

COSMETICS AND CONSUMERS

Dr.(Mrs.) Sanju Nanda

M.Pharm, Ph.D. (IITD)

**Department of Pharmaceutical Sciences
Maharshi Dayanand University, Rohtak
(Haryana)**

COSMETICS AND CONSUMERS

The cosmetic and personal care industry has been growing at an average rate of about 15% for the last few years. This is mainly accounted from low and medium priced category products, which comprises of about 90% of cosmetic market, in terms of volume¹.

The demand for cosmetic products, particularly in urban population is steadily rising owing to various reasons, for example, mall culture, better purchasing power, concern for looking better, by both men and women, nature of the job, development in advertisement technology and in general, availability of a wide range of cosmetic products (tailor made for different skin types, hair types, etc.). According to one estimate published by US Commercial Services, American Embassy, New Delhi², the per capita expenditure on cosmetics in India is approximately Rupees Thirty (Rs. 30/-) as compared to Rupees One Thousand Six Hundred and Fifty (Rs.1650/-) in some other asian countries. This low penetration and consumption of cosmetics and personal care products in India can in fact become an opportunity for this industry in future. According to this estimate, the current size of cosmetic and toiletries market is about Rs. 4300/- crores, out of which the fastest growing market is of *colour cosmetics* accounting to Rupees Two Hundred and Seventy Five Crores. Amongst the colour cosmetics, 65% accounts for *nail enamels* and *lipsticks*. The market for lipsticks is about Rupees Ninety Five Crore. The sale of these products has been growing steadily over the years. The *hair care products* account for rupees Nine Hundred Crores.

There has been an increasing trend for use of herbal cosmetics and personal care products especially in skin care segment and it accounts for Rupees Four Hundred and Fifty crores.

Cosmetics³ are substances which are defined under the Drugs and Cosmetics Act 1940 and Rules 1945 as “Articles which are meant to be rubbed, poured, sprinkled, or sprayed on or introduced into or otherwise applied to the human body for the purpose of cleansing, beautifying, promoting attractiveness or altering the appearance.”

Cosmetics are luxury articles and for the past few years, usage of cosmetics has increased multifold, resulting into an increased production, import, distribution and sale of cosmetics. These items may contain some ingredients, the constant use of which might prove to be harmful and hence needs control. *No industry makes more extravagant claims for its products than the cosmetic industry.* According to John Bailey, Director, Office of Cosmetics and Colours, Food and Drug Administration, U.S.A.⁴, *“Cosmetic industry sells an image and consumers can choose to believe those claims or not.”*

The safety of cosmetic products is of prime importance for the general consumers. The cosmetic products have to be formulated and manufactured in accordance with Schedule M-II of Drugs and Cosmetics Act 1940 and Rules 1945 and Indian Standards issued by Bureau of Indian Standards, New Delhi, cGMP guidelines of USFDA as well as guidelines of CTFA (Cosmetic, Toiletries and Fragrance Association), IFRA (International Fragrance Association) and similar bodies.

On a global scale, countries are reaching a consensus on the standards of quality of cosmetics by coming under a common umbrella

of CHIC (Cosmetic Harmonization and International Cooperation) initiated in 1999⁵ and revised from time to time.

Cosmetic products are now considered no less than pharmaceutical products (medicines) in terms of ingredient selection and its quality control. They are also required to follow good manufacturing practices. Validation of processes and equipments, labeling requirement, shelf-life testing, animal testing, etc. are now an essential part of cosmetic manufacturing. Certification from standards regulating bodies like BIS (Bureau of Indian Standards) and ISO (International Organization of Standards) adds to the reputation of the cosmetic manufacturing company. Great emphasis is now being laid on the quality, safety and efficacy of the products and hence the concept of Total Quality Management is widely accepted. Concern for environment and prevention of cruelty towards experimental animals has become a sensitive issue. Most of the countries have banned testing on animals⁶. Countries in the European Union have decided to stop animal testing by 2013.⁷

Consumers of cosmetic products have also become aware of respect towards animals. The concern in this area is not only the use of animals for laboratory testing but also with the use of materials and ingredients derived from animal sources. Due to the growing pressure from vegetarians, religious groups and animal rights groups, there is a requirement of writing '*non-animal tested*', '*contains no animal ingredients*', etc. on the label of the product.

