

In the Matter of Rule 17 C (c) of the Drug and Cosmetics Act, 1940.

M/s. Himalaya Drug Company

Order passed by Food and Drug Administration, Maharashtra State, S.No.341, Bandra-Kurla Complex, Bandra(E), Mumbai-51.

No. FDA/A.R./Baby Product/128-05/1

This day of 9th May 2005.

- 1) The events leading to the investigation into the “Baby Products” manufactured by M/s. Johnson and Johnson Ltd. was triggered by a complaint received from Amravati a district head quarter town in the State of Maharashtra. (**Annexure-I**).
- 2) As a part of the larger investigation in to the product quality and product claims of all the “Baby Products” manufactured by all the manufacturers in the industry the **M/s. Himalaya Drug Company**. was also issued a Show Cause Notice No. FDA/A.R./Baby/Wipro/78-05/1 dated 23/03/05 to justify their claims to be a Baby Product and also justify the claims made on the label. (**Annexure II**)
- 3) The company has given its reply. The company has in its written submissions has stated that they are holding the licence bearing No. AUS-83 for the manufacture and sale of Ayurvedic medicines.

A committee comprising of the Commissioner, FDA Maharashtra State, the Joint Commissioner, FDA and Drug Controller, Maharashtra State and the Technical Officer (Ayurvedic), examined the product content and the written explanation of the company.

- 4) FDA Maharashtra got the product analysed and the analysis shows the following composition for the product, Mineral Oil -96% , Vegetable Oil – 4%.
- 5) It is indeed the matter of concern that M/s. Himalaya Drug Care has created Massage Oil as a proprietary Ayurvedic product out of Mineral Oil namely Light Liquid Paraffin. Ayurveda texts and traditions do not talk about Paraffin Oil.
- 6) FDA Maharashtra has checked up with Director of Ayurveda in Maharashtra State who has also confirmed that they use only Til Oil as a massage oil. While we can understand that, Castor Oil, Mustered Oil etc being used in the formulation of an Ayurvedic Products by no stretch of imagination can mineral oil find a place in any Ayurvedic product especially as massage oil.
- 7) M/s. Himalaya Drug Care has totally suppressed the fact that the product “Himalaya Nourishing Baby Oil” contents mineral oil in the list of ingredients.
- 8) M/s. Himalaya Drug Care therefore attract the provision of Section 33EEC, a (ii), a (iii) which empowered the state government to ban the sale of“ Himalaya Nourishing Baby Oil”
- 9) M/s. Himalaya Drug Care have also made the following proprietary claim on the label of the “Himalaya Nourishing Baby Oil”

- a) “An excellent massage oil for the baby,
 - b) The Winter Cherry improves the skin tone
 - c) Aloe-vera moisturizes the skin.
- 10) The company had not submitted any data regarding claim made by them or any literature from Ayurveda text justifying the claims of such a product containing 96% Mineral and 4% Olive Oil with other ingredients in very small quantities to be a massage oil. Therefore we rely on the order made in the matter of M/s. Johnson and Johnson to disprove the claim the company that “Himalaya Nourishing Baby Oil” which is 96% Light Liquid Paraffin is an excellent massage oil.
- 11) FDA Maharashtra now reproduces portions of the order issued in respect of M/s. Johnson and Johnson Ltd. in respect of “Johnson Baby Oil”.
- 12) “The most important claim of the Johnson Baby Oil relates to the claim no.(ii) (It is ideal massage oil for your baby. Daily massage has clinically shown to benefit over all Growth and Development.)

In the well known Text Harry’s Cosmetology 7th Edition, Baby Oils are shown as preparations for cleansing the skin. To quote from the book “They act by forming a thin film protecting the skin against wetting and chaffing. Light Liquid Paraffin is universally recognised as an emollient. The skin of young children and infants has the hazard of nappy or diaper rash arising out of close confining clothes and the uncontrolled urination and defaecation performed by the child at this age. The area in which the excretions are contained by the close fitting nappy provide warm and nutritive environment for proliferation of bacteria that leads to irritation causing discomfort and secondary ulceration. Further the child is susceptible to medical conditions such as eczema etc. requiring medication, It is pertinent to note that nappy rash is unknown in country where diapers are not used and children are left loosely covered with clothes unlike western countries where the children are wrapped in tightly fitting garments”.

