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# FSSAI guidance and notification on nutraceuticals – An insight

Monday, 08 June, 2020

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A nutraceutical is a food or food related component that intends for health benefits even in treatment and prevention of aliments. Many people rely on dietary supplements as alternative therapy that are medicinal herbs and nutraceuticals. There is rising demand for nutraceuticals worldwide. The annual growth of nutraceuticals was found to be 25% in India which is similar to the developed country Japan. In this view, many new companies have begun manufacturing nutraceuticals in India.

The pharmaceutical companies and FMCG (fast moving consumer goods) suppliers placed a key role in the success of Indian nutraceuticals market. The Indian nutraceuticals market is divided into functional foods and beverages and dietary supplements. Over 64% of nutraceuticals market in India is occupied with vitamin and mineral supplements. The Indian nutraceuticals market which has grown from $1 billion in 2008 to $1.8 billion in 2013, has crossed $2 billion in 2014 and is expected to top $4 billion by 2018.

Nutraceuticals are considered as foods by the FSS Act, 2006, Rules and Regulations, 2011. The Food Safety and Standards Authority of India (FSSAI) has issued regulations with respect to licensing and registration of food business, manufacturing, packing and labelling, food product standard and so on.

In FSSA in India (FSSAI) has defined regulatory guidelines for approval of nutraceuticals in the Indian market. This Act consists of 21 chapters and in that the 4th Article that means 22 of the Act says about nutraceuticals, dietary supplements and various functional foods, and these products can be produced/manufactured, marketed that means sold or distributed that means import can be done by any of the company.

In the Nutraceuticals Regulations, 2016, under the 'General Requirements,' the FSSAI has stated that (21) mere combination of vitamins and minerals formulated in tablets, capsules, syrup formats shall not be covered in any of the categories of these regulations except when vitamins and minerals are added.

FSS Regulations, 2011, issued guidance for licensing and registration of food businesses; packaging and labelling; food product standards and food additives; prohibition and restriction on sales; contaminants, toxins and residues; laboratory and sampling analysis. FSS issued regulations for food or health supplements, nutraceuticals, foods for special dietary uses, foods for special medical purpose, functional foods, and novel food in 2015.

The following information shall be included in any claimed novel foods - (a) chemical composition of the engineered food; (b) surface modification/ surface chemistry; (c) primary particle size; (d) solubility; (e) digestibility; (f) amount of nanomaterial if any in the food product; (g) specific claim, if applicable.

Nutraceuticals shall contain any of the ingredients specified in Food Act Schedule

Schedule I
Vitamins and minerals

Schedule II
Essential amino acids and other nutrients

Schedule IV
List of plants and botanical ingredients

Schedule VI
List of ingredients as nutraceuticals

Schedule VII
List of strains as probiotics

Schedule VIII
List of prebiotic compounds

No ingredient other than those specified in Schedule VI shall be used as nutraceuticals with standardisation to marker compounds specified and at daily usage levels specified therein. Only nutraceuticals or extracts of ingredients specified in Schedule IV can be used in nutraceuticals. Ingredients of plant or botanical origin specified in Schedule IV and Schedule VI may be used either in the given form or their extract, subject to the extractive ratios in relation to the daily usage value. Only additives specified in Schedule VA or Schedule VE or Schedule VF should be used for nutraceuticals formulation.

The FSSAI issued notice on Dec 31, 2018, that disallowed the use of several ingredients in nutraceutical foods. The third notification on the subject of Nutraceutical Foods Regulation noted the following: (i) Allowing the use of the ingredient 'Vitamin D3' from lichen (Cladonia rangiferina) as a vegetable source in the products listed under Nutraceutical Regulations, until the time the proposed amendments on Nutraceutical Regulations are finalised and notified. (ii) Subject to compliance, mustard powder will continue to be used as an ingredient in products covered under the Nutraceutical Regulations. (iii) Discontinue certain ingredients mentioned in the notice. (iv) Allow food business operators (FBOs) to sell existing formulations with simple combinations of vitamins and minerals, only up to one recommended dietary allowance, in dosage forms such as tablets, capsules, and syrups. This is effective for a period of three months from the date of the current notification, or until further orders are announced, whichever is earlier.

FSSAI has directed Nutraceutical Regulations to stop using 14 ingredients lacking scientific data for safe usage. The country's apex food regulator ordered FBOs to discontinue the use of raspberry ketone, silica, angelica sinensis, paullinia cupana, saw palmetto, notoginsing,

chlorella growth factor, pine bark extracted to pinus radiate, pine bark extracted from pinus pinaster, Vitamin D3-veg, chaga extract, oxalobacter formigenes, phytavail iron and tea tree oil.

FBOs were also asked to discontinue antichoke, kale powder, salvia hispanica, cashewfruit, passion fruit, kiwi fruit extracts, broccoli and enzymes, including pectinase and xylanase, as health supplements. However, their use in products was not prohibited, but FBOs cannot claim that the products are supplement or nutraceuticals. No further manufacturing of products using these ingredients will be allowed until these ingredients are assessed and approved by the authority. Further, FBOs are directed to furnish information and data in respect of these ingredients within one month.

The label of nutraceuticals products should mention “Nutraceuticals” Recommended Usage Warning for the risk of excess consumption. Prohibitions on labelling claims must mention for Nutraceuticals Products Cure of disease claims, e.g. “Prevents bone fragility in post menopausal women,” implied cures for disease claims through pictures, vignettes or symbols.

Increased demand of nutraceuticals products in India evidenced their possible success rate in prevention and treatment of diseases. Hence, it needs regulatory authorities on product quality and safety in order to minimise the adverse events, toxicity, adulteration, misuse, overdose during human consumption. As food products are reaching from one country to another, maintaining safety and quality standards as per various regulatory guidelines set by the respective governments becomes important. To maintain quality and safety concerns of nutraceuticals all the new companies and existing companies should follow the regulatory guidance of FSSAI for better use.

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