The awareness towards environmental issues together with a trend towards green politics and consumerism has developed public opinion to a degree where products may be accepted or rejected

according to their environmental performance. Controversy concerning the ozone layer and the use of aerosol products is a standing example.

The Drugs and Cosmetics Act 1940 is a Consumer Protection Legislation which is mainly concerned with the standards and quality of drugs and cosmetics manufactured and sold in India.

SALE OF COSMETICS IN INDIA⁸

It is for the information of the readers that cosmetics are exempted from any sales licence, provided that the cosmetics, if of Indian origin, are manufactured by the licensed manufacturers. But there is a prohibition on the manufacture and sale of certain cosmetics, viz.

- i) Any cosmetic, which is not of a standard quality or is misbranded or spurious, or
- ii) Any cosmetic containing any ingredient which may render it unsafe or harmful for use, viz, containing *hexachlorophene, mercury, lead* or *arsenic* compounds as colourants or those containing colours other than prescribed.
- iii) Manufacture and sale of cosmetics is also prohibited unless those have been manufactured in accordance with the condition of a licence issued for the purpose or have been imported in contravention of any legal provision.

MANUFACTURE OF COSMETICS⁹

A person licensed to manufacture cosmetics should comply with the following conditions, as specified in schedule M-II of the Drugs and Cosmetics Act 1940 and Rules 1945. The factory premises should be

situated in hygienic surroundings and kept clean and should be distinct and separate from premises used for residential purposes. The license should possess adequate space, building and equipment for the manufacturing process. The production of cosmetics should be conducted under the direction and personal supervision of competent technical staff who should be a whole time employee and should either hold Diploma in Pharmacy, approved by the Pharmacy Council of India or be a registered Pharmacist under the Pharmacy Act or should have passed intermediate examination with Chemistry. As per the conditions of the license, any change in the technical staff should be reported to the licensing authority. The Drugs and Cosmetics Act 1940 is a punitive Act. Anybody manufacturing cosmetics in contravention of the Act and the Rules is punishable with imprisonment upto one year or fine upto Rupees 1000/- or with both on first conviction and for the manufacture of spurious cosmetics, imprisonment upto three years and with fine. The penalty for subsequent offences in both the case is imprisonment upto 2 years or fine upto Rupees 2000/- or with both (subject to revisions or amendments).

IMPORT OF COSMETICS¹¹

Despite the fact that a rule exists for the import of cosmetics, one can see the market flooded with the so called imported cosmetics, especially coloured cosmetics like *lipsticks*, *nail lacquers*, for example from China, Hong Kong, Singapore, USA, etc. The Rule¹⁰ clearly states that all consignments of cosmetics sought to be imported shall be accompanied by an invoice or statement showing the name and quantities of each article of cosmetic included in the consignment and

the name and address of the manufacturer. However, the import of the following class of cosmetics is prohibited.

- Cosmetics that are not of standard quality.
- Cosmetics containing any harmful or unsafe ingredients.
- **Misbranded** cosmetics, meaning cosmetics which contain colours other than those prescribed or are not labeled in the prescribed manner or make any false or misleading claims.
- **Spurious** cosmetics meaning cosmetics which are substitutes for other cosmetics or resemble other cosmetics in a manner likely to cause deception or are imported under the names of other cosmetics or bear names of manufacturers which are fictitious or who are truly not manufacturers.
- Cosmetics intended for use on the eyebrows or eyelashes or around the eyes containing coal tar dyes or intermediate dyes.
- Cosmetics coloured with arsenic or lead compounds.
- Cosmetics containing *hexachlorophene* or *mercury* compounds.
- Cosmetics whose use is likely to involve any risk to users.

Any product is identified by the contents and information declared on the label of the container. Same holds true for cosmetic products also. Label of a cosmetic product should be prepared in accordance with the provisions of the Drugs and Cosmetic Act 1940 and Rules 1945 (Schedule 'S'). Subject to the provisions of the Act, no person shall sell or distributes any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and labeled and packed in accordance with these rules.

MANNER OF LABELLING¹²

Subject to other provisions of the Rules, a cosmetic shall carry

1. **On both the inner and outer labels**

- a) the name of the cosmetic
- b) the name of the manufacturer and the complete address of the premises where the cosmetic has been manufactured. If the size of the container is very small, where the address of the manufacturer can not be given, the name of the manufacturer and his principal place of manufacture shall be given along with the pin code.

2. **On the outer label**

A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semisolids, combined with numerical count, if the content is subdivided. Provided that this statement need not appear in case of a package of perfume, toilet water or the like, the net content of which does not exceed 60 ml or any package of solid or semisolid cosmetics, the net content of which does not exceed 30 gms.

3. **On the inner label, where a hazard exists**

- a) adequate direction for safe use
- b) any warning, caution or special direction required to be observed by the consumer.
- c) a statement of the names and quantities of the ingredients that are hazardous or poisonous.

4. **A distinctive batch number :-** It is that number by reference to which details of manufacture of the particular batch from which the substance in the container is taken, are recorded and are

available for inspection, the figures representing the batch number being preceded by the letter "B".

5. **Manufacturing licence number** :- the number being preceded by the letter 'M'.
6. Where a package of a cosmetic has only one label, such label shall contain all the information required to be shown on both the inner and outer labels, under these rules.

LABELLING OF HAIR DYES¹³

Hair dyes containing *para-phenylene diamine* (PPD) or other dyes, colours and pigments shall be labeled with the following legend in English and local languages and these shall appear on both the inner and the outer labels.

Caution - The product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying directions should first be made. This product should not be used for dyeing the eyelashes or eyebrows as such a use may cause blindness. Each package shall also contain instructions in English and local languages on the following lines for carrying out the test :

"This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow to it dry. After twenty four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should however be carried

out before each and every application. This preparation should on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result'.

FLUORIDE IN TOOTHPASTES¹⁴

The special provisions relating to the toothpaste containing fluoride are :-

- Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.
- Date of expiry should be mentioned on tube and carton.

COSMECEUTICALS - Cosmetics or Drugs

As the science of cosmetology has advanced, the product performance is expected to improve and the mode of action of products will come under increasing scrutiny. Hence, the definition of products as cosmetic or drug assumes much greater importance. Consequently, the performance and mode of action of the cosmetic product must be carefully considered, since they may well be the determining factors that classify the product as a drug under the purview of various 'Acts' on the basis of claims made and thereby place stringent restrictions on its sale, distribution etc. Products that intend to treat or prevent disease, or otherwise affect structure or function of the human body are considered drugs.

Cosmeceuticals are topical cosmetic-pharmaceutical hybrids¹⁵, intended to enhance the beauty through ingredients that provide additional health-related function or benefit. They are applied topically

as cosmetics, but contain ingredients that influence the biological function of skin.

Though the claims made about drugs are subject to high scrutiny by the Food and Drug Administration (FDA) review and approval process, cosmetics are however not subject to mandatory FDA review. Much confusion exists regarding the status of '*cosmeceuticals*'. Although, there is no legal class called *cosmeceuticals*, this term has found application and recognition to designate the products at the border line between cosmetics and drugs.

Cosmetics that make therapeutic claims are regulated as drugs and cosmetics and must meet the labeling requirements for both¹⁶. For such product, the regulations require that *active ingredients* be listed first on these products, followed by the list of cosmetic ingredients in order of decreasing predominance. *Active ingredient* is the chemical that makes the product effective and the manufacturer must have proof that it is safe for its intended use. Before products with both a cosmetic and drug classification can be marketed, they must be scientifically proven safe and effective for their therapeutic claims. If they are not, FDA may consider them to be misbranded and take regulatory action.

Some countries have the classes of products that fall between the two categories of cosmetics and drugs, for example, Japan has '*Quasi drugs*', Thailand has '*Cosmetic type drugs*'. USA has listed some specialized topical preparations as *over-the-counter* (OTC) drugs on the basis of review of the safety and efficacy of the drug constituents, for example, *antiacne products, antidandruff shampoos, antiperspirants, oral care products, sunscreen products, antiwrinkle creams, fluoridated toothpastes*, etc. **In India, more clearer guidelines are required.**

COSMETICS AND CONSUMERS

A common myth exists about the use of cosmetics that it is predominantly used by the fairer sex, that is, by the females. But the truth is that cosmetics are used by men, women as well as children. Out of the 28 cosmetics that are listed in Schedule 'S'¹⁷ of the Drugs and Cosmetic Rules 1945, they can be categorized widely as

- **Commonly used cosmetics** : Toothpowders, Toothpastes, Hair Oils, Cold creams, Henna, Depilatories, Shampoos, HairDyes.
- **Cosmetics used by men** : Shaving creams, After shave lotions, Colognes, Hair creams, Brilliantine's.
- **Cosmetics used by women** : Lipsticks*, Face powder*, Nail lacquer*, Bindi.

