



**Breastfeeding
Promotion Network of India**

(Registered Under Societies Registration
Act XXI of 1860, Delhi R.No. S-23144)

BP-33, Pitampura, Delhi-110 034

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BPNI/IMS Act/2019/003

July 17, 2019

Smt. Smriti Zubin Irani
Hon'ble Minister
Ministry of Women and Child Development
Government of India
Shastri Bhawan
New Delhi-110001

Sub: Violation of Section 9(2) "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act 1992, and Amendment Act 2003" (IMS Act).

Dear Smt. Smriti Irani Ji

India enacted the "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act 1992, and Amendment Act 2003" (IMS Act) which came into force on August 1993. An offence committed under the law is cognizable.

The Government of India notified "Breastfeeding Promotion Network of India (BPNI)" wide No G.S.R. 540 (E), dated the 27th June 1994, to monitor the compliance with the above Act.

As per the section 9(2) of the IMS Act, "No producer, supplier or distributor referred to in sub-section (1), shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conference, educational course, contest, fellowship, research work or sponsorship".

Perusal of the clinical Trial Registry (attached) maintained by the Indian Council of Medical Research (ICMR) has revealed that Nestle India Limited, a producer of infant milk substitutes is sponsoring research "Multicentric Observational Study to Observe Growth in Preterm hospitalized infants" in five hospitals.

According to the legal opinion obtained by BPNI, Nestle India Limited and its concerned officials, responsible for the conduct of its business, have infringed section 9(2) of the IMS Act.

We request you to initiate action for effective enforcement of the IMS Act and initiate appropriate action against Nestle India Limited.

We seek your appointment to brief you personally on this issue.

With regards,

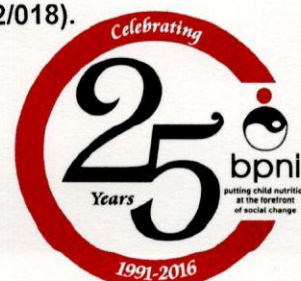
Yours Sincerely,


Dr. Arun Gupta
Central Coordinator BPNI

Copy to: - Shri Rabindra Panwar, Secretary, Ministry of Women & Child Development, GOI

Encl Annex-1-copy clinical trial registry page CTR/2018/12/016715(Registered on: 18/12/018).

As a policy, BPNI does not accept funds of any kind from the companies manufacturing baby foods, feeding bottles etc. and from organization/industry having conflicts of interest.





Clinical Trial Details (PDF Generation Date : - Mon, 06 May 2019 07:14:01 GMT)

CTRI Number	CTRI/2018/12/016715 [Registered on: 18/12/2018] - Trial Registered Prospectively	
Last Modified On	07/02/2019	
Post Graduate Thesis	No	
Type of Trial	Observational	
Type of Study	Prospective observational	
Study Design	Other	
Public Title of Study	Multicentric, observational study to observe growth in Preterm hospitalized infants .	
Scientific Title of Study	Growth and nutritional biomarkers in preterm infants in NICU – a Multicentric Study in India	
Secondary IDs If Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Monjori Mitra
	Designation	Research Director
	Affiliation	Medclin Research Pvt. Ltd.
	Address	Medclin Research Pvt. Ltd. Acropolis , Unit No. 10/5 , 10th floor 1858/1, Rajdanga main road Kolkata WEST BENGAL 700107 India
	Phone	09831075734
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Monjori Mitra
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	Phone	09831075734



