REGULATIONS AND GUIDELINES: A CRITICAL REVIEW OF NUTRACEUTICALS

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ABSTRACT
The term Nutraceuticals is derived by the combination of nutrition and pharmaceutical. In 1989, by Stephen DeFelice, the term combines "pharmaceutical" and "nutrient," aligning with the preventive philosophy inspired by Hippocrates. Now-a-days these Nutraceuticals play a major role in the world to enhance the health conditions of humans. At present the society facing many health problems due to nutritional imbalance. As a result, if "food is your medicine" in such a situation, it would be ideal to obtain a healthy body and mind. The emphasis is on global harmonisation and harmonized technical requirements for registration of nutraceutical products in this market. The main aim to introduce the Regulations and Guidelines for nutraceuticals is to improve the product quality and safety of nutraceutical products during human consumption. The article delves into the regulatory framework, emphasizing good manufacturing practices (GMP), and highlights global market growth. The regulatory framework in India, governed by the Food Safety and Standards Act, 2006, is explored, along with the complexities of product registration and health claims. The article underscores the need for clearer regulations and Guidelines to foster the growth of the nutraceutical industry in India. This review article explores the evolving landscape of nutraceuticals Guidelines and regulations, defined as non-specific biological therapies aiming to prevent and manage diseases while enhancing overall health.

Keywords: Nutraceuticals, regulations, Nutraceutical products, health claims, good manufacturing Practices, guidelines.
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INTRODUCTION

Nutraceutical products can be thought of as non-specific biological therapies that are intended to prevent cancerous processes, manage symptoms, and enhance overall health. "Nutraceutical" is a term derived from the combination of the words "pharmaceutical," which refers to a medicinal drug, and "nutrient," which is a nourishing food component. Stephen DeFelice, the founder and chairman of the Foundation for Innovation in Medicine, an American organization based in Cranford, New Jersey, came up with the name in 1989.Using the proverb "let food be your medicine" from Greek physician Hippocrates, regarded as the father of medicine, as a guide, nutraceuticals are based on the philosophy of prevention. One of the most crucial areas of research is their function in human nutrition, which has broad ramifications for patients, healthcare professionals, regulators, and food producers. It was in 1989 that Stephen Defelice, MD, the founder and chairman of the Foundation for Innovation in Medicine (FIM), located in Cranford, New Jersey, combined the words "nutrition" and "pharmaceutical" to create the term "nutraceutical." "A food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease," is how Defelice defines a nutraceutical. (1)

There are instances when the terms "functional food," "dietary supplements," and "nutraceuticals" overlap. With an eye toward safety, these products have been given specific definitions and regulations over the years by the rules and regulations pertaining to this area of products. These guidelines have changed more as more products are being released onto the market. The foundation for the creation of these products is provided by food science research. These products make unique health benefit claims or, frequently, claims that they can cure particular illnesses or disorders. Policies concerning these goods differ from nation to nation, and numerous goods have introduced to the market. Establishing the policy for nutraceuticals will be less confusing if there is a clear understanding of what nutraceuticals are in a regulatory system. Currently, though, the regulatory landscape for nutraceuticals varies based on the legal system in each nation. (2)

The words "nutrition" and "pharmaceutical," which were first used in 1989 by Stephen DeFelice, MD, the chairman and founder of the Foundation for Innovation in Medicine (FIM), are combined to form the term "nutraceuticals." NJ's Cranford. "A food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease," is how DeFelice defines a nutraceutical. (3)

Conversely, the term "nutraceutical" lacks a regulatory definition and is primarily used in the marketing domain. The phrase is used to describe a variety of products, including processed foods like cereals, soups, and beverages, as well as isolated nutrients, dietary supplements, and herbal products. According to data gathered by the National Health and Nutrition Examination Survey (NHANES) from 2003 to 2006, which included all forms of dietary supplements, 53% of American adults took at least one dietary supplement, most often multivitamin/multimineral products. In the US, women took dietary supplements at a higher rate than men. (4)

