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 Delhi110002

Dated, the 5th May, 2020

Notice

Reference is drawn to a notice no. Stds. /WG-Advertising and Claims/FSSAI-2017dated 4th September, 2019 conveying the procedure to apply for approval of claims specified under FSS (Advertising & Claims) Regulations. As per the said notice, the Claim Support Dossiers (CSD) to be submitted by FBOs should provide a succinct summary of published scientific data comprising in-vitro, in-vivo and human studies data.

2. In this regard, FBOs are directed to submit the summary of published scientific data as per the format specified at Annexure.

This issues with the approval of the Competent Authority.

(A.C Mishra)
Joint Director
(Science & 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. Members of Expert Committee on Claims

Annexure

Format for providing summary of claim support data

1A. Summary of in-vitro data

Material tested (1)	Microbes / Cell lines / organ culture / other test system (2)	Concentrations tested, negative and positive controls used (3)	Variables, biomarkers, performance indicators evaluated / measured(4)	Results obtained (5)	Reference of publication(6)

(1) Describe the material tested, purity, in case of botanicals or biological material provide information on their standardization / marker compounds tested / activity tested.

(2) Provide information on bacteria, yeast or any other microbes against which testing was done including their NTCC / Accn. Number / details of cell lines / details of organ culture or tissue culture or any other system.

(3) Provide information on Concentrations tested, negative and positive controls used in the experiments.

(4) Provide information on what aspects were measured as outcome of the test. For example IC 50, cytotoxicity, dye uptake or reduction in dye uptake, preventing rate of growth.

(5) Give brief summary of the results obtained, comparison with controls, and any dose response relations reported.

(6) Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.

1B. Summary of in-vivo data

Material tested (1)	Laboratory animal used / knockout animals if used / isolated organ if used / any other test system (2)	Concentrations tested, negative and positive controls used (3)	Variables, biomarkers, performance indicators evaluated / measured(4)	Results obtained (5)	Reference of publication (6)

(1) Describe the material tested, purity, in case of botanicals or biological material provide information on their standardization / marker compounds tested / activity tested.

(2) Provide information on laboratory animal, knockout animals, live or anesthetized / isolated active organ of animals (isolated ileum, skin cultures, isolated heart as examples) or any other system.

(3) Provide information on Concentrations tested, negative and positive controls used in the experiments.

(4) Provide information on what aspects were measured as outcome of the test. For example IC 50, pharmacological activity measures, gene expression, specific protein uptake or regulation, biochemical markers, toxicology markers.

(5) Give brief summary of the results obtained, comparison with controls, and any dose response relations reported.

(6) Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.

1C. **Summary of human study data**

Nature of study (1)	Material tested and their levels (2)	Nature of volunteers /subjects/ population / patients (3)	Design of study and n =?	Inclusion exclusion criteria (5)	Duration of study (6)	Variables measured (7)	Results obtained (8)	Reference of publication (9)

(1) Describe briefly the nature of study namely – open label, intervention study, randomization, blinding or population study or diet and outcome surveys or epidemiological data collection and analyses.

(2) Provide information on Concentrations tested, negative and positive controls used in the experiments.

(3) Give brief information on nature of subjects / volunteers / patients involved in the study. For example normal healthy volunteers, pre-diabetics, mild to moderate hypertensive patients, volunteers with specified BMI etc.

(4) Give brief summary of the design of the study like matched panels, groups involved, cross over design, superiority study, addition study. State the number of volunteers or subjects or population or patients in each group giving details of number screened, number enrolled, number whose data is available, number drop outs. Also state the statistical analyses of the data reported and test of significance. Also provide approval status of the study by DRB / EC, adoption of informed consent.

(5) List the inclusion and exclusion criteria.

(6) State duration of the study – study period, duration of intervention, wash out period if any and period of observation post stoppage of intervention.

(7) Provide information on what aspects and variables were measured as outcome of the study. For example pharmacological activity measures, biochemical markers, physiological parameters measured using instrumental technics like EEG, TMT, echo, bone density, image analyzers etc. Provide information on ADRs and safety aspects evaluated including quality of life measurements and reported in the study. Specifically state if the study does not report the safety or ADRs or no mention is made of this aspect. If any of the study provided in this summary table covers a Cochrane review or a meta analyses review provide summary of the same.

(8) Give brief summary of the results obtained, comparison with controls, and any dose response relations reported. Provide information on ADRs and safety aspects evaluated including quality of life measurements and reported in the study. Specifically state if the study does not report the safety or ADRs or no mention is made of this aspect.

(9) Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.

2. Further, if any IPR exists, FBO needs to provide the nature of the IPR with a commitment to provide copies of the same, when demanded. If claim support data includes regulatory approvals granted specifically or notified in regulations of other nations, then the same shall be provided in a summary table. In case of specific approvals granted, state the same and authenticated copies of the same should be submitted. For example GRAS listing or ingredients / product / claim approval received by the FBO or applicant.