(* These cosmetics are used by men too, especially those who are associated with the glamour world, theatre, cinema and ramp).

Children are also consumers of cosmetics, for example, Baby oil, Baby shampoos, Baby creams, Baby lotions, etc.

Since the consumer population is huge, careful use of cosmetics is required.

Cosmetic industry economics is dependent on the type of advertisement, and nature of image they sell. As a matter of fact, more amount is spent on the advertisement as compared to its quality control. To sell an image, public appeal of famous sportspersons, film stars and models is capitalized, for example, Shah Rukh Khan for Lux, Virendra Sehwaag and his wife for Dabur Toothpaste, to name a few. Kids and senior citizens are also appropriately involved considering their requirement in the selling of their product. Apart from using expensive and decorative containers and attractive labels, colour gimmicking is resorted to in order to strike a psychological cord of the

consumer with the product which he intends to buy. For example, *Black coloured shampoos* with an *amla* figure on the label or *yellow coloured shampoo*, as an *egg shampoo*. Black hairs are an index of beautiful hair in the Indian context. By colouring the shampoo black and putting an image of amla on the label, the consumer is made to believe that by using that particular shampoo, the hairs will receive the goodness of amla.

Similarly, incorporation of yellow colour to an egg shampoo is basically to capitalize on the fact that the shampoo contains egg which is considered nutritive for the hairs. As a matter of fact, these claims are misleading because even if an amla extract is added in a shampoo, it won't get enough time to exhibit its effect. Similarly, in an egg shampoo, the nutritive value may be expected from the white part of the egg, which is made up of a protein called *albumin*. On the contrary, the yellow colour is imparted by egg yolk which is not made up of protein but rather phospholipids and cholesterol. Otherwise also the egg protein will not be effective and nutritive in a shampoo, because shampoos are used and rinsed off within 2-3 minutes from the hairs. This is also not possible because the hairs are not very absorptive in nature as they are made of dead keratinized cells and will not be able to absorb big molecules like egg protein from their surface. Such exaggerations, which are permitted in advertising is generally referred to as **puffery**. But these claims sometimes exceed to such an extent that the consumer is left cheated. For example, incorporation of almond oil in cosmetic products, creams, lotions, shampoos etc. Most of the times it is added as an '*emotional ingredient*' meaning an ingredient whose mention on the label will tempt the customer to buy it. The product may or may not contain almond oil.

WHO WILL FOOT THE BILL ?

Cosmetics are expensive products and the major reason behind the exorbitant cost is the heavy amounts paid to the models, who endorse these products or advertising agencies who produce such advertisements and create a market for the product. Ultimately the person who really pays for all this is the end-user, that is the **consumer**, as all these costs are added to the cost of the product.

The consumer also suffers due to wastage of the cosmetic product. Most of the cosmetic products, for example, toothpastes, foundation creams, moisturizing creams, hair creams and gels, etc. are packed in plastic tubes. These tubes have a basic fault, that is they have an inherent 'suckback' tendency, which holds a lot of product inside the tube. This goes waste as the product does not extrude out easily and the user is forced to throw the container and buy a new one.

The area in which the consumer is most exploited, cheated and misled is the claim of 'Naturals' and 'Herbals' in cosmetic products.

BE CAREFUL WITH 'NATURALS' IN COSMETICS

During the past decades, there has been a dramatic increase in the use of natural products in cosmetics. A wide range of active principle of various plants and animals including *vitamins, hormones, phytohormones, bioflavonoids, enzymes, tannic acid, fruit acids, amino acids, sugars, glycosides, essential oils and dye stuffs* are being considered useful in cosmetic formulations.