	Fax			
	Email	monjorimr@gmail.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Nestle India Limited Nestlé House, Jacaranda Marg M Block DLF City Phase II, National Highway 8 Gurgaon 122 002, India			
Primary Sponsor	Primary Sponsor Details			
	Name	Nestle India Limited		
	Address	Nestlé House, Jacaranda Marg M Block DLF City Phase II, National Highway 8 Gurgaon 122 002, India		
	Type of Sponsor	Other [FMCG]		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr R Kishore Kumar	Cloudnine Hospital	Department of neonatology, 1533,9th Main,3rd Jayanagar, Bangalore- 560011, India Bangalore KARNATAKA	8066732259 drkishore@cloudninecare.com
	Dr Apurba Ghosh	Institute of Child Health	Room No. 113, Project Room 11, Bires Guha Street, Kolkata- 700017 Kolkata WEST BENGAL	9830052887 apurbaghosh@yahoo.com
	Dr Ravi Shankar Swamy	Manipal Hospital	Department of neonatology, 98, HAL Airport Road, Bangalore -560017 Bangalore KARNATAKA	8025024632 raviswamy@manipalhospitals.com
	Prof Dr Neelam Kler	Sir Ganga Ram Hospital	Department of Neonatology Institute of Child Health Sir Ganga Ram Hospital, New Delhi-110060 New Delhi DELHI	8447732229 drneelamkler@gmail.com
	Dr Saugata Acharyya	The Calcutta Medical Research Institute	Department of Neonatology, 7/2, Diamond Harbour Road Kolkata- 700027 Kolkata WEST BENGAL	9830068567 saugata69@hotmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Ethics Committee of Manipal hospitals	Approved	04/02/2019	No
	Ethics Department, Sir Ganga Ram Hospital	Approved	02/11/2018	No



	Institutional Ethics Committee, The Calcutta Medical Research Institute	Submitted/Under Review	No Date Specified	No
	Institutional Ethics Committee, Cloudnine Hospital, Bangalore	Approved	15/10/2018	No
	Institutional Ethics Committee, Institute of Child Health	Approved	20/11/2018	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Disorders of newborn related to length of gestation and fetal growth	
Intervention / Comparator Agent	Type	Name	Details	
Inclusion Criteria	Inclusion Criteria			
	Age From	0.00 Day(s)		
	Age To	1.00 Month(s)		
	Gender	Both		
	Details	Stable Preterm AGA infants born between 28 to 34 weeks of gestational age who are on enteral feeding, Singleton gestation		
Exclusion Criteria	Exclusion Criteria			
	Details	<ul style="list-style-type: none"> On any other clinical study affecting nutritional management during the study period Decision to not start minimum enteral feed within 48 hours of birth Unable to obtain informed consent from parent (s) or legal guardian prior to the initiation of enteral feeding Infants experiencing early onset sepsis (i.e. symptoms requiring antibiotic therapy and confirmed by a positive blood culture occurring before the 3rd day of life). Presence of clinically significant congenital heart disease Presence of any major congenital malformations, chromosomal abnormality or major gastro intestinal disease known to affect growth Liver failure as detected by (if laboratory data is available) aspartate aminotransferase, alanine aminotransferase, gamma-glutamyl transferase, and direct bilirubin serum values 3-fold higher than reference range. Peri-/intra-ventricular haemorrhage (grade 3-4 in Papille classification) determined using cranial ultrasonography, if it is performed. Other serious disorders of cardiac/ respiratory/ endocrine/ hematological/ gastrointestinal/ other systems, or serious diseases requiring surgical intervention Reasonable potential for early transfer to a non-study institution 		
Method of Generating Random Sequence	Not Applicable			
Method of Concealment	Not Applicable			
Blinding/Masking	Not Applicable			
Primary Outcome	Outcome		Timepoints	



	Growth	Observation period for each infant will be the duration of hospital stay after the initiation of first enteral feed after enrollment in to the study.
Secondary Outcome	Outcome	Timepoints
	Assessment of Feeding intolerance	Observation period for each infant will be the duration of hospital stay after the initiation of first enteral feed after enrollment in to the study.
Target Sample Size	Total Sample Size=75 Sample Size from India=75	
Phase of Trial	N/A	
Date of First Enrollment (India)	01/01/2019	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=1 Months=0 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	The study result will be published in index journal post study completion	
Brief Summary	This is an observational study to be conducted in preterm infants admitted in the NICU with the age of 28 to 34 weeks. the primary objective of the study is to assess the growth outcomes and feeding intolerance observed in the Preterm infants. The study will be conducted in 5 tertiary care hospitals with NICU. The study period is 12 months approximately	