Seminar
on
"Clinical Evaluation/Intervention Studies for New Foods & Food Ingredients: Current Status and Way Forward"
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OPENING ADDRESS

4:51

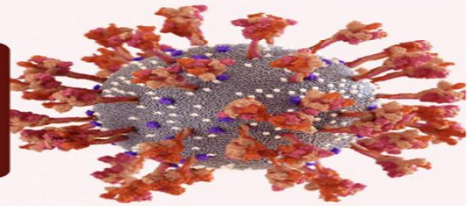
All Mail

Therapy After Recovery and Vaccination

CoVaccine Chronicles | Unite to Fight COVID

docplexus | IIT

A Novel Form of Curcumin and COVID-19



New Curcumin Boosts Immunity in Adults Recovered from COVID-19 and Subsequently Vaccinated

Global reports of breakthrough infections and reinfections raise the need for an adjunct that can confer additional, improved inflammatory immune response post-vaccination. A new curcumin formulation (CURC) was compared with a placebo for its effects on circulating inflammatory biomarkers in 31 adults who had recovered from COVID-19 and received a primary series of monovalent vaccine doses.

How to Decide Whether a Health Claim is substantiated?

- **Do we think that** Assessing their safety and efficacy against the claims is critical to protect consumer's health and wellbeing
- **Do we have to** Generate consumer's confidence
- **Do we require** Human intervention studies for generating efficacy and safety data in support of their proposed health claims
- **Do we require** Studies in Indian population to understand cause effect relationship.

FUNCTION OF FOOD

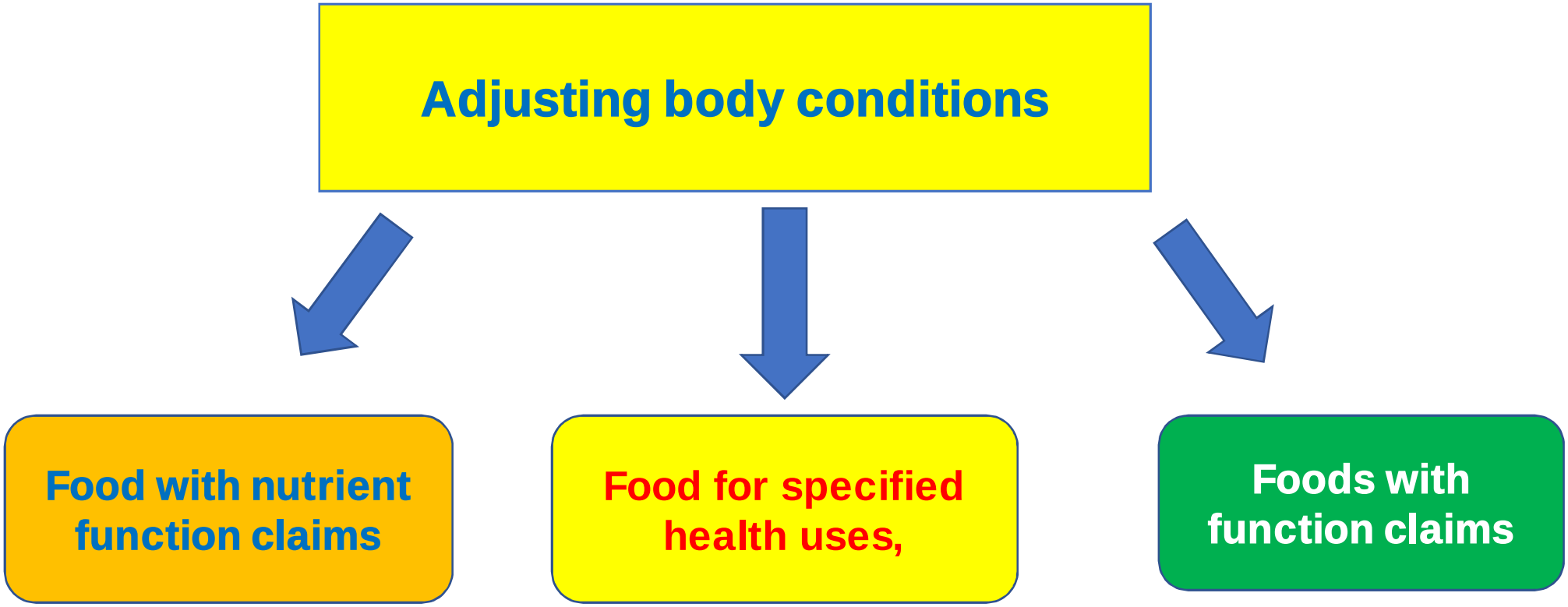
Nutritional function

Sensory function,

Adjusting body conditions

Tanemura et al., 2017)

Health effects of foods with Health claims



(Tanemura et al., 2022)

Food for Specified Health Uses

Refers to foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body.

Intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol etc.

In order to sell a food with specific health claim, data in support of their proposed health claims the assessment for the safety of the food and effectiveness of the functions

The claim must be approved by the National regulator (FSSAI in India).

