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Regulations and Guidelines for Nutraceutical Products: A Review

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ABSTRACT:
This review article explores the evolving landscape of nutraceuticals, defined as non-specific biological therapies aiming to prevent and manage diseases while enhancing overall health. In 1989, by Stephen DeFelice, the term combines "pharmaceutical" and "nutrient," aligning with the preventive philosophy inspired by Hippocrates. The article delves into the regulatory framework, emphasizing good manufacturing practices (GMP), and highlights global market growth, with projections indicating a substantial rise by 2021. Focusing on India, it discusses the challenges in the nutraceutical market, including regulatory ambiguities and the struggle for product approval. 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 to foster the growth of the nutraceutical industry in India.

KEYWORDS: Good manufacturing Practices, Nutraceutical products, guidelines

I. INTRODUCTION:

[1]. Nutraceutical products (Fig. 01) 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.

[2]. 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.

[3]. 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.

[4]. 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.[4]

[5]. 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.

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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.

Fig. 01: Nutraceutical Product

WHAT IS GMP?

Good manufacturing practices:

[6]. The component of quality assurance known as "good manufacturing practices," or GMP for short, guarantees that pharmaceuticals are consistently produced and controlled to the quality standards appropriate for their intended use and as stipulated by the product specification. GMP is also known as "cGMP" or "current good manufacturing practice."

GMP specifies general measures to guarantee that processes required for production and testing are precisely defined, validated, reviewed, and documented, and that the people, facilities, and materials are appropriate for the production of pharmaceuticals and biologicals, including vaccines. It also defines quality measures for both production and quality control. Legal aspects of GMP include distribution duties, contract manufacturing and testing, and handling of product flaws and complaints. Particular GMP specifications applicable to certain product categories, like sterile Pharmacies and biological medicinal products are supplied in a sequence of appendices to the standard GMP specifications.

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.

GLOBAL MARKET GROWTH AND GENERAL DEMAND SCENARIO:

[7]. Growth Prospects for Global Markets and Overall Demand The market for nutraceuticals should grow from $198.7 billion to $285.0 billion globally by 2021.

2016 at a 7.5% compound annual growth rate (CAGR) through 2021. The market for functional beverages is projected to grow at a compound annual growth rate (CAGR) of 8.1% from 2016 to 2021, from $71.5 billion in 2016 to $105.5 billion in 2023. When comparing the functional food market from 2016 to 2011, it grew at a compound annual growth rate of 7.4%, from $64.6 billion to $92.3 billion in 2021. One billion people over the age of sixty-five will live on the planet by 2020. Although industry growth was 7% annually in the first few years, from 1999 to 2002, it doubled to 14% annually in the following years, until 2010. About this time an additional $12–15 billion is added annually. The demand for nutraceuticals is anticipated to increase during the forecast period due to an increase in the risk of diseases like high blood pressure, obesity, diabetes, and cholesterol. High price incurred.In recent years, pharmaceutical companies such as Novartis,

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GSK, and Cadila Healthcare have entered the dietary supplement market. The major participants in the Indian nutraceutical market are pharmaceutical firms and suppliers of fast-moving consumer goods (FMCG). The majority of the India nutraceutical market, 64 percent, is accounted for by supplements containing vitamins and minerals.

GLOBAL MARKET:(Fig. 02)

[8]. After the USA. As of right now, Japan is the second-largest market for nutraceuticals in the world, but it is expected that China will overtake Japan by 2020 due to rising middle-class concerns about lifestyle and health.

[9]. The European Union's strict regulations and approval procedures have prevented the nutraceutical sector from experiencing product innovation. The medical supply Instead of concentrating on the innovation and development of new Nutraceutical products, companies are focusing on marketing already-existing Nutraceutical products to consumers in order to expand their market.9

According to estimates, the global nutraceutical market was valued at $140.1 billion in 2010. Of this, the US accounted for 36% of the market, followed by the EU with 25% and India with just 1.5%.Five The Asian Edition of Bio-spectrum, published on March 16, 2012, states that the Indian nutraceutical market is expected to grow to US$ 2.731 million by 2016." The category that is growing the fastest is functional foods, followed by dietary supplements. However, dietary supplements—particularly herbal and dietetic supplements—provide the chance.

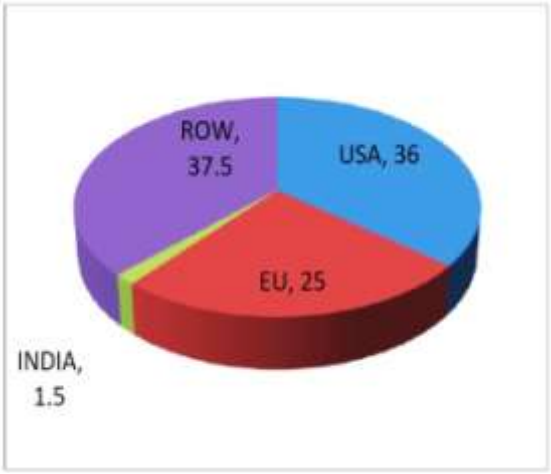

Fig. 02: Global Market

LAWS GOVERNING NUTRACEUTICALS:

[10]. 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.

