

File No. 01/DNU-Representation/Standards/FSSAI-2017  
**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, the 9<sup>th</sup> July, 2018

To,

Commissioner of Food Safety/ Commissioner of Food Safety-In-charge

All States/UTs

**Subject: Sale of Creatine Monohydrate - reg.**

Sir/Madam,

In supersession of this office letter of even number dated 21st December 2017, it may be noted that in the 37<sup>th</sup> meeting of Scientific Panel on Functional Foods, Nutraceuticals, Dietetic Products and other Similar Products held on 17<sup>th</sup> January 2018, the Panel has opined that Creatine which is in the proposed list of inclusion under Schedule VI Part A 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, with the limit maximum 3 gm/day (for adults only), shall be allowed in its common form i.e. Creatine Monohydrate. However, creatine nitrate and its other new forms of creatine need evaluation for their safety and long term toxicity.

2. Further, it may be noted that the above said recommendation is applicable to only those FBOs which fall under Para 3 of FSSAI's letter No. 1-5/Nutraceuticals/FSSAI-2003 dated 6<sup>th</sup> January 2017 (copy enclosed).

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

Yours faithfully,

*Garima Singh*  
(Garima Singh)

Director (Regulatory Compliance)

Copy to:

1. Advisor, Standards, FSSAI
2. All Central Licensing Authority, FSSAI
3. All Authorised Officers, FSSAI
4. CITO, FSSAI-for uploading on FSSAI website.

IT Associate (Sh. Kamal)

**ZF. No. 1-5/Nutraceuticals/ FSSAI-2003**  
**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-110002**

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The 6<sup>th</sup> January, 2017

**Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding enforcement activities on Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purposes, Functional Foods and Novel Food:**

The Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purposes, Functional Foods and Novel Food) Regulations, 2016 have been notified in the Gazette of India vide No. 1-4/ Nutraceutical/ FSSAI-2013 on 23<sup>rd</sup> December, 2016.

2. As per the notification, the Food Business Operators (FBOs) are required to ensure compliance of their existing and new products with all the provisions of these regulations by 1<sup>st</sup> January, 2018.

3. Till this period, FBOs may continue manufacturing, importing, packing, storing, distributing and selling ingredients/products containing such ingredients falling under the categories specified under these regulations subject to compliance with any of the following criteria:

- i. Such Ingredients/Products containing such ingredients were available in Indian market prior to the notification of the FSS Act 2006 and Rules and Regulations made thereunder.
- ii. Such Ingredients/Products containing such ingredients were either granted approval or NOC by FSSAI.
- iii. Licenses were obtained for such Ingredients/products containing such ingredients prior to this direction.

Licenses for such ingredients/products containing such ingredients that are in compliance with the above mentioned criteria may be renewed under the

Food Categories 13.3, 13.4, 13.5 and 13.6 as applicable, for a period up to 31<sup>st</sup> December 2017. Such ingredients/products containing such ingredients are also importable up to 31<sup>st</sup> December 2017.

Notwithstanding anything mentioned above, it is the responsibility of the Food Business Operator to ensure that ingredients/ products containing such ingredients are in full compliance with the provisions of these regulations by 1<sup>st</sup> January 2018.

4. It is also clarified that products covered under these regulations and products mentioned at Para 3 above may also contain such additional ingredients, other than additives, which are either standardised or permitted for use in the preparation of other standardized foods as specified in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

5. 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.



(Sunil Bakshi)

Advisor (Regulations)

To

1. All Food Safety Commissioners.
2. All Authorised Officers, FSSAI.
3. All Central Designated Offices of FSSAI.

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI