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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

F. No. 5/7/1667/2019/CH-RBMCH

Dated:- 02/12/2019

To,
Dr. Arun Gupta
Central Coordinator,
Breastfeeding Promotion Network of India (BPNI),
BP-33, Pitampura, Delhi-110034.

Subject:- Request for action against the violators of Infant Milk Substitutes----

Dear Dr. Gupta,

This has reference to your letter no. BPNI/2019/IMS ACT/06 dated 14/09/2019 on the above mentioned subject. The complaint is in relation to the following studies :

1. CTRI/2014/11/005199) Registered on 13.11.2014, last modification on 21.05.2019.
Title of the study: Study of milk composition from adequately nourished and undernourished mothers
Source of monetary or material support: Nestec Ltd. CH-1800 Vevey, Switzerland Nestec is a subsidiary company of Nestle.

2. CTRI/2018/12/16645) Registered on: 13/12/2018, last modification on 09/01/2019.
Title of the study:- Infant feeding practice and gut comfort: A multi – country, cross-sectional observational study.
Source of Monetary of Material Support: Nestec Ltd. CH-1800 Vevey, Switzerland.

3. CTRI/2015/10/006330 [Registered on: 29.10.2015]-Trial Registered Prospectively. Last Modified on 13.04.2017
Title of the study: Randomized, parallel Group, Multiple Arm Trial : Public Title of Study Oral Nutrition Supplementation study in children's.

Source of Monetary or Material Support: Abbott Nutrition Abbott Healthcare Pvt Ltd 8th Floor, Hallmark Plaza, Sant Dyaneshwar Marg, Bandra (E) Mumbai – 400051 India

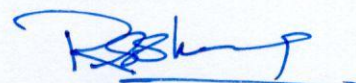
4. CTRI/2016/12/007621 [Registered on: 29.12.2016] Trial Registered Prospectively Last Modified on 05.07.2019

Title of the study: A study of Human Milk Composition in Indian Mothers
Scientific Title of Study: Human milk composition in Indian mothers.

Source of Monetary or Material support.:Abbott Nutrition Research and Development (ANRD). India) S-15, Syngene International Ltd., Biocon Park, Plot No. 2&3, Bommasandra IV Phase. Jigani Link Road, Bangalore – 560099

All the studies are identical to the one for which ICMR has taken a unanimous decision. As per the recommendation of the committee the CTRI is being directed to take necessary action.

Yours sincerely



(R.S. Sharma)

**ICMR Report on Trial No. CTRI/2018/12/016715 registered under ICMR-CTRI
and Violation of IMS Act by Nestle India Ltd.**

The members of the committee perused the relevant material and discussed at length on all the issues and arrived at the following unanimous considered opinion:

1. That the complaint is well founded, and the study in question is violative of Section 9(2) of IMS Act 1993 as amended in 2003, given the fact that the study falls under the definition of research work within the meaning of Section 9(2), and the study is funded and sponsored by Nestle India Ltd., which is a producer/ supplier/ distributor of IMS defined under the Act.
2. In the light of above observations, the committee recommends the following immediate actions:
 - a. The study should be terminated immediately by the appropriate authority. The investigators should be asked to change the CTRI registration status to 'terminated' citing the reasons for the same.
 - b. DCGI should examine whether the respective institutional ethics committees, which permitted this study, were constituted in accordance with existing regulations. Further, the respective ethical committees may be directed to explain how they permitted such study in violation of Section 9(2) of IMS Act.
3. The committee feels that following step is necessary to act as a deterrent for similar acts of commission and omission in future, given the fact that the complainant (BPNI) in this case has been notified by Government of India to monitor compliance of IMS Act:
 - a. Invoke the provisions of prosecution of the violators of Section 9(2) of IMS Act under Sections 20, 21 and 22 of the Act.
4. The CTRI should be familiarized regarding the provisions of IMS Act in relation to research work. If CTRI has any reason to believe that there is an infringement of this Act in an Indian study submitted to it for registration, it should defer its registration, and should bring it to the notice of appropriate authorities.
5. It is recommended that the IMS Act should be displayed on the websites of Ministry of Health and Family Welfare, Medical Colleges and Hospitals (Government and Private), ICMR and CDSCO for better implementation.