

In the Matter of Rule 17 C (c) of the Drug and Cosmetics Act, 1940.
M/s. Johnson and Johnson Ltd.

**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/123-05/1
This day of 5th 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) The complainant alleged that, he had purchased Johnson Baby Oil, B.No. B.M.3161, D/M-Oct. 2003 for his child. The Baby Oil was massaged by the complainant on the baby. The baby then developed big blisters. The complainant rushed the baby to the doctor and doctor advised that the use of baby oil should be stopped. Accordingly the complainant stopped the use of baby oil and thereafter the blisters subsided. The complainant lodged a complaint with Johnson and Johnson Ltd. (**Annexure –II**). M/s. Johnson and Johnson Ltd. replied that their products were thoroughly tested for quality and safety to minimise risk for the users. They mentioned that there could be a particular person allergic or unusually sensitive to a specific ingredient present in the oil. M/s. Johnson and Johnson analysed the control samples held with them and came to the conclusion that all was well with the product. M/s. Johnson and Johnson’s representative however did not meet the complainant to understand the clinical reasons for the skin reaction and whether such a reaction was one of the anticipated reactions arising out of the use of “Baby Oil” on babies.
- 3) As a part of regulatory responsibility FDA Maharashtra investigated the complaint by collecting information from Johnson and Johnson Ltd, all the data relating to the product composition, method of manufacturing, method of testing, redressal of public complaints in respect of Johnson’s Baby Oil.
- 4) M/s. Johnson and Johnson Ltd has been issued licence in form –32 and 32A to manufacture Baby Oil with the following composition. **Annexure- III**.
 - i) Mineral Oil 99.785 %
 - ii) Tocopheryl acetate 0.1%
 - iii) Vit. A & D3 mixture 0.1%
 - iv) Perfume 0.015%
- 5) The formula shows that, Johnson’s Baby Oil is almost totally Light Liquid Paraffin to the extent of 99.785% (the company had not even mentioned L.L.P. on the label). Which is a well documented emollient to be applied for rashes, itching and to prevent dryness as a moisturizer.
- 6) Johnson Baby Oil makes the following label claims.
 - a) Vitamin D enriched.
 - b) Clinically mildness proven.
 - c) Pure mild and gentle baby oil which is specially enriched with Vitamin D. It is the ideal massage oil for your baby.

- d) Daily massage has clinically shown to benefit overall growth and development.
- e) Mildly perfumed and non staining .
- 7) The company's specific proprietary claims on the Johnson's Baby Oil as a Massage Oil rest on the 0.215 % of the product composition shown to be added as skin conditioner to Light Liquid Paraffin.
- 8) To ascertain the validity of the claims made by "Johnson's Baby Oil" as a massage oil especially suitable for babies. M/s. Johnson and Johnson was directed to justify the label claim. M/s. Johnson and Johnson submitted the details of the manufacturing protocols, test reports safety to FDA Maharashtra. M/s. Johnson and Johnson also confirmed that, "Johnson Baby Oil" is not a Trade Mark which means that any manufacturer can manufacture and claim a **cosmetics body oil** product to be **Baby Oil**.
- 9) Buying behavior of the "Baby Products" shows that young parents believe the Baby Oil to be a Massage Oil in view of the heavy advertisements made by the manufacturers in the Electronic Media and Print Media. . The claims of the Johnsons's Baby Oil as a Massage Oil therefore needed to be investigated further for the truthfulness of the claim. FDA Maharashtra also decided to investigate other Johnson Baby products alongwith "Johnson Baby Oil" for the label claims.
- 10) 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 (**Annexure –IV**). M/s. Johnson and Johnson was given 15 days time to reply to the show cause notice. M/s. Johnson and Johnson made oral and written submission to the FDA and FDA Maharashtra ring all the points listed in the show cause notice.
- 11) A committee comprising of the Commissioner, FDA Maharashtra State, the Joint Commissioner, FDA and Drug Controller, Maharashtra State and the Technical Officer (Allopathic Products), FDA heard the oral and written submission made by M/s. Johnson and Johnson.ltd.
- 12) The oral hearing took place in the office of FDA Maharashtra on 19/04/2005 and 03/05/2005. M/s. Johnson and Johnson was represented by a team of top Managers namely the Managing Director, Regional Director Medical and Scientific Affairs, the Vice President Technical, General Manager Legal amongst others. The list of the managers representing the Johnson and Johnson is listed at (**Annexure-V**).
- 13) FDA Maharashtra now examined in detail the submissions filed by M/s. Johnson and Johnson in respect of the label claims of all the Baby Products and also on the quality of the products perse.
- 14) In the show cause notice dated 15/03/05 and subsequent correspondence FDA Maharashtra had raised the following issues ..
1. M/s. Johnson and Johnson claim to the various products listed in the show cause notice as "Baby Products" labeled for use by infants and children is not justified.
 2. "Baby Products" manufactured by M/s. Johnson and Johnson are not patented or registered with Trade Mark Authorities as "Baby Product".

