

File No. Stds./WG-Advertising and Claims/FSSAI-2017
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi 110002


Dated, the 04 September, 2019

Notice

FSSAI has notified the Food Safety and Standards (Advertising and Claims) Regulations, 2018 on 19th November, 2018, which under sub-regulation 12 stipulates the procedure for approval of claims on food products along with applicable fees specified by the Food Authority from time to time.

2. Accordingly, FSSAI has constituted an Expert Committee on Claims for the purpose of scrutiny and assessment of health claims, specifically disease risk reduction claims and other claims made in advertisements.
3. It has been decided that all food business operators who wish to seek prior approval of claims on their food products as per the provisions of the above Regulations shall submit a duly filled application as specified in Annexure-A along with a fees of Rs. 50,000/- (Fifty Thousand Only) in the form of demand draft payable to Senior Accounts Officer, FSSAI. Such claim applications shall be for a product/ingredient in a product and a maximum of 3 claim statements shall be assessed against a single application.
4. Claims approved by FSSAI shall not be construed for the purpose of promotion of sale, supply, use and consumption of articles of foods, specifically ascribing it to FSSAI logo or license number in any way. Further, the Authority may also withdraw such approvals, as and when found appropriate, on availability of new scientific data/evidence.

This issues with the approval of the Competent Authority.


(Kumar Anil)
Advisor (Standards)

To
CITO for uploading on FSSAI's website

Copy to:

1. PPS to Chairperson, FSSAI
2. Sr. PS to CEO, FSSAI
3. All Divisional Heads, FSSAI
4. All Food Safety Commissioners of States/ UTs
5. Members of Expert Committee on Claims
6. Members of Scientific Committee and Scientific Panels

Application Form for Approval of Claims on food products

S.No.	Information required (All points are mandatorily required to be filled by the applicant except Point No. 20)	
1.	Name and Address of the Applicant	
2.	Name, email and contact number of the authorised signatory (All communications relating to the application will only be made through the above email and phone number)	
3.	License Number	
4.	Central/State License (Also attach a copy of your license along with the application form)	
5.	Nature of license/License Category	
6.	Name of the food product	
7.	Product Composition	
8.	Product Category	
9.	Does your ingredient/product fall under Non-specified category? If yes, please attach copy of approval letter from FSSAI.	
10.	Type of Claim(s) required (On product/Ingredient)	
11.	Name of ingredient, nutrient or substance on the basis of which the claim is to be made;	
12.	Claim Statement	
13.	Justification for the claim statement (How is the claim clear and meaningful and help consumers to comprehend the information provided?)	
14.	Is the ingredient/product on which claim is intended to be made protected under Intellectual Property Rights (IPR)/patented?	
15.	Are any of the claim functions protected by IPR?	
16.	Scientific substantiation supporting documents/material***	

17.	Cause-effect relationship studies in respect of "reduction of disease risk claims" (Well-designed human intervention studies conducted by or under guidance of established research institutions)	
18.	Validated Method of analysis of ingredient or substance for which the claim is to be made	
19.	Interaction / Contraindications / Possible Adverse Effects / Warnings/Advisories on the food product	
20.	Any other useful information	

Date of application:

(Authorised Signatory)

***Adequate published scientific literature/studies should form part of Claim Support Dossiers (CSD) to be submitted by the applicants. Such dossiers should provide a succinct summary of published scientific data comprising in-vitro, in-vivo and human studies data. Hard copies of important publication(s) be also appended to the summary data in the CSD with a commitment to provide copies of any other publications listed in the summary statement, if demanded by the Authority. Such succinct summary shall be provided separately in respect of each claim statement for which application has been made. Unpublished or under communication studies, if any, either undertaken by the applicant or reported by other organisations may also be provided where available in full form.

Disclaimer: Information provided in Claim Support Dossiers shall not be a guarantee for approval of claims.