F. No. Std/SP-05/T(Nutraceutical-2022)(part-1)-(Part-1)

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety & Standards Act, 2006) FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the 17 November, 2023

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022

In exercise of the power conferred under Section 92 of the Food Safety and Standards Act, 2006, FSSAI has framed draft FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 and the same were operationalised *vide* direction dated 29.03.2022 superseding the *FSS* (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. The direction of 29.03.2022 was further revised *vide* direction dated 10.05.2022 to permit additional food additives and enzyme/proteins for Health Supplements.

- 2. The provisions of these draft regulations as specified in the direction dated 29.03.2022 together with the provisions specified in the direction dated 10.05.2022, were reoperationalised with effect from 01.10.2022 *vide* direction dated 18.10.2022 and later reoperationalised with effect from 01.04.2023 *vide* direction dated 11.04.2023. As the finalization of these draft regulations is likely to take some more time before being notified, it has been decided to again re-operationalise the provisions specified in the direction dated 11.04.2023, for a period of three months from 1st October, 2023.
- 3. This issues with the approval of the Competent Authority in exercise of the powers vested under Section 18(2)(d) read with Section 16(5) of Food Safety and Standards Act, 2006.

(Anil Mehta)
Director
S&S Division
FSSAI, New Delhi

To:

- 1. ED(CS)-with a request to communicate to Food Safety Commissioners of all States/UTs and all Regional Directors, FSSAI
- 2. Director (TICD)-with a request to communicate to all Authorized Officers

Copy to:

- 1. PPS to Chairperson, FSSAI
- 2. PS to CEO, FSSAI
- 3. Head (S&S)
- 4. Advisor (QA)
- 5. CITO, FSSAI-with a request to upload the direction on the FSSAI website