3. "Baby Products" manufactured by M/s. Johnson and Johnson do not figure in the list of standardised cosmetics products approved by the BIS.
 4. Ingredients used in the manufacture of "Baby Products" do not contain any ingredient that can be set to be specially suitable to meet the needs of children/infants.
 5. The products have not been tested on children and the data obtained by carrying out clinical trials on adults ranging in age from 19 to 58 years have been utilized to certify the clinical safety of the "Baby products" for children.
 6. "Baby Products" manufactured by M/s. Johnson and Johnson does not have the approval of the Drug Controller of India to be labeled as a "Baby Product".
 7. "Baby Products" have chemicals like Mineral Oil, Isopropyl Myristeate etc, that are used in all the Cosmetics made for adults and therefore the "Baby Products" of M/s. Johnson and Johnson contain no special ingredient to qualify to be "Baby Products"
- 14) The company in its reply made the following submissions.
1. That the "Johnson and Johnson "Baby Products" are being manufactured all over the world as per the stringent global standard of the company.
 2. The products are subject to extensive safety and quality control checks by scientific and medical experts and all the ingredients used in the products are extremely safe.
 3. That mineral oil used in the manufacture of Johnson Baby Oil is extremely pure and its use in baby oil is well documented for its safety and efficacy.
 4. The products of M/s. Johnson and Johnson are duly licensed as "Baby Product" and M/s. Johnson and Johnson is not claiming any proprietary or trademark rights over "Baby Products". These products do not need to meet any statutory requirement for labeling as "Baby Cosmetics Products".
 5. There are no specific BIS standards for Baby Products except Baby Soap and Baby Powder. M/s. Johnson and Johnson conforms to the BIS standards prescribed for Baby Soap.
 6. The company has submitted data for clinical safety based on the trials conducted on adult volunteers and have extrapolated these data to children to come to the conclusion that the products are clinically safe.
 7. The company's product do not require approval of Drugs Controller of India to be labeled as "Baby Products"
 8. The product specifications for "Baby Products" are different from those for the adult cosmetic products. The concentration of the ingredients used in the "Baby Products" are lower than those used in the adult cosmetic products and therefore these Baby Product formulation are suitable for babies.

15) M/s. Johnson and Johnson submitted data on the number of complaints received by them from the consumers in respect of the use of the “Baby Products” of Johnson and Johnson and the action taken by M/s. Johnson and Johnson on these complaints. **Annexure-VI** gives the summary of written complaints received by M/s. Johnson and Johnson alongwith the product samples. **Annexure-VII** lists both oral and written complaints received in respect of only Johnson’s Baby Oil. The complaints are for the period of 14 months from January 2004 to February 2005.

16) The manufacturing facilities and the supplier’s facilities of the company were visited by the officers of FDA Maharashtra. We are satisfied from the report filed by the officers and the submissions made by M/s. Johnson and Johnson that M/s. Johnson and Johnson are following the G.M.P. in respect of the manufacturing of the “Baby Products”, testing of the ingredients and finished products and quality control measures. **Therefore FDA Maharashtra do not have any apprehensions about the quality of the products perse and we would hereafter examine only the misbranding by of the “Baby Products” manufactured by M/s. Johnson and Johnson as defined under Section 17C (c) of the Drugs and Cosmetics Act, 1940** which reads as under.....