However when purchasing drugs, dietary supplements or cosmetics and personal care products, consumers must always be cautious of their effects and possible side effects, even if the product is

labeled “natural”. The commonly held belief that “natural” products come from nature, may be giving consumers a false sense of security about their safety. Just because the products are labeled, or advertised as “natural” does not guarantee that the product is safe or harmless for consumer or safer than similar products not bearing the “natural” label. The California Department of Human Services found in a random sample of herbal stores that nearly one third of these “natural” remedies contained either heavy metals (such as lead, arsenic and mercury) or undeclared pharmaceuticals¹⁸.

In order to understand what the “natural’ label says about a drug or cosmetic product, consumers need to understand how the government regulates the claim of natural. The Government agencies are still working in this direction and hence there are no regulations or guidelines, regarding the use of ‘plant derived’ claims on these products. The poor regulations on cosmetic products as well as their enforcement, not only in India but even in highly developed and aware countries like USA, leaves the customers to be cheated.

There is a need for greater regulation of the “natural” products regarding labeling, advertising and industry standards. **Consumers will not only be interested in regulations for use of such claims but this is also their right.**

These regulations should make it mandatory for the manufacturer to declare on the label, the percent of natural ingredients, the presence of preservatives, antibiotics, chemicals and other additives and the degree of processing.

COSMETICS SOLD AS AYURVEDIC MEDICINES

Many manufacturers of cosmetic products containing herbal ingredients try to bypass the specifications and evaluation Standards laid down by various regulatory agencies like Bureau of Indian Standards by writing on their label “Ayurvedic medicine”. Most of the toothpowders (Dant Manjans) come under this category. A study reported in Journal of Science and Pharmacy¹⁹ reveals that a number of toothpowders available in Indian market as *Dantmanjans* are labeled as Ayurvedic medicine. They are also reported to fail many tests prescribed in IS 5383-1978 (Toothpowders) of the Bureau of Indian Standards, especially, *presence of hard and sharp edged particles*²⁰.

Recently, Maharashtra FDA has taken steps to check this trend by sending show cause notices to **Ozone Pharmaceuticals** for their ‘No Marks’ skin cream and sought certain clarifications from the company²¹. According to FDA officials, the advertised claims of Ozone Ayurvedics, who are the manufacturers of the ‘No Mark’ range of personal care products revealed that the company has been making misleading claims about the ‘No Marks’ cream, as it contains antibacterial and hyperaemic (blood circulation enhancing) agents in it, which comes under the category of drugs.

Hair dyes selling as Kali Mehendi has been found to contain Para Phenylene Diamine (PPD) along with Henna by a consumer activist group and reported in CONSUMER VOICE²².

CONSUMER ‘TIPS’ (While Purchasing Products With Naturals)

- Consumers should not automatically assume that “natural” is always best²³. They should understand the label properly before using the products.

- They should remember that all things 'natural' are not safe. For example, *Lanolin* extracted from sheep wool is a common allergen and an ingredient in many moisturizers.
- Products promoted as 'natural' may always not necessarily be inert. They may many a times be pharmacologically active and quite potent.
- The consumers must check the list of ingredients on the label carefully. They should also try to understand that the 'natural claim on the label is actually a hype or an advertisement or really effective. For example, *almond oil* in a shampoo or *milk* in a baby lotion.
- Consumers must always read the instructions on the label or inserts very carefully before using a natural product. They should also follow instructions very carefully.
- In case of any doubt, they should contact a *Pharmacist* or a *Doctor*.
- Consumers can obtain specific information about a cosmetic ingredient in various references such as the International Dictionary of Cosmetic Ingredients, Internet, etc.
- In case of a grievance, the consumer should have the courage to file a complaint either with the *Drugs Control Office* or the *Consumer Forum*.

COSMETIC PRODUCTS FOR BABIES²⁴ - Some Startling facts

In the recent past, the Maharashtra FDA has been taking a number of consumer goods companies to task on various consumer related issues. The most high profile so far has been the notices sent to *Johnson and Johnson* and *Wipro* for their respective "baby oils" containing mineral oil, believed to be unfit for babies.