DIETARY SUPPLEMENT HEALTH EDUCATION ACT (DSHEA) 1994: (Fig. 03)

Senate President Orrin G. Hatch introduced this legislation in the Senate; it defines dietary supplements and legal prerequisites required for the promotion in the US of dietary supplement products.

According to the law, a dietary supplement is as a result, a dietary supplement is a thing thatincludes one or more of the subsequent food ingredients:

- vitamin
- mineral
- a botanical or herb
- An acid amino
- a food item that people can use to enhance the diet by raising the overall consumption of that component through food;
- a component, metabolite, or concentrate extract, or a blend of any one of the earlier.
- Additionally, according to DSHEA, dietary supplements have to be products meant to be taken orally.

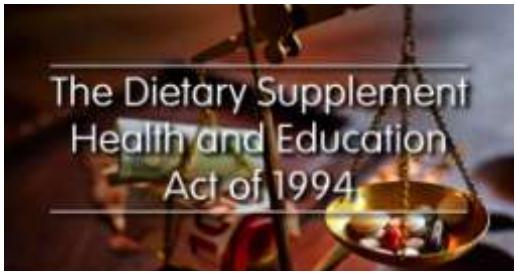

Fig. 0:3 Dietary Supplement Health Education Act (DSHEA) 1994

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FOOD SAFETY STANDARD AND STANDARDS ACT (FSSA): 2006

[11]. 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.

[12]. 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 labeled 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.

INDIAN NUTRACEUTICAL MARKET:(Fig. 04)

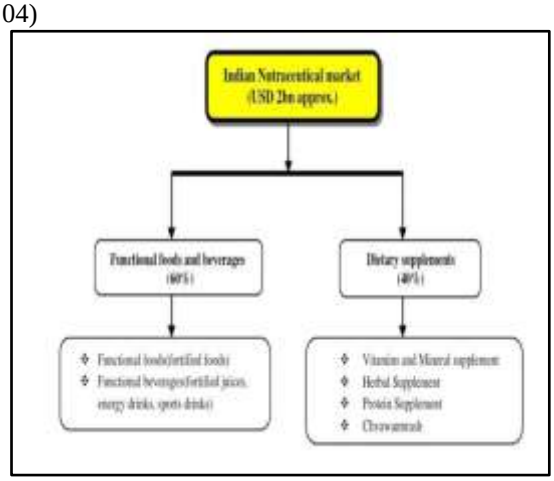

Fig. 04: Indian nutraceutical market

DIETARY SUPPLEMENT REGISTRATION IN INDIA:

[13]. For a product to be marketed in the Indian market, Nutraceuticals must be registered. Although the FSS act of 2006 outlines the process for registering nutritional items, no set format is available for this purpose.

[14, 15]. The absence of a suitable roadmap for product registration causes the Indian nutraceutical companies to struggle greatly to get their products approved.

[16]. In May 2011, the Food Safety and Standard Rules, 2011 were released by FSSAI.The guidelines for food businesses, product licensing and registration, packaging, and labeling procedures are provided in this rule. guidelines for food items and the additives that are included in them. The nation has put the FSS regulations into effectretrieved August 5, 2011.This makes it possible to establish a single legislation with appropriate authority to control the production, distribution, and sale of goods inside the nation.Nevertheless, because the precise rules governing the registration of nutraceuticals and start Nutraceuticals in India continue to encounter the following difficulties(Fig. 05).

As per the FSS requirements from 2011

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a) In order to sell food items in India, one must register their manufacturing site and receive a Form A/B manufacturing license (obtained from the state licensing authority, save for those indicated under schedule D).

b) A license from the Central Licensing Authority is required in order to import any food or food product into the nation.

These are the required documents for the registration approval.

