F.No.K-11020/5/97-DCC (AYUSH)
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
(Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)
(AYUSH)

Red Cross Building, 1, Red Cross Road,
New Delhi- 110001,
Dated: October 14, 2005

O R D E R

WHEREAS it has come to the notice of the Government of India in the Ministry of Health & Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) that due to unsatisfactory Agricultural and cultivation practices relating to the medicinal plants used in preparation of Ayurveda, Siddha & Unani (ASU) and general environmental pollution, the presence of heavy metals above the permissible limit therein cannot be ruled out. Therefore, it has become expedient in the interest of public health to introduce mandatory testing for heavy metals for every batch of Ayurveda, Unani and Siddha drug manufactured by all licensees.

Now, therefore, in pursuance of the powers conferred under Section 33 EEB of the Drugs and Cosmetics Act, 1940, (23 of 1940), Government of India in the Ministry of Health and Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy(AYUSH) hereby makes testing for heavy metals namely, Arsenic, Lead, Mercury and Cadmium mandatory for export purposes in respect of every batch of purely herbal Ayurveda, Siddha and Unani drugs by every licensee. Permissible limits for Arsenic, Lead and Cadmium will be as recommended by WHO publication "Quality Control Methods For Medicinal Plants & Materials". In case of Mercury, the permissible limit will be one ppm.

Conspicuous display on the container of purely herbal Ayurveda, Siddha and Unani drugs to be exported the words "HEAVY METALS WITHIN PERMISSIBLE LIMITS" will be mandatory with effect from 1st January, 2006.

ASU Drug manufacturers who do not have in-house laboratory facility shall get their drugs tested by any approved drug testing laboratory.

This is a process of self-certification for export purposes and the A.S.U. drug manufacturer will be held responsible if proper batch-wise testing is not done before self-certification. This process of self-certification would be extended for sale within the country in due course.

(SHIV BASANT)
JOINT SECRETARY TO GOVT. OF INDIA

- **Drug Controller General (India)/All State Drug Controllers/All State Drug Licensing Authorities.**
- **Director General Foreign Trade, Ministry of Commerce/Central Board of Excise & Customs, Ministry of Finance.**
- **All Ayurveda/ Siddha/Unani Drug Manufacturers Associations.**
- **All State Health Secretaries.**

F.No.K-11020/5/97-DCC (AYUSH)
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
(Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)
(AYUSH)
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Red Cross Building, 1, Red Cross Road,
New Delhi- 110001,
Dated: October 13 2005

O R D E R

WHEREAS it has come to the notice of the Government of India in the Ministry of Health and Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) that the Good Manufacturing Practices (GMP) as prescribed for the preparation of Ayurveda, Unani and Siddha (ASU) drugs under Rule 157 of the Drugs & Cosmetics Rules 1945 and Schedule T thereto are not being followed by a very large number of Ayurveda, Siddha and Unani Drug Manufacturers in spite of sufficient time being allowed and financial assistance being provided to the ASU drug manufacturers to become GMP compliant.

Now, therefore, in pursuance of Section 33P of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Government of India in the Ministry of Health and Family Welfare, Department of AYUSH, hereby directs that all the State ASU Drug Licensing Authorities take action against the defaulting ASU drug manufacturers for revocation of their licenses under Rules 157, 158 and 159 of the Drugs & Cosmetics Rules, 1945 for failure to comply with the Good Manufacturing Practices notified under Schedule 'T' of the Drugs & Cosmetics Rules, 1945.

(SHIV BASANT)
JOINT SECRETARY TO GOVT. OF INDIA

Copies to :

. **Chief Secretaries/Health Secretaries of All States/U.Ts.**

. **Drug Controller General (India)/All State Drug Controllers/All State ASU Licensing Authorities/All State Directors of ISM&H.**

. **All Ayurveda/Siddha/Unani Drug Manufactures Associations.**

F.No.K-11020/5/97-DCC (AYUSH)
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
(Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)
(AYUSH)
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Red Cross Building, 1, Red Cross Road,
New Delhi- 110001,
Dated: October 10, 2005,

ORDER

In exercise of the powers conferred under Section 33P of the Drugs & Cosmetics Act, 1940 Government of India in the Ministry of Health and Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) directs the State Licensing Authorities of Ayurveda, Unani and Siddha (ASU) drugs to ensure full compliance by all ASU drug manufacturers of the provisions of Rule 161 (1) and (2) relating to displaying on the label of the container or package of an Ayurveda, Siddha and Unani drug, the true list of all the ingredients (official and botanical names) used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein. In case all the ingredients can not be mentioned on the label because of their large number the same shall be indicated in the leaflet to be inserted in the package. Further that the container of a medicine shall conspicuously display the words 'Caution to be taken under medical supervision' if the list of ingredients contains a substance specified in Schedule E(1) of the Drugs and Cosmetics Rules, 1945. The State ASU Drug Licensing Authorities shall forthwith cancel or suspend the licenses of the defaulting ASU Drug Manufacturers under Rule 159 of the Drugs & Cosmetics Rules, 1945.

(SHIV BASANT)
JOINT SECRETARY TO GOVT. OF INDIA

Copies to :

. **Chief Secretaries/Health Secretaries of All States/U.Ts.**

. **Drug Controller General (India)/All State Drug Controllers/All State ASU Licensing Authorities/All State Directors of ISM&H.**

. **All Ayurveda/Siddha/Unani Drug Manufactures Associations.**