It is therefore not surprising that Baby Oil containing entirely Light Liquid Paraffin based cosmetics oils have become popular because of the inherent property of Light Liquid Paraffin as an emollient and as moisturizer. It is also used in light application after bath to combat dryness of the skin.

Before we examine the claim of M/s. Johnson and Johnson regarding the use of the Baby Oil as Massage Oil in India, we would also like to refer to the traditions of massaging babies with vegetable oils. It is an Indian tradition to massage babies with vegetable oil most notably Til Oil. The child is exposed to the morning Sun to get the benefit of Vitamin D. The baby is thereafter given a quick bath. For dry skin and rashes Castor Oil is used as an emollient. The benefits of massaging vegetable oil containing Ayurvedic ingredient are contained in the various Ayurveda Texts.

M/s. Johnson and Johnson claim that Baby Oils have less viscosity and therefore reduced friction making it good for massage. Unlike natural oil it does not get absorbed by the skin nor does it become rancid. Hence makes an ideal massage oil. M/s. Johnson and Johnson have also made available scientific papers listing the benefits of massaging for babies.

We do not agree with the submissions made by M/s. Johnson and Johnson substantiating their claims of Johnson Baby Oil as

“ideal massage oil for your baby. Daily massage has clinically shown to benefit over all Growth and Development” because .

i) We refer to the paper titled **“effect of massage and use of oil on growth blood flow and sleep pattern in infants by professors from the College of Medical Sciences and G.T.B. Hospital Delhi.** and published in the Indian Journal of Medical Research 112, Dec. 2000. PP 212,217. To quote from the study **“ Vegetable Oils appear comparatively better in terms of growth and blood flow. Sesame Oil is better choice for massage as it significantly improved growth as well as blood flow as compared to the Mineral Oil (Johnson Baby Oil) which showed reduced blood flow. The available literature shows that, vegetable oils are well absorbed from the skin while there is negligible absorption of the mineral oil. Further mineral oils may clog the pores the skin. Other reference papers filed by M/s. Johnson and Johnson do not compare the benefits obtained by massage of Mineral Oils vis-à-vis Vegetable Oils on children in India.**

Available literature also show that Sesame Oil is rich in vitamins, carbohydrates, proteins. Its benefits as antioxidants, immunomodulation, on cardiovascular system and gastrointestinal system are also well documented. Treatment of infants with sesame oil are shown to produce remarkable improvement in skin pathology and unlike paraffin oil with no side effect or know adverse reaction.

Thirty-nine complaints were filed with the company between January 2004 to February, 2005 for skin reactions in respect of Johnson Baby Oil. This is a significant number for M/s. Johnson and Johnson to have initiated a safety study on account of massaging of baby oil. FDA Maharashtra believe that consumers purchase Johnson Baby Oil as Massage Oil and further FDA Maharashtra believe that for every complaint received there are a large number of complaints that go unreported due to lack of awareness and generally the indifferent attitude of manufacturers to redress such complaints satisfactorily. BIS specification number IS 4011:1997 at 4.5 talks about carrying restricted consumer test which M/s. Johnson and Johnson could have carried out on Indian Babies. In the Popular book on Baby Care written by Dr. R.K. Anand clearly recommends the use of vegetable oil for massaging and specifically discourage the use of mineral oil on the tender skin of babies for such use.

We had also referred the issue relating to the use of Mineral Oil in Baby Oil to the K.E.M. Hospital, Mumbai and the opinion of the Dean is shown at **Annexure IX.** The Dean K.E.M. Hospital has recommended the following

- a) Full ingredients /contents of the Baby Oil must be displayed on the oil.
- b) The product should carry safety warnings as regarding effects on skin, conditions where it should be avoided and instructions in case of reactions.
- c) If there is any change in safety status in other parts of the world it should also be reflected in the label of the products sold in India.

- d) Massage of the baby with mineral oil has some beneficial effects. However in some cases it irritates skin and allergy and rashes can occur. Suitable warning should be given in the label.

FDA Maharashtra therefore rejects M/s. Johnson and Johnson's claim in respect of Johnson Baby Oil being an ideal Massage Oil. FDA Maharashtra do agree that Baby Oil is an emollient to be applied lightly as a moisturizer and for protection against nappy rashes etc. Any massaging with Mineral Oil must carry an appropriate safety warning".