FDA, Maharashtra, investigated baby products manufactured by M/s Johnson and Johnson Ltd. on the basis of a complaint received from the parent of a child in Amravati, Maharashtra. The complainant had alleged that he had purchased Baby Oil, Batch Number, BM 3161, D/M Oct. 2003, for his child and the child was massaged by this oil. As a consequence of using this oil, the baby developed blisters on his skin. The use of the said baby oil was stopped on medical advise and thereafter the blisters also subsided. Then a complaint was lodged. As a consequence of the complaint, FDA Maharashtra investigated the complaint by collecting information from Johnson and Johnson, Ltd. relating to product composition, method of manufacturing, method of testing, redressal of public complaints in respect of Johnson's Baby Oil. Since the manufacturer of Johnson Baby Oil made the following label claims as

- a) Vitamin D enriched and
- b) It is the ideal massage oil for your baby. Daily massage has clinically shown to benefit overall growth and development.

The claims of the Johnson's Baby Oil as a massage oil therefore needed to be investigated further for the truthfulness of their claims. FDA Maharashtra also decided to investigate other Johnson Baby Products along with "Johnson Baby Oil" for the label claims. A show cause notice was issued to M/s Johnson and Johnson on 15th March 2005 in respect of all the baby products manufactured by them. The claims made by Johnson and Johnson for their baby cosmetics and FDA's decision on them is tabulated below.

Baby Cosmetics : Johnson & Johnson Ltd., Baby Cosmetics Product

Johnson's Baby Oil

Complaint	Use of this baby oil caused big blisters in the child. Blisters subsided when the product's use was stopped.
Formula	Mineral Oil - 99.785% Tocopheryl Acetate - 0.1% Vitamin A & D 3 Mixture - 0.1% Perfume - 0.015%
Label	No mention of Mineral Oil (light liquid paraffin) on the label
Company's Claim	Vitamin D enriched Ideal massage oil for your baby Daily massage has clinically shown to benefit overall growth and development
FDA's Decision	<ol style="list-style-type: none"> 1. Company did not list all the ingredients on the label 2. Vitamin D in the oil provides no benefits. 3. Baby not benefited by this oil as LLP is irritant

Johnson's Baby Cream

Company's Claim	Protects the skin dryness.
FDA's Claim	No objections to the claim made.

Johnson's Baby Hair Oil

Company's Claim	A light non-greasy hair oil enriched with pro-vitamin B5 that penetrates deep into baby's scalp-Nourishes roots of the hair and keeps baby hair healthy.
FDA's Claim	<ol style="list-style-type: none"> 1. Company has not submitted any data to substantiate their claim of benefit to babies on account of use of Mineral Oil that forms 99.789% of the total composition of the product. 2. Claim of D-Panthenyl Triacetate at 0.11% is not justifiable.

Johnson's Baby Shampoo

Company's	No more tears formula is as gentle to eyes as pure
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Claim	water. Gently cleanses your hair and scalp without stinging your baby's eyes. Added conditioner nourishes and softens baby's fine hair enhancing hair manageability and extra shine. Shampooing with JOHNSON' BABY SHAMPOO (with conditioner) leaves your baby's hair soft and healthy. Gentle enough for daily use.
FDA's Claim	This is an adult product. Claims substantiated by data obtained from clinical trials conducted on adult citizens in USA. This product is a misnomer to be a "Baby Product".

Johnson's Baby Milk Soap

Company's Claim	It contains natural milk extract known for its nourishing properties to help make baby's skin naturally smooth and soft.
FDA's Claim	Milk protein is 0.1% of the total composition - Claim not substantiated by the company.

Johnson's Baby Moisturizing Soap and Johnson's Baby Moisturizing Soap Blossoms

Company's Claim	<ol style="list-style-type: none"> 1. Enriched with goodness of coconut oil, helps moisturize your baby's skin while cleansing it ever so gently 2. Picture of broken Coconuts exhibited on the label.
FDA's Claim	Coconut oil not present as ingredient, hence no claims can be made by company to the goodness of the Coconut oil being available in the soap.

Johnson's Baby Lotion

Company's Claim	<ol style="list-style-type: none"> 1. With special skin oils that nourish, moisturize and leave skin soft and younger looking because 2. Soft skin keeps your age a secret
FDA's Claim	Johnson's Baby Products are basically targeted towards Baby Care, while the claims relate to adults,

	therefore FDA Maharashtra finds no justification for Johnson to make these claims.
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Johnson's Baby Milk Lotion

Company's Claim	Helps nourish skin, leaving it baby soft, smooth and fair.
FDA's Claim	Company's claim is totally misplaced because baby's skin is already soft, smooth and babies do not require cosmetic products for regular use to change the colour of skin.