Food safety standard and standards act (FSSA): 2006 (5-6)

This act was established in 2006 to create the Food Safety Authority (FSSA), a statutory body that oversees the production, distribution, sale, and import of food in order to guarantee its availability domestically. By virtue of the FSS Act of 2006 and its rules and regulations from 2011, nutraceuticals fall under the category of foods. "Foods for special dietary uses or functional foods or nutraceuticals or health supplements" is defined as follows in Section 22(1) of the FSSA:

A. Foods that are specifically prepared or processed to meet specific dietary needs resulting from a specific physical or physiological condition, as well as specific diseases and disorders, and that are labelled as such; the ingredients of these foods must differ significantly from those of regular foods of a comparable nature, if such regular foods exist. These foods may include one or more of the following ingredients:

• Plants, botanicals, or botanical parts in the form of single or combined powder, concentrate, or extract in water, ethyl alcohol, or hydro alcoholic extract;

• Minerals, vitamins, proteins, metals, or their compounds, or enzymes (within allowable limits) or amino acids (in amounts not to exceed the Recommended Daily Allowance for Indians);

• Materials derived from animals;

• A food item that humans can use to augment their diet by consuming more food overall;

B. A product designed for oral administration that bears the label "Food for special dietary uses or functional foods or Nutraceuticals or health supplements or similar such foods," meaning that it is not intended for use as a conventional food and can be prepared as powders, granules, tablets, capsules, liquids, jelly, or other dosage forms but not parenteral;

• A drug as defined in clause (b) and an Ayurvedic, Siddha, and Unani drug as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), as well as any regulations issued thereunder, do not constitute such a product;

• Makes no claims to treat or lessen any particular illness, ailment, or condition, with the exception of for specific health benefit or similar promotion claims) as may be allowed by FSSA regulations;

• Excludes substances listed in Schedules E and E(I) of the Drugs and Cosmetics Rules, 1945, as well as prescription drugs and psychotropic substances as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made thereunder. (23 of 1940) and the regulations derived from it.

GMP guidelines

1968 saw the adoption of the first GMP draft text by the WHO. The WHO GMP was acknowledged as a crucial component of the WHO Certification Scheme in 1969 when the World Health Assembly recommended the first version of the scheme to assess the quality of pharmaceutical products entering the global market. The Expert Committee on Biological Standardization (ECBS) adopted a supplementary annex on biological medicinal products in 1991. This annex lays out the general methodology for the quality control of biological medicines, which encompass a range of products including vaccines, blood and blood products, antigens, cell and tissue therapies, biopharmaceutical products, and others. Many more nations have adopted the WHO GMP guidelines, and over 100 countries have integrated its provisions into their own national drug laws. and methodology in establishing their own national GMP specifications. The WHO Certification Scheme and the prequalification of vaccines for purchase by UN agencies are still based on the WHO GMP. (7)

Global market overview

The study on Global Market Growth & Demand suggests that worldwide nutraceutical industry has been developed at a compound annual growth rate (CAGR) of 7.5% to $285.0 billion from 2016 to 2021. The functional beverages market is reached $105.5 billion by 2021, up from $71.5 billion in 2016, at an 8.1% CAGR from 2016 to 2021. The functional food industry is reached $92.3 billion by 2021, up from $64.6 billion in 2016, at a 7.4% CAGR from 2016 to 2021. By 2025, the globe will have 1 billion people aged 60 and up. While the industry expanded at 7% per year between 1999 and 2002, the next several years up to 2010 experienced double that growth at 14% per annum. Currently, roughly $12-15 billion is contributed each year.