“ 17C – Misbranded cosmetics – For the purposes of this Chapter a cosmetics shall be deemed to be misbranded,-

(c) – if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.”

17) FDA Maharashtra raised the following questions to M/s. Johnson and Johnson during the oral hearing.

- 1) The supporting evidence for the label claims, product-wise.
- 2) The ingredient in the products that give the effect claimed and how?
- 3) As in the case of the infant food why not list all ingredients alongwith their percentage and appropriate caution and side effects as required to be mentioned on the label so that customer can make informed decision for buying “Baby Products”
- 4) Justify that the claims made on “Baby Products” are not in conflict with established tradition in our country regarding the use of traditional baby products.
- 5) In India the labeling standards are not prescribed in detail and hence why not follow the labeling guidelines issued by U.S. FDA.

18) M/s. Johnson and Johnson gave written replies and made oral submissions alongwith supporting data on 3rd May 2005.

19) We have examined the company’s submissions, perused the reference texts on Cosmetology (Harry’s Cosmetology and Cosmetics Science and Technology edited by Balson and Sagarin)(**Annexure-VIII**) and also aware of the tradition and practices followed in our country in respect of various baby product further supported by the Ayurvedic Texts, and in the light of these information our findings in respect of the truthfulness of the claims under Section 17C (c) for the “Baby Products” manufactured by M/s. Johnson and Johnson are.....

1) **Johnson's Baby Oil.** –

The company makes the following label claim.

- i) **It is pure mild and gentle.**
- ii) **It is ideal massage oil for your baby. Daily massage has clinically shown to benefit over all Growth and Development.**
- iii) **Vitamin D enriched.**
- iv) **Mildly perfumed non staining.**

Out of four claims claim number (i) and (iv) are factual and FDA Maharashtra have no objection to these claims.

In respect of claim number (iii) **Vitamin D enriched** company's data submitted to us show that Vitamin D3 is present to the extent of 0.1% in the total formulation alongwith Vitamin A. However the benefits accruing to babies by absorption of Vitamin D from such low concentration of Vitamin D present in the Baby Oil is not established by M/s. Johnson and Johnson. Further the typical Baby Oil formula as given in Harry's Cosmetology does not make any mention about adding Vitamin D in standard Baby Oil formulation. So FDA Maharashtra do not consider this label claim as substantiated by M/s. Johnson and Johnson.

2) 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.

2) Johnson's Baby Cream

FDA Maharashtra have no objections to the claims made in respect of Johnson's Baby Cream for protecting the skin against FDA Maharashtra ting and dryness.

3) Johnson's Baby Lotion.

The claims made by M/s. Johnson and Johnson are as under.

- 1) Clinically proven mildness - FDA Maharashtra have no objection to this claim.
- 2) With special skin oils that nourish moisturise and leave skin soft and younger looking because
- 3) Soft skin keeps your age a secret.

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.

4) Johnson's Baby Milk Lotion.

The claims made by M/s. Johnson and Johnson are..

1. Clinically proven mildness. Gently mositurize- FDA Maharashtra have no objection to this claim
2. Helps nourish skin leaving it baby soft, smooth and fair.

FDA Maharashtra do not accept this claim. This claim is totally misplaced because baby's skin is already soft, smooth and babies don't require cosmetics products for regular use to change the colour of skin.

5) Johnson's Baby Hair Oil.

The claims made by M/s. Johnson and Johnson are as under.

- 1) Pure mild and gentle – FDA Maharashtra do not have objection.
- 2) A light non-greasy hair oil enriched with pro-vitamin B5 that penetrates deep into baby's scalp –
- 3) Nourishes roots of the hair and keeps baby hair healthy.

