

File No. 15(31)2020/FoSCoS/RCD/FSSAI
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
Food Safety Compliance System (<https://foscoss.fssai.gov.in>)

Dated, the ¹⁴ 11th September, 2020

Order

Subject: Food businesses manufacturing products covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 to be covered under the purview of Central Licensing Authorities-reg.

At Present, the food businesses operators (FBOs) manufacturing products covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 hereinafter referred to as '**Nutraceutical Regulations**' are being licensed by the State as well as the Central Licensing Authorities under the General manufacturing i.e. FBOs having production capacity of 2MT per day are eligible for State License while FBOs having production capacity of more than 2MT per day are eligible for Central License.

2. Now Considering the complexity and sensitivity of the products covered under the Nutraceutical regulations and of the products covered under it, it has been decided with the approval of the Food Authority to license food businesses manufacturing products covered under the said regulations through Central Licensing Authorities only, irrespective of turnover of the FBOs. Henceforth, the Central License option shall be available for manufacturers of food products covered under Nutraceutical regulations.

3. Accordingly, all existing State Licensed FBOs having license for the food products under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 shall migrate to Central License with a modification fee of Rs. One Thousand [Rs. 1000] only and the payment of the differential amount between State License fee and Central License fee for remaining number of complete years of validity of their existing licenses by **31st December 2021**. Further, State Licensed FBOs manufacturing products under Nutraceutical Regulations shall not be able to apply for renewal of their license after 31st December 2021.

4. All existing applications for new/modification licenses [under processing] with State Licensing Authorities shall stand rejected and fee paid shall be refunded to the concerned FBOs in such cases. Such FBOs shall be required to resubmit the application with full fee to the concerned Central Licensing Authorities.

P.T.O

5. It is further informed that FSSAI has already enabled food businesses to migrate/modify their licenses from State License to Central License without change in existing license number w.e.f 1st June 2021, thereby facilitating food businesses to save overhead costs and undue hassle which otherwise, might have occurred due to change in existing license number and subsequently loss of pre-printed packaging material, if any.
6. This issues with the approval of the Competent Authority.

Yours sincerely,


(Inoshi Sharma)

Executive Director (CS)
Email: ed-office@fssai.gov.in

To -

1. All Food Business Operators, Associations, Food Safety Mitra and other Stakeholders
2. Commissioner of Food Safety of concerned States/UTs
3. Directors of all Regional Offices, FSSAI
4. Head (IT) – for uploading on website

Copy for information to -

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