

THE DRUG AND COSMETIC ACT AND RULES

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ACT AND RULES

Introduction

The Drug & Cosmetic Act was passed in 1940 and Rules 1945 with the objective of :

- Regulating Import, manufacture, distribution and sale of drug & cosmetics
- The act provide for the manufacture, distribution and sale of drugs and cosmetics by qualified and trained persons only
- The act regulates the import of drugs in India, so that no substandard or spurious drug will enter into India.

- The act prohibits the manufacture of substandard or spurious drug in the India.
- The act also provide for the control over the manufacture, sale & distribution of Ayurvedic, Siddha, Unani & Homeopathic drugs
- To establish Drugs Technical Advisory Board(DTAB) and Drugs Consultative Committees (DCC) for Allopathic and allied drugs and cosmetics.
- Regular inspection of licensed premises by drug inspectors.

- Act provide special provisions to regulate the preparation, standardization & storage of biological & special products.
- To prescribe the manner of labeling & packing of the various classes of drugs & cosmetics.

DEFINITIONS

❖ Drugs:

All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

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❖ Cosmetic:

Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and includes any article intended for use as a component of cosmetic.

❖ Misbranded drugs: •

- if it is so colored, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
- if it is not labeled in the prescribed manner; or
- if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

❖ **Adulterated drug** : A drug shall be deemed to be adulterated

- if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
- if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
- if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

❖ **Spurious drugs:** A drug shall be deemed to be spurious

➤ If it is imported under a name which belongs to another drug; or

➤ If it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

- If it has been substituted wholly or in part by another drug or substance; or
- If it purports to be the product of a manufacturer of whom it is not truly a product.
- ❖ **Misbranded cosmetic:** A cosmetic shall be deemed to be misbranded
 - If it contains a colour which is not prescribed; or
 - If it is not labeled in a prescribed manner; or
 - If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

❖ **Spurious cosmetic:** A cosmetic shall be deemed to be spurious if

➤ If it is imported under the name which belongs to another cosmetic; or

➤ If it is an imitation of, or is a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly or conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

- If the label or the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist; or ☐ If it purports to be the product of a manufacturer of whom it is not truly a product.

❖ **Patent or proprietary medicine: Means**

- In relation to *Ayurvedic, Siddha or Unani* systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of *Ayurveda, Siddha or Unani* systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as listed in the First Schedule;

➤ In relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board

❖ **Manufacture:** Manufacture in relation to any drug or cosmetic includes

- Any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

❖ **Homeopathic medicines:** Include

- any drug which is recorded in Homeopathic proving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative homeopathic literature of India and abroad and which is prepared according to the techniques of Homeopathic Pharmacy and covers combination of ingredients of such homeopathic medicines but does not include a medicine which is administered by parenteral route.