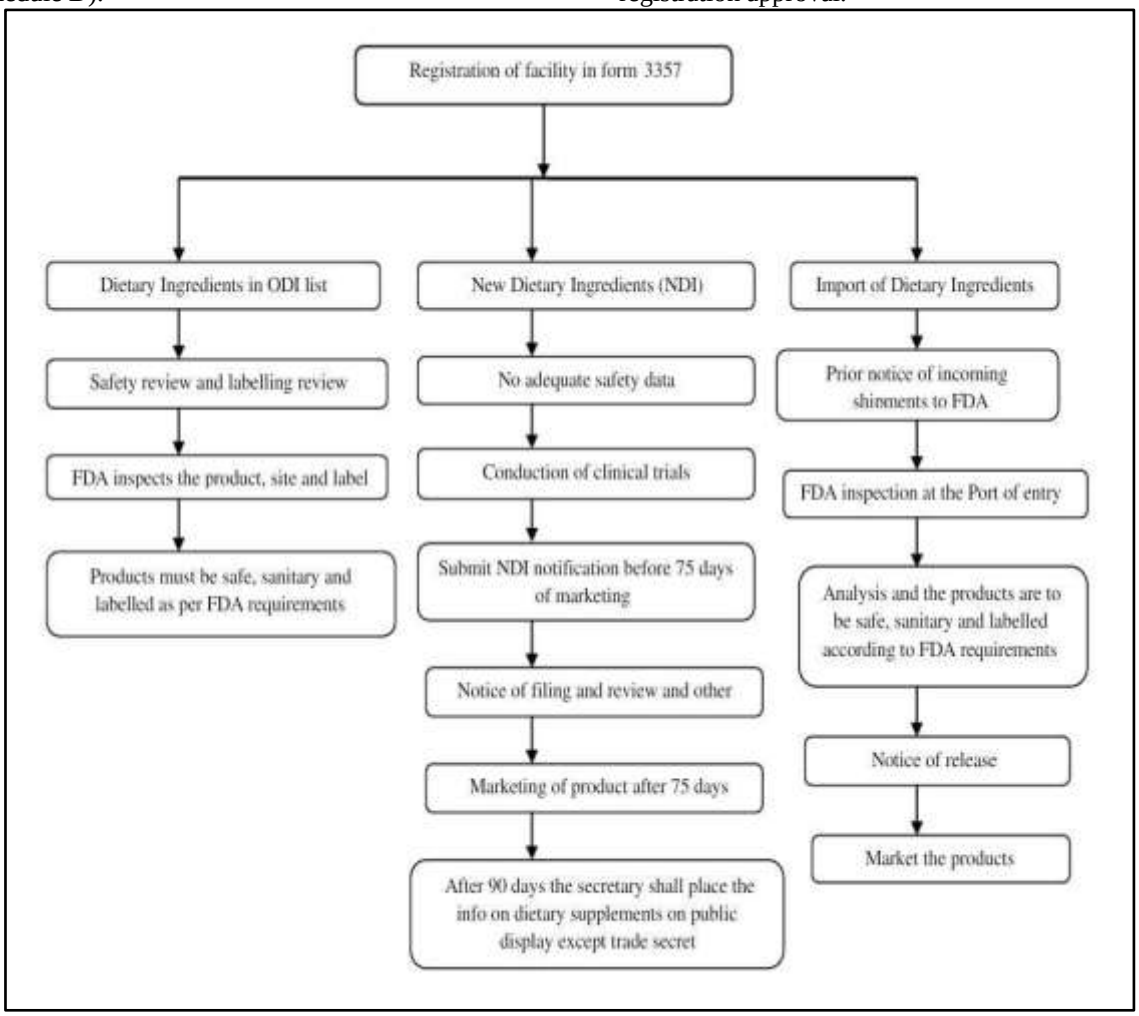

Fig. 05: The clearance process regulatory framework

- Application for registration form A
- Form for Self-Attested Declaration
- Manufacturing license/import license:
- Schedule 2 Application Form B and the license received in Form C
- Form for Self-Attested Declaration
- Copies of the ensuing records.(Fig. 06)