Cosmetics Products labeled as Baby Products are extremely expensive as compared to the traditional products. Aggressive promotion using medical fraternity and heavy advertisements in the print and electronic media have resulted in these products making deep inroads in to the psyche of the target group viz. the mothers and young parents. Most of these target group buy these products at fancy prices believing that these products have special attributes that add value growth, development and health of the babies.

FDA Maharashtra are not against Johnson and Johnson Ltd., or any other company introducing new products in the country based on new ingredients. However the target consumer's right to information to make informed buying of such products should not be short –circuited. This is particularly true for baby products because the babies for whom these products are intended for use do not have a say in decision making. It is young parents and expectant mothers who make the informed choice whether to go for a traditional products or chemical based products introduced from the west. **For making the informed choice the rights of these persons to full information about all the ingredients present in the product including their percentage should be honored. They are also entitled to full information on adverse reactions and claims validated by the regulatory authorities. This is already being done by the Central Government in respect of Baby Food and therefore it will be appropriate for the Advisor Ayurveda to examine and issue guidelines under labeling rules directing all the manufacturer to declare complete composition of the Baby Products on the lines of Baby Food.**

Based on the above justification in respect of usage of Mineral Oil as Baby Oil we reject the claim of Himalaya Nourishing Baby Oil to be a proprietary Ayurvedic medicine.

As provincial regulator FDA Maharashtra are not empowered to give directions to enforce our observations in respect of all of the Baby Products. However in the larger Public Interest and by virtue of the powers vested under Rule 50 and 51 (2) in the State Drugs Controlling Authority FDA Maharashtra issues the following directions to Himalaya Drug Company.

- 1) The product "Himalaya Nourishing Baby Oil" by virtue of presence of Mineral Oil to the extent of 96% in the product labeled as Proprietary Ayurvedic Medicine attracts 33EEC. Necessary follow up action including prohibition of the sale of "Himalaya Nourishing Baby Oil" shall be issued by the Licensing Authority (Ayurveda), Maharashtra State,
- 2) FDA Maharashtra will restore the Ayurvedic status of product in case the Advisor (Ayurveda) Government of India approves the formulation of Ayurvedic Massage Oil containing 96% Mineral Oil as an Ayurvedic proprietary medicine and advises FDA Maharashtra accordingly.

- 3) Himalaya Drug Company shall not make any claim regarding any benefit arising on account of use of the "Himalaya Nourishing Baby Oil" to babies except with the written approval of the Drugs Controller of India to avoid misbranding under Section 17C (c) of the Drugs and Cosmetics Act.

A copy of this order is also submitted to the Drugs Controller India, Advisor Ayurveda and Secretary, AYUSH for issuing further necessary directions to FDA Maharashtra on this order.

**(A. Ramkrishnan),
Commissioner,
Food and Drug Administration
Maharashtra State, Mumbai.**

**(Dr. Walchale),
Technical Officer (Ayurveda),
Food and Drug Administration, M.S.
And
Licensing Authority Maharashtra State,**

**(A.T.Vhatkar),
Joint Commissioner,(H.Q.),
Food and Drug Administration, M.S.,
And
Drugs Controller, Maharashtra.**

To,
M/s. Himalaya Herbal Health Care Ltd.,

- 1) Smt. Uma Pillai, Secretary, Department of AYUSH, Government of India. New Delhi.
- 2) Shri. Tarachand, Joint Secretary, Department of AYUSH, Government of India. New Delhi.
- 3) Dr. Sharma, Advisor, Ayurveda, Department of AYUSH, Government of India. New Delhi.
- 4) Director of Ayurveda, Karnataka State, Bangalore.
- 5) Drugs Controller General of India, Nirman Bhavan, New Delhi.
- 6) Dr. S.P. Agrawal, Director General of Health Services, Nirman Bhavan, New Delhi.
- 7) P.S. to Minister, Food and Drug Administration, Maharashtra State, Mantralaya, Mumbai-32.
- 8) P.S. to State Minister, Food and Drug Administration, Govt. of Maharashtra, Mumbai.
- 9) Shri. G.S. Gill, Principal Secretary, Medical Education & Drug Department, Mantralaya Mumbai-32.