OTHER COSMETIC COMPANIES HAULED UP BY FDA MAHARASHTRA

- Wipro - Baby Oil
- Emami
- Wipro Consumer care
- Ozone Ayurvedics 'No Marks' Personal Care Products
- R S Hair Care - Ayurvedic Hair Dye

As a provincial regulator, FDA Maharashtra was not empowered to give directions to enforce their observations in respect of all of the baby products.²⁴ However, in the larger public interest, FDA Maharashtra issued the following directions to M/s Johnson and Johnson Ltd. and to other baby product cosmetics manufacturers whom it had issued show cause notices for their baby products.

- 1) Johnson and Johnson's Baby products shall carry prominently safety warnings regarding the side effect that may be caused on account of use of these products due to the presence of chemicals like light liquid paraffin (LLP), isopropyl myrestate, etc.
- 2) Johnson and Johnson shall not make any claim regarding any benefit arising on account of use of the baby products to babies except with the written approval of the Drugs Controller of India

to avoid misbranding under section 17 C (c) of the Drugs and Cosmetics Act.

- 3) FDA Maharashtra gave time to the company till 01/08/2005 to substantiate its claims, failing which it will take action.
- 4) The above stipulations will not be applicable in case the manufacturer chooses to drop the word "Baby" from the title of the product. It can however be sold as a regular cosmetics.
- 5) Similar orders shall be applicable to all the manufacturers of Baby cosmetic products to whom FDA, Maharashtra had issued show cause notice.

A copy of the order issued to M/s Johnson and Johnson Ltd. is also submitted to the Drugs Controller, India, New Delhi for taking necessary legal and administrative action so that uniform action policy will be made applicable to all baby-products cosmetics and there manufacturers throughout India.²⁴

AN ALERT CONSUMER IS AN ASSET TO THE NATION²⁵

Here are described some terms which are enigmatic for the consumers. The consumer is advised not to be carried away by these terms and test each product on a small part of the skin before using it.

- **Hypoallergenic** - it implies that products making this claim are less likely to cause allergic reactions. There are no prescribed scientific studies required to substantiate this claim.
- Likewise, the terms "*dermatologist - tested*", "*sensitivity tested*", "*allergy tested*" or "*non irritating*", carry no guarantee that they won't cause skin reactions. FDA has tried to establish official definitions for the use of certain terms such as "*natural*" and "*hypoallergenic*", but its regulations were overturned in court.²⁶ So

companies can use them on cosmetic labels to mean anything or nothing at all.

The consumers are also informed that few ingredients are either *restricted* or *prohibited* by regulation for use in cosmetics.²⁶ They are :

- Arsenic
- Bithionol
- Mercury compounds
- Vinyl chloride
- Halogenated salicylanilides
- Zirconium complexes in aerosol cosmetic
- Chloroform
- Methylene chloride
- Chlorofluorocarbon propellants
- Hexachlorophene
- Methyl methacrylate monomers in nail polishes
- Phthalates (under scrutiny)²⁷ in nail lacquers.

Consumers should report cosmetics adverse reactions to the Drug Regulatory Bodies of their respective states.

SELF HELP IS THE BIGGEST HELP

Cosmetics generally do not cause serious injuries but sometimes they can be harmful.

Good common sense and a few precautions can help consumers protect themselves against hazards associated with the misuse of cosmetics.

- Never forget that cosmetics are also formulated with a wide variety of chemicals and solvents. Use them minimally.
- Cleanse the skin before going to bed and remove all make-up.

