

Instruction No.16/2020-Customs

F.No.401/21/2020-Cus.III
Government of India
Ministry of Finance
Department of Revenue
Central Board of Indirect Taxes & Customs
(Single Window Project)

Room No. 229, North Block, New Delhi
Dated:24. 07.2020

To,

All Principal Chief Commissioners/Chief Commissioners of Customs/ Customs (Preventive)
All Principal Chief Commissioners/Chief Commissioners of Customs & Central Taxes, GST
All Principal Commissioners/ Commissioners of Customs/ Customs (Preventive)
All Principal Commissioners/Commissioners of Customs & Central Taxes, GST

Subject: Prohibition of selling of Health Supplement containing PABA (Para Amino Benzoic Acid) a banned ingredient – Reg.

Madam/Sir,

Kind attention is drawn to the advisory dated 16.07.2020 on the mentioned subject issued vide File No.4(12) 2017/ Gujarat/RCD/FSSAI by the Joint Director (RCD), Food Safety & Standard Authority of India, Ministry of Health and Family Welfare, Regulatory Compliance Division enclosing FSSAI Order No. Stds/Nutr(DGCI)/FSSAI-2017 (Pt.I) dated 29-06-2018 (copy enclosed).The operative para 2 of the advisory is reiterated below for ease of reference:

"2. FSSAI vide Order No. Stds/Nutr(DGCI)/FSSAI-2017 (Pt.I) dated 29-06-2018 (copy enclosed) has banned the use of PABA (Para Amino Benzoic Acid) in the products covered under Nutraceuticals 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 Any product containing such ingredient which is already manufactured/ imported shall be withdrawn from the market immediately.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 the notice that several health supplements and nutraceutical products containing PABA are still being sold on e-commerce platform."

2. The advisory has been issued with a request to circulate Order dated 29-06-2018 to all Customs Officials working as Authorized Officers to comply and to ensure that imported products containing banned ingredient shall not be cleared through their respective point of entries.
3. Suitable instruction may be issued for mandatory compliance by the departmental officers and the trade.
4. Any issues faced in implementation of this instruction may be brought to the notice of the Board.

Encls: As above



(Babu Lal Meena)
Deputy Commissioner,
Single Window Project,Cus.III

F. No. 4(12)2017/Gujarat/RCD/FSSAI
Food Safety & Standard Authority of India
(A Statutory Authority Established under Food Safety & Standard Act, 2006)
Ministry of Health and Family Welfare
Regulatory Compliance Division

FDA Bhawan, Kotla Road, New Delhi

Dated: 16th July, 2020

Advisory

Subject: Advisory for prohibiting sell of Health Supplement contains PABA (Para Amino Benzoic Acid) a banned ingredient-regd.

Food Safety and Standard Authority of India (FSSAI) has been established under FSS Act, 2006 for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

2. 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 on e-commerce platform.

3. All e-Commerce FBOs are advised to de-list /remove such products which contain PABA or any prohibited ingredients by FSSAI immediately from their website.

4. This issues with the approval of Competent Authority.


(Parveen Jargar)
Joint Director (RCD)
Tel: 01123231679

To,

E-Commerce Food Business Operators as per list attached herewith.

Copy to:

1. All Authorised Officers, FSSAI – To comply above order and to ensure that imported products containing banned ingredients shall not be cleared through their respective point of entries.

2. Director (Customs) & Commissioner (Single Window Project, CBEC) – with the request to circulate it to all Customs Officials working as Authorised Officer to comply above order and to ensure that imported products containing banned ingredients shall not be cleared through their respective point of entries.

List of E-Commerce Food Business Operators

S. No.	Company Name	Registered Office Details.	Email IDs
1.	M/s Snapdeal	M/s Snapdeal, Jasper Infotech Pvt. Ltd., 246, 1st Floor, Phase 3, Okhla Industrial Area, New Delhi 110020, India.	Pawan.kaul@snapdeal.com Pawan.paul@snapdeal.com pranav@snapdeal.com
2.	M/s Amazon	M/s Amzon, Brigade Gateway, 8th Floor, 26/1, Dr. Rajkumar Road, Malleshwaram West, Bengaluru, Karnataka 560055.	sanjac@amazon.com
3.	M/s Big Basket	M/s Big Basket, No. 7, Service Road, Off 100 Feet Road Indiranagar Landmark: Above HDFC Bank Bangalore, Karnataka 560071.	Anantha.padmanab@bigbasket.com seshu@bigbasket.com seshu@bigbasket.com hari@bigbasket.com
4.	M/s Flipkart	M/s Flipkart Internet Private Limited, Vaishnavi Summit, Ground Floor, 7th Main, 80 Feet Road, 3rd Block, Koramangala, Bengaluru 560034, Karnataka, India.	Sanjiv.saddy@flipkart.com satyajeet.b@flipkart.com tabrez.ahmad@flipkart.com
5.	M/s E Bay	M/s eBay India Private Limited, 14th Floor, North Block, R-TECH Park, Western Express Highway, Goregaon (East), Mumbai 400063, Maharashtra, India.	ebayindia.helpdesk@gmail.com dl-ebay-in-grievance-officer@ebay.com vidmay.naini@ebay.com tabrez.ahmad@flipkart.com
6.	M/s Shopping Indiatimes.Com	M/s Indiatimes Shopping aZzShopping Limited, Top Floor, 10, Darya Ganj, New Delhi-110002, India	social@indiatimes.co.in nitten.gupta@indiatimes.co.in

Date: 15th 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 F. No. 13/Nutra (DGCI)/FSSAI-2017 dated 29.12.2017. "01".

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 'Par-aminobenzoic acid (PABA)', 'Vanadium', 'Prenolol' 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 leucotomum*' 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 1 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 cepana*
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