |

[No. K. 11020/22006-DCC (Ayushi)]

SHIV BASANT, Jt. Secy.

Foot Note: The Principal rules were published in the Gazette of India vide notification number F. 28-10/45-H (I), dated the 21st December, 1945 and subsequently amended vide notification number G.S.R. No. 678(E) dated 31-10-2006.

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