1. **Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017**

2. **Food Safety and Standards(Advertising and Claims) Regulations, 2018**

Studies from Indian population would be important to support their safety and efficacy

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 11th September, 2017

F. No. 12/PA Regulation/Dir (PA)/FSSAI-2016.—Whereas the draft of the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 were published as required under section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F.No. 12/PA Regulation/Dir (PA)/FSSAI-2016, dated the 31st January, 2017, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 9th February, 2017;

And whereas objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (v) of sub- section (2) of section 92 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations, namely:—

Regulations

1 Short title and commencement.— (1) These regulations may be called the 'Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.'

4. Procedure for grant of prior approval.—(1) The manufacturer or importer of non-specified food shall submit an application in FORM – I of these regulations along with necessary documents and fee to the Food Authority.

(2) The Food Authority shall scrutinize the application and information provided by the applicant.

(3) The Food Authority may direct the applicant to submit additional supporting documents, data or clarifications, if required.

FORM – I

(*See* sub-regulation (1) of regulation 4)

(Application for approval of non-specified food and food ingredient)

1. Application for (Please tick √):-

- ○ Novel food or novel food Ingredients or processed with the use of novel technology
- ○ New additives
- ○ New processing aids including enzymes

3. Additional specific information:—

(a) Novel food or novel food Ingredients or food processed with the use of novel technology:-

(1) The target group for the said proposed food, if any

(4) Safety Information (Documents on risk assessment or toxicity studies to be attached)

(a) Information on human studies including dietary exposure, nutritional impact and potential impact on the consumer if any

(b) Toxicological studies including results of Ame's tests to test mutagenecity, chromosomal aberration tests, studies for reproductive toxicity, prenatal developmental toxicity studies

(c) Allergenicity (published or unpublished reports of allergenicity or other adverse effects in humans associated with the food consumption; may include reports prepared by World Health Organisation or by other national or international agencies responsible for food safety or public health)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 13th March, 2018

F.No. 1-94/FSSAI/SP(Claims and Advertisements)/2017.—The following draft Food Safety and Standards (Advertisements and Claims) Regulations, 2018, which the Food Safety and Standards Authority of India proposes to make, with previous approval of Central Government, in exercise of the powers conferred by clause (k) of sub section (2)

3.4 Health Claims.-

(4) Where a claimed benefit is attributed directly to the product or used on labels, advertisements or any other means as a mode of communication to the consumer, it shall be based on statistically significant results from appropriate scientific research study(s), OR a well designed, randomized double blind (Unless technically not feasible) clinical study(s), conducted by OR under guidance of established research institutions, in line with the principles of GCP (Good Clinical Practices) and Peer Reviewed OR published in a Peer reviewed reputed scientific journal with an impact factor of not less than 1 at the time of submission of paper.

7.Health claims.- (1) Health claims shall comply with the following conditions and declarations, namely:-

(5) Where a claimed health benefit is attributed directly to the product, it shall be based on statistically significant results from well-designed human intervention studies, conducted by or under guidance of established research institutions, in line with the principles of GCP (Good Clinical Practices) and peer reviewed or published in a peer reviewed reputed scientific journal.

Our Target

- **Novel foods or ingredients only**
- **Establishing efficacy where such data is not available or not generated in Indian population.**

Human Intervention Study in Food

- **Is it a new concept ?**
- No-
- **1747**-Dr. James Lind conducted a systematic clinical experiment using citrus fruits (orange and lemon) to treat scurvy
- **1794** - This work was verified when lemon juice and sugar was issued on board the *HMS Suffolk*, a British Navy ship, during a 23-week, non-stop voyage to India - landed without any serious outbreak of scurvy.
- Prior to this time, scurvy was a leading cause of disease and death among sailors.

Why not adopt methodology of New Drugs and Clinical Trials Rules, 2019

- **Country has an effective mechanism for conducting Clinical Trials for Drugs under New Drugs and Clinical Trials Rules, 2019**

- **Is there any need for separate guideline for food?**

Food human intervention trials	Drug clinical trials
Designed to evaluate specific marketing claims	Document the safety and efficacy of a specific drug for a specific intended use
Tend to be more pragmatic and exploratory as they document human experiences with specific foods in the context of the human diet	Tend to be more explanatory as they document specific drug doses and schedules and specific disease responses.
Typically enroll healthy individuals	Enroll patients with a specific disease type potentially needing the research treatment.
Foods are complex mixtures of ingredients (e.g., plant parts, meats, eggs, chemicals, beverages, whole meals, etc.) designed to be palatable and which may have the general health effect under investigation	Highly purified and designed to have a specific effect on a disease.

OBJECTIVE OF THE SEMINAR

- Sensitize all stake holders regarding the Need for Human Intervention Study
- Modalities of conducting of such human intervention study
- Help each stake holder to know - DO's and Don'ts
- Need for availability of a well documented

GUIDANCE DOCUMENT

Can we devise a decision tree approach for better understanding and clarity.

Who are the Stake holders

- **Food Business Operators(FBO)**
- **Contact Research Organisation (CRO)**
- **Participant: volunteers to take part in the clinical trial**
- **Investigator: A researcher who helps conduct the clinical trial—such as a doctor.**
- **Study coordinator: Works with investigator to manage the clinical trial—such as a nurse.**
- **Ethics committees,**
- **Institutional Review Board (IRB)**
- **Sponsors,**
- **Regulatory agencies,,**
- **Patient advocacy groups.**

Expected Outcome of this SEMINAR

Preparation

of

a White Paper

on

Best Practices for Conducting Human intervention/ clinical evaluation activities in Food.


Thank You!
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