

RCD-15001/6/2021-Regulatory-FSSAI (E-1475)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act,
2006)
(Regulatory Compliance Division)
FDA Bhavan, Kotla Road, New Delhi-110002

Dated 08th April, 2022

Subject: Direction under Section 16(5) regarding misleading advertisement and marketing of ORS substitute Products-Reg.

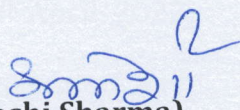
Reference is drawn to the sub-regulation 2.2.1(3) of Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and sub-regulation 4(3) of Food Safety and Standards (Labelling and Display) Regulations, 2020, which stipulates that, "*Pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.*"

2. FSSAI is in receipt of several representations/complaints regarding misuse of the term 'ORS' (Oral Rehydration Salts) by certain fruit-based or non-carbonated or Ready to Drink beverage manufacturers licensed under FSSAI by labelling/using terms similar to the ORS like '**ORSL**', '**ORSL Rehydrate**', '**Electro Plus ORS**' etc. The product 'ORS' is a Drug under Drugs and Cosmetics Rules 1945 which is used for the treatment of acute diarrhoea and has a specific composition prescribed by the Drugs Controller General of India (DCGI). However, the marketing and labelling of the fruit based beverages etc. being manufactured by the FBOs under FSSAI Licenses and naming such products with the terms which contain '**ORS**' is not only misleading for the ordinary consumers but also harmful for the patients who may consume such products as ORS especially in case of the children suffering from diseases like diarrhoea, gastroenteritis, etc. may have serious health repercussions.

3. In this regard it is clarified that use of term 'ORS' or similar to 'ORS' and/or depiction of the food products as 'ORS' on their labels or through advertisement is not allowed under the FSSRs and use of such terms may render the products as '**Misbranded Food**', as defined under Section-3 of the FSS Act. Such acts/products are in violation of the provisions of Section 23 and 24 of the FSS Act, 2006 which may render such FBOs liable for punishment under Section 52 and Section 53 of Food Safety and Standards Act, 2006.

4. Accordingly, the Commissioners of Food Safety of all States/UTs and Central Licensing Authorities are hereby advised to take appropriate actions against such FBOs under their respective jurisdictions including issuance of improvement notices under Section-32 of FSS Act, 2006 to them to rectify the labelling defects highlighted immediately while ensuring that the term 'ORS' is not used in the labelling of such products failing which appropriate legal action as per the provisions of the FSS Act, 2006 and Regulations made thereunder for violation in this respect shall be initiated against the defaulting FBOs

5. This issues with the approval of the Competent Authority in exercise of the power vested under Section 16 (5) of Food Safety and Standards Act, 2006.


(Inoshi Sharma)
Executive Director (CS)

To

1. All Regional Directors, FSSAI
2. All Central Licensing Authorities
3. The Commissioners of Food Safety of all States and UT's.

Copy for information to:

1. Drugs Controller General of India (DCGI), FDA Bhawan, New Delhi.
2. SPS to CEO, FSSAI
3. PA to Advisor (S&S)