File No. 15(15)2018/CLAs/RCD/FSSAI

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety and Standards Act, 2006)
Regulatory Compliance Division

FDA Bhawan, Kotla Road, New Delhi - 110002

Dated, the \8 October, 2019

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding Standards of Formulated Supplements for Children and issues of their license- reg.

The Food Safety and Standards Authority of India vide Gazette Notification F.No. Stds/03/Notification (CFOI&YC)/FSSAI-2017, dated 16th November, 2018 had notified the Food Safety and Standards (Food Products Standards and Food Additives) Eleventh Amendment Regulations, 2018 specifying standards for 'Formulated Supplements for Children'

- 2. These standards specify the requirements of formulated supplements for children of age above 24 months till 36 months. It is clarified that standards for complementary food for the age group 24 to 36 months specified under 'Formulated supplements for children'. Therefore, any complementary food taken in addition to home foods except Food for Special Dietary Use (FSDU) and Food for Special Medical Purpose (FSMP) for the age group 24 to 36 months shall need to comply with these standards.
- 3. No such products should be allowed henceforth under the category of proprietary foods in view of the sensitivity of the target group involved, while processing applications for new license or renewal of existing licenses.
- 4. The Food Business Operators who already have license for the said category under Proprietary Food may be advised to get their existing license modified accordingly as early as possible, however, before renewal of their existing license.
- 5. The Licensing Authorities may consider pending and new licensing applications accordingly w.r.t 'Formulated supplements for children' under food category 13.2, i.e. Complementary food for older infants and young children. It may be ensured that henceforth no license shall be issued or renewed to proprietary food products under the food category 13.2.
- 6. This issues with the approval of Competent Authority in exercise of the power vested under Section 16(5) of Food Safety and Standards Act, 2006.

(Dr. Shobhit Jain)

Executive Director (Compliance Strategy)

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- 1. Commissioner of Food Safety of All States/UTs
- 2. All Central Licensing Authorities, FSSAI
- 3. CITO, FSSAI-for uploading on FSSAI website.