T-13011/1/2022-DCC-Part(4)

I/55488/2022

भारतसरकार/ Government of India
आयुष मंत्रालय/ Ministry of Ayush

**NBCC Office Block-3 (2nd Floor),**
**East Kidwai Nagar, New Delhi-110023.**

To,

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

**Subject: Illegal Activity and sale of "Neolacta" Continues-reg.**

Sir,

The undersigned is directed to refer to your letter no.BPNI/IMS Act/2022/032 dated 02.09.2022 on the subject mentioned above and to state that State Licensing Authority of Karnataka vide order dated 29.08.2022 (**copy enclosed**) has cancelled the license No.AUS-993 dated 24.11.2021 of M/s Neolacta Lifesciences Rrt. Ltd. No. 63, KIADB, Bommasandra, Jigani Link Road, Jigani, Anekal Taluk, Bengaluru-560105, with effect after two weeks of receipt of the said order.

2. This issues with the approval of Competent Authority.

**Encl: As above**

Yours faithfully,

Signed by Madan Lal Meena
Date: 21-09-2022 12:34:34
Reason: Approved

**(Madan Lal Meena)**
**Under Secretary to the Government of India**

# Proceedings of Government of Karnataka
# Department of AYUSH

**Sub:** Withdrawal of product approval under License No.AUS-993 dated 24.11.2021, issued in favour of M/s. Neolacta Life Sciences Private Limited, Jigani, Anekal Taluk, Bengaluru-560 105.

**Read:** 1. Drugs & Cosmetics Act 1940 & Rules thereunder
2. New Drugs & Clinical trial Rules 2019
3. Government of India letter dated:04-07-2022
4. W.P. No. 14488/2022 dated: 19-07-2022
5. Show Cause notice dated:05-07-2022
6. Proceedings of Technical Expert Committee dated: 11-07-2022
7. Personal hearing dated:26-08-2022

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**Preamble:**

License No.AUS-993 in Form 25-D was issued to M/s. Neolacta Life Sciences Private Limited, Jigani, Anekal Taluk, Bengaluru-560 105 to manufacture ten Ayurvedic drugs on 24-11-2021.

Show-cause notice No.Ayush/22/DLA/1/2021 dated 05.07.2022 was issued by the Drug Licensing Authority, hereinafter referred to as the "Authority" to the above referred Company to show cause as to why the license in No.AUS-993 should not be withdrawn, within 7 days from the date of receipt of the said notice.

In response to the above referred show-cause notice M/s. Neolacta Life Sciences Private Limited, hereinafter for the sake of brevity referred to as the "Company" had sent 1) a response dated 11.07.2022 styled as interim response and 2) response dated 15.07.2022 styled as points for consideration.

The company had requested for a personal hearing and also to furnish the copy of the communication of the Government of India, Department of Ayush, dated 04.07.2022 referred to under the Show-Cause notice dated 05.07.2022.

The authority had sent a intimation to the Company, intimating the date fixed for personal hearing. However in the meanwhile the Company had approached the Hon'ble High Court of Karnataka, challenging the show-cause notice dated 05.07.2022 bearing No.Ayush/22/DLA/1-2021 on 19.07.2022 in W.P.No.14488/2022.

In view of the filing of the Writ Petition by the Company the intimation regarding the personal hearing to the Company was withdrawn.

There after the above referred Writ Petition came to be disposed of by the Hon'ble High Court by its Order dated 29.07.2022, by making the following order:-

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*c) the above apprehension of the learned counsel for petitioner can be addressed this way that his client's explanation in contemplation would be considered by the second respondent and order shall be issued in accordance with law; however, the said order shall not be given effect to for a period of two weeks from the date it is communicated to the petitioner. This would do justice to both the sides.*

Sd/-
Judge"..

The Authority has complied with the above referred order dated 27.09.2022 passed in W.P.No.14488/2022 by the Hon'ble High Court of Karnataka, Bengaluru.

