

**File No. 15(31)2020/FoSCoS/RCD/FSSAIpt10 (E-2173)**  
Food Safety and Standards Authority of India  
(A Statutory Authority established under the Food Safety and Standards Act, 2006)  
**(Regulatory Compliance Division)**  
FDA Bhawan, Kofla Road, New Delhi-110002

Dated, 8<sup>th</sup> August, 2022

**Advisory**

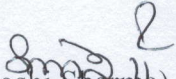
**Subject: Examination and scrutiny of license modification applications in FoSCoS for products covered under FSS (Nutraceutical) Regulations, 2022-reg.**

Various instances/representations have come to the notice of FSSAI that the Licensing Authorities are scrutinizing already licensed products, whenever an FBO applies for modification of their respective license application, especially in case of products covered under FSS (Nutraceutical) Regulations, 2022. Further, it has been noted that such reviews lead to inordinate delays in processing of modification applications and the FBOs are subjected to scrutiny of their products for which they already have been granted valid licenses.

2. Since FBOs are migrating from State license to Central license for nutraceutical products and such products have been already been examined by the State Licensing Authorities before grant of license, re-examination of all the licensed products may not be appropriate at the stage migration from State to Central category.

Therefore, the Central Licensing Authorities are hereby advised to scrutinize only those products which have been applied for under the modification application at hand and desist from re-examining the already licensed products, unless there is a food safety issue or specific complaint reported against a product/FBO so as to avoid any inordinate delays in processing of modification applications.

This issues with the approval of the Competent Authority.

  
(Inoshi Sharma)

ED, Compliance Strategy  
Email: enforcement1@fssai.gov.in

**To**

1. All Regional Directors
2. All Central Licensing Authorities

**Copy to**

1. PS to CEO, FSSAI
2. PA to Advisor (Science and Standards), FSSAI
3. CTO – for uploading on FSSAI website

Date: 3 August 2017

Advisor


Subject: Examination and setting of license modification application for FSSAI for products covered under FSS (Pharmaceutical) Regulations, 2017.

Various manufacturers have come to the notice of FSSAI for the license modification of their respective license applications for FSSAI. The products are already licensed products, whereas as per the provisions of FSS (Pharmaceutical) Regulations, 2017, it has been stated that such applications for modification of license shall be processed only after the products are submitted to scrutiny of their products for which they should have their license valid.

Since FSSAI are migrating from State license to Central license for pharmaceutical products and such products have been already been examined by the State Licensing Authorities before grant of license, examination of all the licensed products may not be required in the migration from State to Central category.

Therefore, the Central Licensing Authorities are being advised to undertake only those products which have been applied for under the modification application in their State. While examining the already licensed products, unless there is a lead entry, State or Central Licensing Authorities are requested to avoid any further delay in processing of modification applications.

The same with the approval of the Central Authority.

  
S. K. Singh  
Joint Enforcement Officer

1. All Regional Directors
2. All Central Licensing Authorities