FSSAI clarifies on Food for Special Medical Purpose in foods akin to drugs

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FSSAI has issued a guidance note 'specifically' on food for special medical purpose (FSMP), as it was in receipt of large number of applications for approval under the FSS Non-specified Food and Food Ingredients Regulations (NSF), while the product actually falls under the FSS (Health Supplement, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations.

FSSAI clarified that FSMP is a special dietary formulation intended for supporting nutritional needs of persons with disease or disorders through a food route and cannot be used as a drug for the prevention of a disease. "Most of the FSMP formulations are made up of one or more purified and well characterised ingredients from botanical source or synthetic molecule having pharmacological activity and can be formulated in tablets, capsules or liquid," the document clarifies and adds that these products are to be used under the direction of a medical practitioner.

Meanwhile, on examining the FSMP applications under the NSF regulations, the FSSAI has said that the Authority shall critically examine the products potentially falling under FSMP categories with one or more ingredients of botanicals, herbs and ingredients of animal origin, which also have a drug like activity, to determine whether these products would be best suited under food regulations or drug regulations. "In case of ambiguity, the authority will err on the side of caution and categorise such ingredients/ products to be more akin to drugs. Their use will not be permitted under the FSS Regulations, as a caution to protect consumers," reads the statement by FSSAI.

With the guidance note, the FSSAI has also provided details of products falling under health supplement, nutraceuticals, food for special dietary use, and food for special medical purpose in a tabular manner to make it easy for the FBOs to distinguish between these.