File No. . 4(12)2017/Gujarat/RCD/FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
Regulatory Compliance Division
FDA Bhawan, Kotla Road, New Delhi – 110002

Dated: 16th July, 2020

To,

(i) Commissioner of Food Safety of all States/UTs
(ii) All Central Licensing Authorities

Subject: Surveillance and enforcement to prohibit sell of Health Supplement and nutraceutical products contains PABA (Para Amino Benzoic Acid) a banned ingredient–regd.

Sir/Madam,

FSSAI vide Order No. Stds/Nutr(DGCI)/FSSAI-2017(Pt.1) dated 29-06-2018 (copy enclosed) has banned the use of PABA (Para Amino Benzoic Acid) in the products covered under Nutraceutical Regulations due to safety concerns with immediate effect. Para No. 2 (c) of the said order also directs the FBOs that no further manufacturing of products using this ingredient is allowed. Any product containing such ingredient which is already manufactured / imported shall be withdrawn from the market immediately. However, it has come to notice that several health supplements and nutraceutical products containing PABA are still being sold in the market as well as on e-commerce platforms.

3. In view of the above, Commissioner of Food Safety of States/UTs are requested to carry out surveillance and enforcement and ensure compliance of Order No. Stds/Nutr(DGCI)/FSSAI-2017(Pt.1) dated 29-06-2018. The action taken report on surveillance and enforcement on above issue may please be communicated to this office at the earliest.

4. This issues with the approval of the Competent Authority.

Encl: As above.

Yours sincerely,

16/7/2020

(Dr. Shobhit Jain)
Executive Director, (Compliance Strategy)
Tel: 011-23237433
Email: ed-office@fssai.gov.in

Copy to: -

(i) All Food Business Operators
(ii) CITO, FSSAI –with a request to upload it on website.

F. No. Stds/Nutra(DCGI)/FSSAI - 2017 (Pt I)
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 25th June, 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.

In supersession of the direction dated 29.12.2017 (referred to hereinafter as 'earlier direction') regarding clarification on implementation of FSS (Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (referred to hereinafter as 'Nutraceutical regulations'), the following timelines are laid down with respect to compliance to these regulations to ensure smoother transition for food businesses:

(i) New ingredients and additives recommended by the Scientific Panel for inclusion in Nutraceutical regulations and proposed to be included in the existing Schedules as per Annexure I of the earlier direction are allowed to continue to be used in the existing formulations* after 30th June, 2018 till such time the proposed amendment of the Nutraceutical regulations in this regard are finalized and notified. However, the Food Business Operators (FBOs) shall comply with the provision with respect to permissible limits of ingredients/additives as given at Annexure-I of the earlier direction.

(ii) The earlier direction dated 29.12.2017 contained list of 33 ingredients, which were not recommended by the Scientific Panel for inclusion in the Nutraceutical regulations due to lack of data. The Scientific Panel has again reviewed the use of these ingredients based on the additional data made available by the FBOs and the following decisions have been taken accordingly:

(a) FBOs are allowed to continue to use the ingredients namely 'S-acetyl glutathione (50 – 600 mg/day, Max)' and 'alpha cyclodextrin' (already covered under 'other fibre sources' as mentioned in Schedule VI, Part B of the Nutraceutical regulations) 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.

(b) FBOs are directed to discontinue the use of ingredients namely 'Succinic acid' and 'Inosine' in the products covered under Nutraceutical Regulations with immediate effect as they are withdrawn by the applicant

*Criteria given in para 3 of the direction issued vide ZF. No. 15/Nutraceuticals/FSSAI-2009 dated 6th January, 2015.

and no further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported are allowed to be sold till 30th September, 2018.

(c) FBOs are directed to discontinue the use of ingredients namely 'Para-amino benzoic acid (PABA)', 'Vanadium', 'Prenolit' and 'Selenium dioxide' in the products covered under Nutraceutical Regulations with immediate effect due to safety concerns and no further manufacturing of products using these ingredients are allowed. Any product containing these ingredients which are already manufactured/ imported shall be withdrawn from the market immediately.

(d) FBOs are directed to discontinue the use of ingredient namely 'D-ribose' in health supplements/nutraceuticals with immediate effect and no further manufacturing of health supplements/nutraceuticals containing this ingredient for consumption by general population in unsupervised usage is allowed. For use of D-ribose in Food for Special Medical Purpose or Food for Special Dietary Use, prior approval shall be obtained from Food Authority. However, any such products containing this ingredient which is already manufactured/ imported are allowed to be sold till 30th September, 2018.

(e) FBOs are directed to discontinue the use of ingredients namely 'Ipriflavone' and *'Polypodium leucotomos'* 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 are allowed to be sold till 30th September, 2018.

(f) FBOs are directed to discontinue the use of ingredients/enzymes namely 'Artichoke', 'Kale Powder', *'Salvia hispanica'*, 'Cashew fruit', 'Passion fruit', 'Kiwi fruit extract', 'Broccoli', 'Enzymes (Pectinase and Xylanase)' as health supplements/ nutraceuticals. However, FBOs may use these ingredients/enzymes in the products as general ingredients, if permitted under Food Safety and Standards Regulations, without claiming any benefits as health supplements/ nutraceuticals for such ingredients. Further, any such products containing these ingredients which are already manufactured/ imported making any such claims are allowed to be sold till 30th September, 2018.

(g) FBOs are directed to discontinue the use of ingredients listed under Appendix -I of this direction in the products covered under Nutraceutical

Regulations with immediate effect due to lack of adequate data and no further manufacturing of products using these ingredients is allowed until these ingredients are assessed and approved by the Authority. Further, FBOs are directed to furnish information/data in respect of these ingredients within one month from the date of this direction for further assessment by the Food Authority.

(iii) 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 six months from the date of this direction or till further orders, whichever is earlier.

(iv) FBOs are allowed to continue the food business of their existing formulations containing vitamins and minerals in Food for Special Dietary Use without referring to the energy value (kcal/kJ) as specified under Schedule III, till such time the proposed amendment of the said regulations are finalized and notified.

2. 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.

Encls.: As above

(P. Karthikeyan)
Assistant Director (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.

1. Raspberry ketone
2. Silica
3. *Angelica sinensis*
4. *Paullinia cupana*
5. Saw palmetto
6. Notoginseng
7. Chlorella Growth factor
8. Pine bark extracted from *Pinus radiata*
9. Pine bark extract from *Pinus pinaster*
10. Vitamin D3 (Veg)
11. Chaga extract (*Inonotus obliquus*)
12. *Oxalobacter formigenes*
13. Phytavail iron
14. Tea tree oil