FSSAI prohibits use of 14 ingredients under Nutraceutical Regulations

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FSSAI has directed the food business operators (FBOs) involved in manufacturing of health supplements and nutraceuticals, foods for special dietary use and for special medical purposes and functional and novel foods, governed under the Nutraceutical Regulation, to stop using 14 ingredients lacking scientific data for safe usage.

The directive by the country’s apex food regulator asked the FBOs to discontinue the use of raspberry ketone, silica, angelica sinensis, paullinia cupana, saw palmetto, notoginseng, 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.

P Kartikeyan, assistant director, regulations/Codex, FSSAI, stated in the directive that FBOs were directed to discontinue the use of ingredients listed in the products covered under the Nutraceutical Regulations with immediate effect due to the lack of scientific data.

“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 (i.e until July 29, 2018) for further assessment by the authority,” the statement read.

Further, the use of succinic acid are inosine is also discontinued, but the sale of products containing these ingredients is permitted until September 30, 2018.

The directive added that FBOs were directed to discontinue the use of
ingredients such as para amino benzoic acid (PABA), vanadium, prenolit and selenium dioxide, used for the product category under the Nutraceutical Regulations, with immediate effect. FBOs were also directed to withdraw any product containing these ingredients immediately.

The order also prohibited the use of D-ribose in health supplements and nutraceuticals, while for foods for special medical purpose and dietary use, approval from the authority was needed. Besides, the use of ipriflavone and polypodium leucotomos was also banned as they exhibited the properties of drugs.

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.

The directive, meanwhile, stated that the FBOs were allowed to continue the food business of existing formulations and combinations of vitamins and minerals only up to the recommended dietary allowance (RDA) in dosage formats, such as tablets, capsules and syrups, for a period of six months from June 29 (the date of issuance of this directive) without referring the energy value, –kcal/kj, as specified.