Nutraceutical demand is predicted to rise as the prevalence of disorders such as high blood pressure, obesity, diabetes, and cholesterol rises throughout the forecast period. The high expense of healthcare services has led in increased public interest in nutraceuticals in recent years. (8)

Laws governing nutraceuticals

Depending on the nation, several laws with varying names regulate nutraceuticals. Even the term itself varies by region, ranging from dietary supplements to nutraceuticals, and some nations classify nutraceuticals as food. A dietary supplement, in general, is a substance that is taken orally and consists of a dietary ingredient that is intended to be an addition to a diet. Nutraceuticals are referred to by a variety of definitions and terms around the world. For example, in the United States, they are called dietary supplements; in Canada, they are called natural health products; in Australia, they are called complementary medicines; in the European Union, they are called food supplements; and in India, they are called foods for special dietary use. (9)

Nutraceutical regulation in India (10-12)

The Food Safety Standards Authority of India (FSSAI) is the governing authority in the nation that grants approval for the registration of Nutraceuticals and food products. It also improves public awareness of the country's food safety regulations. The Food Safety Standard and Standards Act was adopted in 2006 to create a legislative agency that regulates the manufacturing, storage, distribution, sale, and import of food and food items in order to make sure their availability within the country. Nutraceuticals are classified as foods under the FSS legislation of 2006 and the rules and regulations of 2011. They issue a regulation regarding licensing, registration of food business, manufacturing, packing and labelling, and food product standard. The FSSA is divided into 12 chapters, each containing 101 parts and two schedules. The FSSA integrates the key elements of the Prevention of Food Adulteration Act of 1954, with the goal of creating a single point of reference for all issues concerning food safety and standards. The Food Safety and Standards Authority of India (FSSAI) is established by the regulatory authority of FSSA, with a chairperson and 22 members.

The FSSAI will be aided in carrying out the requirements of the FSSA by a Central Advisory Committee (CAC), Scientific Panels (SPs), and a Scientific Committee (SC), each with specialized functions. After conducting the necessary scientific review, the Food Authority may enlist certain nutraceuticals as approved from time to time. Nutraceutical labelling must comply to the packaging and labelling criteria outlined in the Food Safety and Standards (Packaging and Labelling) Regulations, 2011. The Food Safety and Standards Act will encourage producers to do product R&D, establish dependable processes, and conduct clinical research. These FSS act regulates the food, nutraceuticals, food for medical purpose, dietary food and novel food. The Foreign Direct Investment Act they also Provide a new opportunity for foreign companies to manufacture and market Nutraceutical goods in India. In India, dietary supplements are called "foods for special nutritional purposes". According to the Food Safety Standards Authority (FSSA), "foods intended for specific dietary or functional foods, dietary supplements, or dietary supplements" is

- Foods that are specially processed or formulated to meet special dietary requirements arising from certain physical or physiological conditions or certain diseases and disorders and are presented significantly as different such are from the composition of normal foods. It is necessary to distinguish between the compositions of these foods that differ from each other in the presence of such ordinary foods, and in the presence of such ordinary foods, the composition of equivalent ordinary foods. Equivalent properties if they must be significantly different.
- Minerals, vitamins, proteins, metals, or their compounds, or amino acids should not exceed the Recommended Daily Allowance for Indians.
- A product labelled as "Food for specific dietary applications or functional foods or nutraceuticals or health supplements or similar such foods" that is not intended for use as a conventional food and is available in powders, granules, tablets, or other similar forms.
- Such a product does not contain a medication or Ayurvedic medicine.
- Does not make any claims to cure or alleviate any specific illness, ailment, or condition (save for limited health benefit or promotion claims as allowed by FSSA laws).

Eligible Products for FSSAI License

Nutraceuticals Regulations' cover the following eight categories of Functional foods:

1. Health Supplements
2. Nutraceuticals
3. Food for Special Dietary Use
4. Food for Special Medical Purpose
5. Specialty food containing plant or botanicals
6. Foods Containing Probiotics
7. Foods Containing Prebiotics
8. Novel Foods

Documents Requirement for FSSAI

Food License

The documents required to register the food license for FSSAI is based on kind of registration- – The Registration for Food License in Form A and Form B is depends on annual turnover of food business. For tiny FBO only registration with food, authority is required.

