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 11th April, 2023

Subject: Direction under Section 18(2)(d) read with 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 1st October, 2022 *vide* direction dated 18.10.2022. 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 18.10.2022, with effect from 1st April, 2023.
- 3. This issues with the approval of the Competent Authority in exercise of the power vested under Section 18(2)(d) and 16(5) of Food Safety and Standards Act, 2006.

(Dr. Amit Sharma) Director (Regulation)

To:

- 1. All Food Safety Commissioners
- 2. All Authorized Officers, FSSAI
- 3. All Central Designated Officers, FSSAI
- 4. CITO, FSSAI for uploading on the website

Copy for information to:

- 1. PPS to Chairperson, FSSAI
- 2. PS to CEO, FSSAI
- 3. All Divisional Heads, FSSAI