

BPNI/2022/033

September 22, 2022

Dr. Bharati Pravin Pawar,
Hon'ble Minister of State,
Ministry of Health and Family Welfare,
Government of India,
Nirman Bhawan,
New Delhi-110011

Sub: Neslak Biosciences – commercial processing of mother's milk and violating the *Infant Milk Substitutes Feeding Bottles, and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992, and Amendment Act 2003. (IMS Act)*

Dear Madam,

With reference letter no T-13011/1/2022-DCC-Part (4) (via email received dated 22 September 2022) Ministry of Ayush cancelled the licence of 5 products of 'Neolacta' made from mother's milk. Opinion of the technical expert committee, invoking Drugs and Cosmetics Act and Rules and the New Drugs and clinical Trial rules 2019 led to this decision. The Ministry also had a detailed hearing from the company representatives and considered their representations. The Ministry decided that the products manufactured do not come under the definition of drugs and decided to withdraw the five products of 'Neolacta' that don't qualify for being an 'Ayurvedic Proprietary Medicine'. The Ministry also thought that products of Neolacta raise an issue of women and human rights.

BPNI wishes to place a similar case of a company "Neslak Biosciences"
<https://neslak.com/hapines/#how-use>

1. The company 'Neslak' claims to transform mother's milk into powder form and provides it in 'HapiNes Sachets' and further guides mothers to make use of this powder by dissolving in clean water through a bottle. By definition 'HapiNes' is an infant milk substitute according to the *Infant Milk Substitutes Feeding Bottles, and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992, and Amendment Act 2003- Section 2-g* "infant milk substitute" means any food being marketed or otherwise represented as a partial or total replacement for mother's milk, for infant up to the age of two years.

2. Neslak claims to be FSSAI licensed. (PDF attached)

3. The company promotes its products to doctors. A message sent to pediatricians is pasted below. It violates the IMS Act as Section 3 of IMS Act prohibits any person from promoting the 'infant milk substitute'.

"Dear Doctor, Beyond the collaboration that Neslak Biosciences offers to hospitals towards setting human milk banks, we are now offering first-in-India service for mothers ...HapiNes is a service for mothers to transform their own milk into easy-to-use and store powder form. HapiNes helps mothers overcome breaches in breastfeeding, in situations such as re-joining work, night-time feeding, travelling or when mother is sick."

4. In a response to a Parliament question (2225) in the Lok Sabha on 29 July 2022, commercialization of mother's milk, it was stated as below.

“(a) to (f): Food Safety and Standards Authority of India (FSSAI) has informed that Food Safety and Standards Act, 2006 and Rules and Regulations do not cover the commercial processing/selling of human milk.....

As per the national guidelines on Lactation Management Centre (LMC) in Public Health Facilities, Donor Human Milk (DHM) cannot be used for any commercial purpose....”

In this case, the company 'Neslak' is doing commercial processing of mother's milk. We believe there is grave risk of commercialization of human breastmilk not only by the company but also at individual level in the informal market and it will be a massive ethical issue. This is also misleading service to mothers as they pay INR 6000 to convert their own milk into powder, while mothers could feed their babies their own milk kept in the refrigerator or freezer.

Promotion to doctors violates the IMS Act in letter and spirit.

BPNI, therefore, requests you to take immediate action to stop the commercialisation and cancel the license of this company.

With regards,

Yours Sincerely,



Dr. Arun Gupta
Central Coordinator BPNI

Copy to Shri S Gopalakrishnan, Chief Executive Officer, FSSAI, GOI