The company has not submitted 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. As in the case of Johnson's Baby Oil we do not accept that Mineral Oil is superior to traditional oil like Coconut Oil, Almond Oil, Til Oil etc. Further by no stretch of imagination can a claim be made that 100% mineral oil will keep baby's hair healthy unless substantiated. The statement that D-panthenyl Triacetate at 0.11% in the composition of hair oil does job of nourishing the routes of hair and keep hair healthy is also unsubstantiated

6) No more tears Johnson's Baby Shampoo

The claims made by M/s. Johnson and Johnson are as under.

- 1) No more tears formula is as gentle to eyes as pure 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'S BABY SHAMPOO (with conditioner) leaves your babies hair soft and healthy. Gentle enough for daily use.

This is an adult product. The claims are substantiated by data obtained from clinical trial conducted on adult citizens in USA. FDA Maharashtra therefore says that this product is a misnomer to be a "Baby Product".

7) Johnson's Baby Milk Soap

One of the claims in respect of Johnson's Baby Milk Soap is as under.

- 1) Johnson's Baby milk soap contains natural milk extract known for its nourishing properties to help make baby's skin naturally smooth and soft.

FDA Maharashtra say that at 0.1% of the total composition of the soap product the benefit accruing to the babies on account of use of the milk protein is not substantiated by Johnson and Johnson.

8) Johnson's Baby Moisturizing Soap and Johnson's Baby Moisturizing Soap Blossoms.

One of the claims in respect of Johnson's Baby Moisturizing Soap and Johnson's Baby Moisturizing Soap Blossoms are as under.

- 1) Johnson's baby moisturizing soap enriched with goodness of coconut oil helps moisturise your baby's skin while cleansing it ever so gently.
- 2) The label is also exhibits the picture of broken Coconuts indicating the presence of coconut oil as ingredient in the product.

Since Coconut Oil is not present as ingredient no claims can be made by M/s. Johnson and Johnson as to the goodness of the Coconut oil being available in the soap.

In respect of Johnson's Baby Oil and Johnson's Bay Hair Oil M/s. Johnson and Johnson has not even mentioned the presence of Mineral Oil in the product on its label even though 99.785 % of the composition of the product is Light Liquid Paraffin Oil and all the properties of the products are derived from L.L.P. In respect of other products full list of ingredients have not been given by M/s. Johnson and Johnson. M/s. Johnson and Johnson has adhered strictly to the Drugs and Cosmetics Rules wherein it is sufficient to list only the key ingredient which M/s. Johnson and Johnson had chosen to decide subjectively.

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 Drug Controller of India 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.**

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 M/s. Johnson and Johnson.

- 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, Isopropyl Mysterate 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 17C (c) of the Drugs and Cosmetics Act.
- 3) FDA Maharashtra further direct that Johnson and Johnson shall have time up to 01/08/05 to bring necessary approval from the Drugs Controller of India regarding the approval of the claims. In case Johnson and Johnson fails to secure the necessary approval from the Drug Controller of India for the "Baby Products" as above in respect of the claims then the Joint Commissioner (Head Quarter) and Drug Controller, Maharashtra shall take further necessary steps to issue directions to the company under the Drugs and Cosmetics Acts 1940 and Drugs and Cosmetics Rules, 1945, not to manufacture for sale in the State of Maharashtra any cosmetics product titled as "Baby Cosmetics Product"
- 4) The above stipulations will not be applicable in case the manufacturer choosing to drop the word "Baby" from the title of the product and positions the products as regular cosmetics.
- 5) These orders shall be applicable to all the manufacturers of Baby Cosmetics Products to whom this Administration has issued Show Cause Notice.

A copy of this order is also submitted to the Drugs Controller India for taking necessary legal and administrative action as he may deem fit.

sd/-
(A. Ramkrishnan),
Commissioner,
Food and Drug Administration
Maharashtra State, Mumbai.

sd/-
(A.T.Vhatkar),
Joint Commissioner (H.Q.),
And
Drugs Controller, Maharashtra.

sd/-
(K.B. Shende),
Technical Officer.
Food and Drug Administration, M.S.