

F. No. Stds/Nutra(DCGI)/FSSAI - 2017 (Pt 1)
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 31st December, 2018

Subject: Implementation of Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (Nutraceutical Regulations).

In continuation to the direction issued under Section 16 (5) of Food Safety and Standards Act, 2006 dated 29.06.2018 and 24.08.2018 on the above cited subject, decision w.r.t the 14 ingredients listed under Appendix I of the direction dated 29.06.2018 are as follows:

- i) FBOs are allowed to continue to use the ingredient namely 'Vitamin D3' from lichen (*Cladonia rangiferina*) as veg source in the existing products covered under Nutraceutical Regulations, till such time the proposed amendment of the Nutraceutical regulations in this regard are finalized and notified.
- ii) FBOs are directed to discontinue the use of ingredient namely Raspberry ketone, Silica, *Angelica sinensis*, Chlorella growth factor, Chaga extract, Tea tree oil (*Melaleuca alternifolia*) in the products covered under Nutraceutical Regulations with immediate effect as no additional information has been provided by the applicant. No further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under aforesaid regulations before 29.06.2018 are allowed to be sold only up to a period of 30 days from the date of this direction.
- iii) FBOs are directed to discontinue the use of ingredients namely '*Oxalobacter Formigenes*' in the products covered under Nutraceutical Regulations with immediate effect since they exhibit properties of a drug and no further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under aforesaid regulations before 29.06.2018 are allowed to be sold only up to a period of 30 days from the date of this direction.
- iv) FBOs are directed to discontinue the use of ingredients namely *Paullinia cupana* (Guarana), Saw Palmetto, Notoginseng, Pine bark extract from *Pinus radiata*, Pine bark extract from *Pinus pinaster* in the products covered under Nutraceutical Regulations with immediate effect due to lack of adequate data such as history of safe usage in India for 15 years and also specific advantage of these plants over the already listed Indian plants/botanicals. No further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/

imported under aforesaid regulations before 29.06.2018 are allowed to be sold only up to a period of 30 days from the date of this direction.

- v) Based on the clarification provided by FBO that phytavail iron is mustard powder from *Brassica juncea* which is already covered under Schedule IV of the Nutraceutical regulations, it has been decided that no specific inclusion is required and ingredient mustard powder can be continued to be used in products covered under Nutraceutical Regulations subject to compliance with the aforesaid regulations.

2. Further, FBOs are allowed to continue the food business of existing formulations containing mere combinations of vitamins and minerals only up to one RDA in dosage formats such as tablets, capsules and syrups for a period of three months from the date of this direction or till further orders, whichever is earlier.

3. This issues with the approval of the Competent Authority in exercise of the power vested under Section 16 (5) of Food Safety and Standards Act, 2006.

Encl: As above



(Sunil Bakshi)
Advisor (Regulations / Codex)
FSSAI, New Delhi.

To

1. All Commissioners of Food Safety of All States/UTs.
2. All Authorised Officers, FSSAI.
3. All Central Designated officers, FSSAI.

Copy for information:

1. PPS to Chairperson, FSSAI.
2. PS to CEO, FSSAI.
3. All Divisional Heads in FSSAI, New Delhi.