The Authority, has sent a fresh communication dated :17-08-2022 to the Company fixing the date of personal hearing.

In response to the above referred communication dated:17-08-2022 the Authorized Representatives of the Company Mr. Madhu, Director of the said company along with others appeared and submitted their oral submissions. The copy of the communication dated 04.07.2022 of Ministry of Ayush Government of India, was also furnished to the Authorized Representative of the Company. The submissions made on behalf of the Company by their Authorized Representatives was heard at length and the matter was reserved for passing orders.

The authority has carefully examined the interim response dated 11.07.2022, the points for consideration dated 15.07.2022 and oral submissions made by the Authorized Representative of the company and the materials placed on record.

Basis the Article which was published in Times of India under the Title "Commercial sale of Mother's milk under Ayush License has thrown up ethical questions", the Government of India, Ministry of Ayush, has issued directions to withdraw license issued to the Company, since the product Nari Ksheera/Stanya(Mother's milk) does not come under the definition of medicines under Ayurveda, Siddha and Unani drugs as per section 3(a) of Drugs and Cosmetics Act, 1940 and collection and selling of Nari Ksheera/Stanya(mother's milk) has involved several ethical issues including human rights, women rights which are very sensitive.

Considering the response submitted by the Company and also the directions issued by Government of India, Ministry of Ayush the Technical Expert Advisory Committee meeting was convened on 11.07.2022 to review the product approval given to the Company and on re-verification of the documents submitted by the Company decided that Nari Ksheera does not come under the Definition of Drug as per Sec 3(a) of Drugs and Cosmetics Act 1940 it is decided to withdraw five products namely PHBM (Pasteurized human breast milk), PHBM70 (Pasteurized human breast milk), MMF (mother's Milk factor), MMF Plus(Mother's Milk Factor)Powder, Neolact 70(Human milk

for reconstitution) powder, products which contain only Nariksheera as the ingredient and does not qualify as Ayurvedic Proprietary Medicine category under Sec 3(h) of Drugs and Cosmetic Act 1940 as the product contains only one ingredient.

Since the approval for production of the products by the said company using mother's milk has led to ethical issues and women and human rights and it is found that the Company has also violated New Drug and Clinical Trial Rules 2019,in the Committee it was unanimously decided to withdraw - the approval given for manufacturing PHBM ( (Pasteurized human breast milk) with almond oil, PHBM 70 (Pasteurized human breast milk) with almond oil, MMF (Mother's Milk factor) Powder with almond oil, MMF Plus (Mother's Milk factor) Powder with almond oil, Neolact 70 (Human Milk for Reconstitution) powder with almond oil using mother's milk as ingredient . As per the decision taken by the Technical Expert Advisory Committee and as per the directions of Ministry of Ayush, Government of India, the following order is passed:-

**ORDER**

For the reasons stated above the approval given for manufacturing Ayurvedic products under the license No.AUS-993. Dated :24-11-2021 to **M/s Neolacta Lifesciences Pvt. Ltd.** No. 63, KIADB, Bommasandra, Jigani Link Road, Jigani, Anekal Taluk, Bengaluru-560105, are hereby withdrawn and the license issued to the said firm is cancelled with effect after two weeks of receipt of this order.

Endorse the copy of the above order to the Company by Register Post with Acknowledgment Due.

Drug Licensing Authority
Drug Licensing Authority
Department of AYUSH
Dhanvathari Road, Bengaluru-09

Bangalore
Date:29.08.2022

To,

1. M/s Neolacta Lifesciences Pvt. Ltd. No. 63, KIADB, Bommasandra, Jigani Link Road, Jigani, Anekal Taluk, Bengaluru-560105.
2. The Advisor, Ministry of AYUSH, Govt. of India, "AYUSH Bhawan" 'B' Block, GPO Complex, INA, New Delhi -110023.
3. Drug Inspector (Ayurveda), Directorate of AYUSH, Dhanvantari Road, Bangalore- for necessary action.
4. Office copy