Annual Turnover Registration / License

- If the annual turnover is below 12 Lakhs, then the food business operator must undergo Basic Registration in FORM A to get approval license
- If the annual turnover is in between 12 lakhs – 20 Crores then the food business operator must register in FORM B that is for State License
- If the annual turnover is Above 20 Crores, then they must apply for Central License FORM B

Documents required with Form A

- Passport size photograph of FBO
- Documents for Identity Proof such as ration card, voter ID card, Pan card, driving license, passport, Aadhar card, Senior Citizen
- Supporting documents (if any needed) NOC Municipality/Panchayat, NOC by Health

Documents required with Form B (State License and central license)

- Form B must be properly completed and signed (in duplicate) by the authorised signatory's proprietor or partner.
- Manufacturing and processing units must offer a blueprint layout of the processing units.
- It is mandatory for companies to list the address and contact details of Partners/ Proprietor / Executive Members of society.
- Aadhar card or any address proof or any ID which is issued by Government authority
- The manufacturer should notify the list of food category to be manufactured
- Analysis report of water used as an ingredient in food approved for portability / from the Institute of Public Health
- A manufacturer should submit a Copy of License
- If there is Food Safety Management System plan or certificate
- Transporters should submit the documentary proof for Turnover and the transporters should declare the number of vehicles that are transporting
- A photo of Production unit
- Declaration form

Regulatory Requirements in India (13-14)

As the nutraceutical regulation is evolving in India, with the recent implementation of FSSA, there is a possibility that some of the content is conflicting/confusing, but for Indian industry to take a shape, this has to be streamlined. In order to enter the Indian nutraceutical market, some of the very important areas to focus include product evaluation, actual product analysis, procuring licenses and developing India-specific health and label claims.

1. **Product Evaluation:** In Indian conditions, the formulations behave very funnily and get mixed up in classifications. Hence, the due diligence in terms of carving a specific amount for each ingredient and the combination of ingredients becomes very crucial. In order to perform product assessment as per Indian regulatory definition, it is of utmost importance to examine each active ingredient and additive in the con text of permissibility, standards and dosage of vitamins/minerals allowed as per the therapeutic, prophylactic, or RDA for Indians. Also, manufacturers are unclear whether their products will be classified as food or food supplement or drug in the context of the Prevention of Food Adulteration Act 1954 and Rules 1955, Food Safety and Standards Act 2006 and Drugs and Cosmetics Act 1940 and Rules 1945.

   The Food Safety and Standards Rules 2011 highlight the regulatory enforcement structure and procedures that central government proposes to make. The structure has a hierarchy from commissioner of food safety to the number of officers and designations such as food safety officer, food analyst, etc., who will be involved in the product analysis process at different points. Various steps involved in product evaluation are as follows

   - Preparation of extracts from documents
   - Sample collection
   - Sample dispatch to competent authority (different procedures for bulk pack and single pack)
   - Food analysis
2. **Licenses:** Although the new FSSA promises to simplify licensing and registration processes for nutraceuticals, the actual process varies depending on the number of para meters. To get the product registered in India, the number of licenses (almost 4 5) will be required depending on the actual product status such as whether:
   - The company wants to sell bulk drug or finished formulation
   - The company is importing finished product or bulk ingredient
   - The product to be imported is with or without an India-specific label and will
   - the claims be developed in India
   - The company has packaging license
   - It requires a manufacturing license
   - It requires a marketing license
   - The number of documents will have to be furnished by the food importer to the government authority along with registration application dossiers. The inter link through its regulatory product offerings provides regulatory support for the following licensing procedures, which need to be taken care of before launching these products in India.
   - Import licensing
   - Manufacturing licensing
   - Marketing licensing

- Other State Licenses/Licenses and Country Required by Regulators before Launch these products in India.

