

FSSAI notice on format for submitting data to support claims made by FBOs

Wednesday, 13 May, 2020

Ashwani Maindola, New Delhi

The Food Safety and Standards Authority of India has issued a notice releasing a 'format' to submit the summary of published scientific data to support the claims made by FBOs.

The FSSAI has sought summary of published scientific data for human studies besides in-vitro and in-vivo studies in a prescribed format to support the claims made by the FBOs in relation with their products.

For human study data, the format includes questions like nature of study, material tested and their levels, nature of volunteers/subjects/population/patients, design of study, inclusion and exclusion criteria, duration of the study, variables measured, results and reference for the publication.

According to the FSSAI, in September 2019 a notice was issued for the procedure to apply for approval of claims specified under the FSS –Advertising & Claims –Regulations and a Claim Support Dossier –CSD was sought in support of the claims made by the FBO.

The September 4, 2019, notice of FSSAI had asked the FBOs to file application for approval of the claims with a fees of Rs 50,000 along with adequate published scientific literature/studies forming part of the claim support dossiers. However, there was no format prescribed then for submission of the documents.

According to an industry insider, the Advertisement & Claims matter is going on since many years. The basic data was / is provided by "Advertising Standards Council of India" and is still actively doing such work for FSSAI and the present circular is in continuation of the descriptive part of Advertisement & Claims as a supporting data for such claims and so on.

Meanwhile, the format for providing summary of claims to support in-vitro data includes parameters like material tested, microbes/cell lines/organ culture/ other test system, concentration tested, negative and positive controls used, variables biomarkers, performance indicators, result obtained and reference for the publication.

For in-vivo data, parameters included were laboratory animal used/knockout animal if used/isolated organ if used/any other test, concentration tested & positive control used, variables, performance indicators evaluated measured, result obtained and reference for the publication.

Further, the FSSAI has released a FAQ answering questions related to the regulations governing advertisement and claims, which were notified in November 2018 and subsequently operationalised on June 28, 2019.