File No. RCD-15001/18/2021-Regulatory-FSSAI (E- 8678)
Food Safety and Standards Authority of India
(A Statutory body under Ministry of Health and Family Welfare)
(Regulatory Compliance Division)
FDA Bhavan, Kotla Road, New Delhi-110 002

Dated, the 12 th. October, 2023

To

- 1. The Commissioners of Food Safety of all States/UTs,
- 2. All Regional Directors, FSSAI
- 3. All Central Licensing Authorities, FSSAI

Subject: Enforcement Action in respect of products with the ingredient S-Adenosyl-L-Methionine (SAMe) under FSSAI license -reg.

Sir/Madam,

It has been brought to the notice of Food Authority that the ingredient/products with S-Adenosyl-L-Methionine (SAMe) are available in the market or under e-commerce platform with FSSAI license.

- 2. In this regard, it is informed that the ingredient/product with S-Adenosyl-L Methionine (SAMe) has not been considered as 'Food' and the applications for approval of the same as 'Health Supplement/FSMP/FSDU' under Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017 have been rejected/ revoked by the Food Authority.
- 3. In view of the above, it is hereby directed to advise all the concerned enforcement authorities under your jurisdiction to ensure that such products containing S-Adenosyl-L-Methionine (SAMe) as an ingredient alone or in combination with other ingredients are not available in the market with FSSAI license. Further, the E-commerce platforms are also advised to de-list such products with FSSAI license from their respective platforms. The food business operators are also directed to ensure that such products are not sold under FSSAI license either in markets/e-commerce platforms and to modify their active licenses, if any, accordingly, failing which, action as per the extant FSS Act, 2006 and Rules thereunder shall be taken by the respective enforcement authorities.

This issues with the approval of the Competent Authority.

Yours sincerely,

Digitally Signed by Rakesh Kumar

Date: 12-10-2023 17:54:51

Reason: Approvedesh Kumar)

Director (Regulatory Compliance Division)

Copy to: CTO, FSSAI- For placing the order on FSSAI's website for information and necessary action by the food business operators including E-commerce FBOs.