**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health)**

**NOTIFICATION**

New Delhi, the 4th August, 2006

**G.S.R. 471(E).**—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 for the information of all persons likely to be affected thereby, and 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 Bhavan, 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, 2006.

   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs & Cosmetics Rules, 1945

   (1) in Schedule K,—

   (i) for the entries at Serial number 12, the following shall be substituted, namely :—

| CLASS OF DRUGS | EXTENT AND CONDITIONS OF EXEMPTION |
|---|---|
| "12. The follwing commonly used drugs, namely<br>1. Substances intended to be used for destruction of vermin or insects, which cause disease in human beings or animals, viz. insecticides and disinfectants.<br>2. Mechanical contraceptives.<br>3. Vaginal contraceptive pessaries containing Nonoxynol.<br>4. Chemical contraceptive having the following composition per tablet :—<br>(1) DL-Norgestrel-0.30 mg. Ethinyloestradiol-0.03 mg.<br>(2) Levonorgestrel-0.15 mg. Ethinyloestradiol-0.03 mg.<br>(3) Centchroman-30 mg.<br>(4) Desogestrel-0.150 mg. Ethinyloestradiol-0.030 mg.<br>(5) Levonorgestrel-0.1 mg. Ethinyloestradiol-0.02 mg.<br>(6) Levonorgestrel-0.15 mg. Ethinyloestradiol-0.03 mg. Ferrous Fumerate-60 mg.<br>5. Preparations applied to human body for the purpose of repelling insects like mosquitoes.<br>6. Medicated Dressings and Bandages for First Aid.<br>7. Oral Rehydration Salts I.P.<br>8. White or Yellow Petroleum Jelly I.P.<br>9. Nicotine gum containing upto 2mg of nicotine.<br>10. Analgesic balms containing only volatile ingredients.<br>11. Gripe Water for infants. | The provisions of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence subject to the following conditions :<br>(a) No drug shall be sold or stored 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.<br>(b) Drugs shall be purchased from a manufacturer or dealer licensed under these Rules, and records of such purchase shall be maintained.<br>(c) Drugs are stored separately.<br>(d) Drugs are sold in the original unopened container of licensed manufactures, provided that in case of drugs packed in strips, single strips can be sold." |

| CLASS OF DRUGS | EXTENT AND CONDITIONS OF EXEMPTION |
|---|---|
| 12. Inhalers containing essential oils meant for relief of cold and nasal congestion. | |
| 13. Lozenges for sore throat. | |
| 14. Creams for burns containing Silver Sulphadiazine or Acriflavine. | |
| 15. Absorbent cotton wool, bandages, absorbent gauze, adhesive plaster, adhesive tapes. | |
| 16. Castor oil, liquid paraffin, Epsom salt, and psyllium preparations. | |
| 17. Eucalyptus oil I.P. | |
| 18. Antiseptic creams and lotions not containing antibiotics or steroids. | |
| 19. Medicated preparations meant for mouth wash and mouth rinse. | |
| 20. Glycerine I.P. | |
| 21. Skin powder meant for prickly heat. | |
| 22. Paracetamol Tablets I.P. | |
| 23. Iodochlorhydroxy quinoline Tablets 250 mg. | |

(ii) for the entries at 13, the following shall be substituted, namely :—

| | |
|---|---|
| "13. The follwing household remedies, namely<br>(ii) Antacid Prepareations<br>(iii) Syrups, lozenges, pills, tablets for cough, cold and sore throat<br>(iv) Liniments for external use<br>(v) Tincture iodine, Tincture Benzoin Co. and Mercurochrome solution in container not exceeding 100ml.<br>(vi) Gum paints<br>(vii) Calcium preparations with or without Vitamin D | The provisions of Chapter IV of the Act and Rules thereunder, which require them to be covered with a sale licence subject to the following conditions :<br>(a) The drugs do not contain any substance specified in Schedule G, H or X.<br>(b) No Drug shall be sold or stored 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.<br>(c) The Drugs shall be purchased from a manufacturer or dealer licensed under these Rules, and records of such purchase shall be maintained.<br>(d) Drugs are stored separately.<br>(e) Drugs are sold in the original unopened container of licensed manufactures, provided that in case of drugs packed in strips, single strips can be sold." |

(iii) the entries at serial numbers 14, 14A, 15, 25, 26, 27, 28 and 33 shall be omitted.

(2) In Schedule P-1, for the entry relating to 'Progestogen Oestrogen (combinations for oral contraception)', the following shall be substituted, namely :—

| 1 | 2 | 3 |
|---|---|---|
| "Progestogen-oestrogen (Combinations for oral contraception) | Tablets | 21 or 22 with or without 7 placebo/Ferrous Fumerate". |

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