- Never share make-up, especially eye make-up, lipsticks, etc. Ask for a disposable applicator for use.
- Never add liquid to a product to bring back its original consistency. Adding other liquids could introduce bacteria that can easily grow out of control.
- Immediately stop using any product that causes an allergic reaction.
- Throw away make-up, if the colour changes or an odour develops.
- Do not use eye make-up if one has an eye infection. It is always desirable to throw away the used cosmetics, when the infection has occurred.
- It is also suggested not to apply eye make up, while moving in a car or a bus. It may result from a small injury or cut to higher maladies like blindness.
- Keep the cosmetic product away from sunlight. Light and heat can degrade the excipients present in the product, including preservatives and fragrances.
- Keep make-up containers tightly closed when not in use.
- Keep cosmetics out of reach of children.
- Never use aerosol beauty products like hair sprays near heat or while smoking, because they can ignite.
- Be careful while using hair sprays and powders, because these products may act as causative substances for respiratory disorders or may even cause lung damage, if inhaled regularly.

CONCLUSION

The Drugs and Cosmetic Act 1940 is a pre-independence legislation and is expected to regulate two highly profit making industries in India that is the *medicines* and *cosmetics*. As substandard medicines are life threatening, drug regulatory bodies, maintain more strict vigil and monitoring is routinely exercised. Unfortunately, *cosmetic regulations are not very strictly followed*. But it should not be forgotten that use of a spurious or irrationally produced cosmetic product could also seriously harm different parts of the human body. It is quite possible that there could be numerous cases of harmful effects of cosmetics going unreported to authorities.

Recent media reports about a consumer complaint to Maharashtra FDA against Johnson and Johnson's Baby Oil has adequately attracted the public attention to the safety issues of cosmetics used in this country.²⁸ Complaints from consumers, like in the Johnson and Johnson case, bring to fore that there is certainly a need to look at the adequacy of existing rules on cosmetics and their proper implementation. Since there is not system of granting premarket approval for cosmetics in India, as it is done in case of medicines, companies producing cosmetics and toiletry preparations are marketing them without any toxicity studies and clinical trials. Cosmetic products labeled as Baby products are extremely expensive as compared to the traditional products. Aggressive promotion using doctors, nurses, and public-endearing advertisements in the print and electronic media have resulted in these products making deep inroads into the psyche of the largest group, viz., the mothers and young parents. Most of these target group buy these products at fancy prices believing that the products have special attributes that help in the growth, development and health of the babies.

There is a strong requirement for implementation and enforcement of provisions of Drugs and Cosmetic Act 1940 and Rules 1945 in the country which will cover the sale, manufacture, import and labeling of cosmetics. In order to have reasonable safety for cosmetic products, it is also now realized that certain new standards should be laid down to test for the safety of ingredients added in cosmetic products, specially, baby cosmetics. Currently, the list of ingredients listed under GNRAS (Generally Not Recognized As Safe) of Bureau of Indian Standards, needs to be reviewed. The stalwarts of cosmetics industry and regulatory bodies should come forward and unite to develop a fresh list of dangerous or harmful ingredients on the lines of 'Hot List'²⁹ of European Directives of the European Union. Such information should also be made available to the general public.

Exaggerated and misleading label claims on cosmetics, specially with naturals and for fairness creams, is one area where urgent regulatory intervention is called for.

A cosmetic product with a therapeutic claim must be scientifically proven safe and effective for its claims, especially *antidandruff shampoos*, before they are permitted to be marketed.

There should also be clear warning statements on labels even if there is a small chance of a problem. It is the *consumers right to information*. Many a times, the product is being purchased on behalf of the consumer by his mother or somebody else. It is the right of these persons to know about all ingredients present, along with their percentage as well as any adverse reactions. In case of a grievance, the consumer should feel free to take help of any of the following agents.

- **Government** - Drug Control Authorities of their respective States or Central Government.

Consumer Disputes Redressal Agencies (Consumer Courts)

- *District Level* - District Forum (Consumer Disputes Redressal Forum)
- *State Level* - State Commission (Consumer Disputes Redressal Commission)
- *National Level* - National Commission (National Consumer Disputes Redressal Commission)
- **Non-Government Bodies** -
 - CORE* - Consumer Online Resource and Empowerment, (National Consumer Help Line), New Delhi
 - CCC* - Consumer Coordination Council, New Delhi
 - CERS* - Consumer Education and Research Society, Ahmedabad.
 - Any Other NGO*
- **Doctors / Pharmacists**
- **Electronic or Print Media**

An alert consumer is an asset to the nation and by being aware of his rights and responsibilities, he can change the trend from *caveat emptor* (buyer beware) to *caveat venditor* (seller beware).

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