3. **Health and label claims:** Developing health and label claims specific to Indian regulatory guidelines is the major element to be focused on while entering Indian market "Health claims" means any expression that states, suggests or implies that a link between a food or ingredient of this food and health. These includes
   - India- specific labelling and packaging requirements
   - Consignment composition packaging for consignment sales and marketing procedures
   - Need a Sample material requirements and declaration of registration
   - Label content and claims
   - Structure - function claim

Health claim:

1. Nutritional Statement

A nutritional claim, such as "low fat," "no added sugar," or "rich in fiber," implies that a meal provides nutritional benefits. A claim is a statement that indicates a link between food and health, such as "lowering cholesterol," "reinforcing the body's natural defense," or improving learning capacity."

2. Disease Claim Reduction:

Any claim says or suggests that taking dietary supplements or one of its ingredients reduces the risk of human disease development considerably.

3. Claim of Structure/Function

A structural claim on a food or dietary supplements label refers to how the product impacts the human body structure. Based on the results of a regulatory assessment of the product, India-specific label content and claims are developed. New entrants should also consider some of the health claims used in India and the requirements to be met to make specific product claims.

Registration process for nutraceutical in India (15-16)

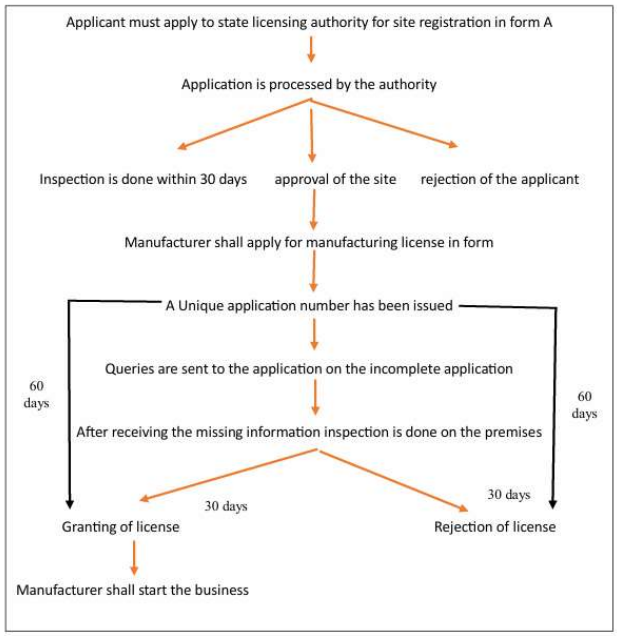

Figure 1: Registration process for nutraceutical in India

Comparative study of nutraceuticals regulation in India and USA (17)

Table 1: Comparative study of nutraceuticals regulation in India and USA

CONTENT	INDIA	USA
Definition	A nutraceutical is a food or food-related component that has been shown to provide health benefits, such as illness treatment and prevention	Nutraceuticals are "foods, or components of foods, that provide medicinal or health benefits, such as sickness prevention and treatment.
Rules	Food safety and standard Authority of India	USFDA
Regulations	Food safety and standard regulation	Dietary Supplement Health and Education Act (DSHEA)
Regulatory Authority	Food safety and standard Authority of India (FSSAI)	Dietary Supplement Health and Education Act (DSHEA)

Health Claims	• Nutritional claim, • Health claim a. Nutraceutical ingredient b. A health related benefit c. other claims	• Health claims • Nutrient claims • Structure/ function claims and related dietary supplement claims
Year in which regulations came into force	2011	1994
Regulatory requirements for registration	• Product evaluation • Licenses • Health & label Claim	• Product licensing • Evidence requirements for safety & efficacy • A Labelling • Heath claims • Good manufacturing practices (GMP) • Adverse reaction Reporting Clinical trials Form for registration
Form for registration	Form A, B&C	• Form 3537
Fees for registration	Rs.100 for registration and Rs.1000 for license	Not required for USA

Labelling and Claims in Nutraceuticals (18-19)

Most products still do not need labelling, as well as stringent regulation over formulas and branding. Health claims on Nutraceuticals serve to inform customers that, when combined with a good diet, they may lessen the risk of certain diseases. As part of the 1990 Nutrition Labelling and Education Act (NLEA), the FDA first authorized seven health claims in 1993. Six further claims have been approved by the FDA since 1993. To help consumers get this information faster, the Food and Drug Administration Modernization Act of 1997 contained a provision to expedite the process of establishing the scientific foundation for health claims.

Despite the fact that food producers may make health claims to advertise their products, leads to benefit customers by offering information on healthy eating habits that may help lower the risk of heart disease, cancer, osteoporosis, high blood pressure, dental cavities, or certain birth abnormalities. Structure /function statements, which may also appear on standard food or dietary supplement labels, are not the same as health claims. Structure/function claims, unlike health claims, do not address illness risk reduction. Furthermore, the FDA neither pre-approves nor authorizes structure / function claims. When a manufacturer makes a structure/function claim, the firm is responsible for ensuring that the claim is accurate and not misleading. Many academic, scientific, and regulatory organizations are examining how to establish the scientific foundation for claims (other than health claims) for nutraceutical functional components. The following are the five categories of health-related statements that can be found on food and dietary supplement labels:

- Nutrient-content claims show the existence of a certain nutrient at a given level.
- Structure and function claims explain the impact of dietary components on the body's normal structure or function.
- Dietary-guidance claims address the health advantages of certain food groups.
- Qualified health claims reflect a growing link between dietary components and illness risk, as recognized by the FDA and substantiated by a substantial body of reliable scientific data.
- Health claims demonstrate a link between dietary components and the risk of illness or health condition, as approved by the FDA and backed by considerable scientific consensus.

CONCLUSION

The evolution of nutraceuticals as non-specific biological therapies reflects a paradigm shift in healthcare, aligning with the preventive philosophy encapsulated in the ancient adage, "let food be your medicine Nowadays nutraceutical products are used to treat various types of diseases and these products are used to enhance the immunity, support and to regulate body functions. Hence to increase the safety and efficacy of nutraceutical products they introduced regulatory authority for each and every country therefore it is important to follow and understand the regulatory requirements to that submitting country. When a new product or entrant wishes to join the Nutraceutical market of a certain nation, it is critical to adhere to the regulatory framework of that country, but this is dependent on the control of purity, effectiveness, and safety. The new regulations would benefit the industry by expanding the scope for new product innovation and imports.

The new regulations cover supplement guidelines for kids above two years old. Previously, the regulations only stated the supplement guidelines for individuals above the age of five. The additional formats covered under the new regulations are drops, gummies, chewable and mouth-dissolving strips, bars, biscuits, and candies. This is an

expansion from tablets, capsules, liquids, semi-solids, pills, jelly or gel, and sachets allowed in the 2016 regulations. The manufacturers earlier were not able to manufacture and import some supplement products because there were no relevant guidelines. So, they had to obtain permission from FSSAI for every single product that was not covered under the regulations, now they have to just comply with the regulations.

It can be concluded that FSSA was a significant milestone as it consolidated these diverse regulations into a single statute. It aimed to bring systematic and scientific development to the food processing industry in India by categorizing food products into different heads, including novel foods, genetically modified food, proprietary food, standardized food, foods for special dietary use, and Nutraceuticals. Passing of the Food Safety and Standards Act 2006 marked a crucial initial step towards streamlining and modernizing food safety and standards regulation in India. Prior to the FSSA, there existed a complex web of various laws and regulations governing food safety and standards, leading to confusion and inefficiencies. The subsequent introduction of the Food Safety and Standards Regulations in 2011 was a pivotal moment, as it provided detailed guidelines and rules for the manufacture, distribution, and sale of Nutraceuticals in India. These regulations were designed to ensure the safety and quality of these products, thereby safeguarding the health and interests of consumers. While these steps were significant, it's important to acknowledge that there is still work to be done. Efforts should continue to eliminate any remaining overlaps with older laws and regulations, enhance regulatory clarity, and promote compliance within the food industry. This ongoing process will contribute to the growth and maturation of the functional food and nutraceutical sector in India, aligning it with international standards and facilitating its development as a thriving and innovative industry.

CONFLICT OF INTEREST

The authors have no conflict of interest regarding this investigation.

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