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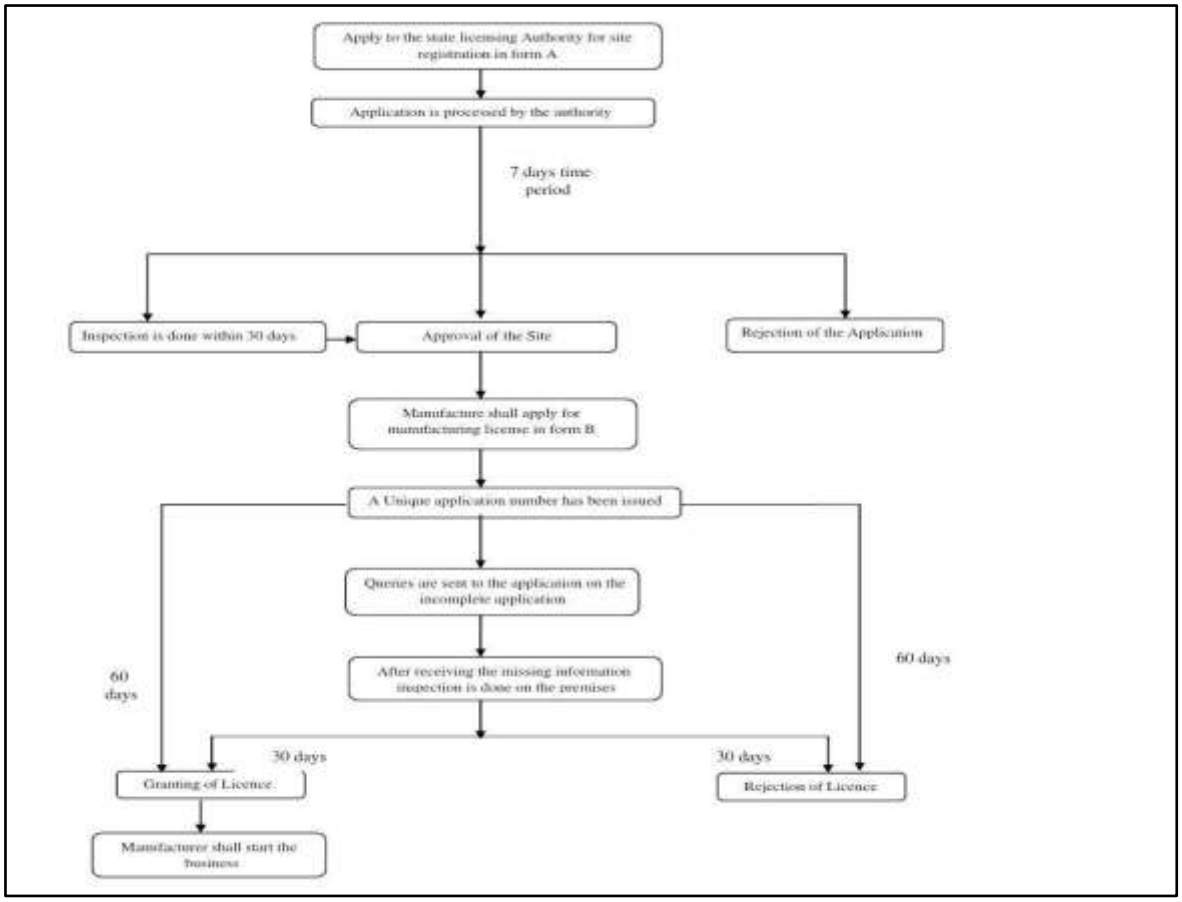

Fig. 06: Dietary supplement registration in India

[17]. Documents that must be sent with a fresh license application or import license request to the State or Central Licensing Authority

- TypeA
- Type B
- The processing unit's layout plan or blueprint
- Directors' List
- List and Name the Equipment That Will Be Used in the Process
- Proof of address and photo ID
- A list of food categories for which manufacturing is sought.
- Authority letter containing the responsible party's name and address
- Report on analysis
- Evidence of ownership of the property Collaboration
- Articles, Memorandum, Affidavit, and Deed
- Manufacturer's NOC
- Food safety management system certification or plan
- Original materials
- Report on pesticide residues in water
- Recall scheme
- NOC

In spite of all of this, the registration of nutritional supplements and their components is still unclear. Because of this, the entrepreneurs that want to sell the nutraceutical product in theaccreditation The following challenges are facing the nation that supplies the raw materials:

i. The authorities are classifying nutritional supplements as drugs in accordance with the definition of drug. particularly those goods that are produced and sold as tablets or as liquid orals with added vitamins and minerals.

ii. The drug's definition includes the empty gelatin capsule. Therefore, everything contained in a gelatin capsule is considered a medication.

iii. A few colorants and additives used in the production of nutraceutical goods are not on the list of ingredients that are permitted for use in food.

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REGULATION OF NUTRACEUTICAL IN INDIA:

[18].In India, we refer to nutraceuticals as "Foods for special dietary uses".
"Foods for special dietary uses or functional foods or nutraceuticals or health supplements" is defined by the Food Safety and Standards Authority (FSSA).

[19].The Food Safety and Standards Act, 2 006 in India created the Food Safety and Standards Authority of India (FSSAI) by combining many act s and directives that were in place to address food-related matters in different Ministries and Departm ents.
To guarantee the availability of healthy and safe fo od for human consumption, the Food Safety and St andards Authority of India (FSSAI) was establishe d to establish science-
based standards for food articles and to regulate the ir manufacture, storage, distribution, sale, and impo rt.
This means that nutraceuticals and dietary supplem ents fall under this category as well. Numerous key laws such as the Edible Oils Packaging (Regul ation) Act of 1947, the Vegetable Oil Products (Co ntrol) Order of 1947, the Fruit Products Order of 19 55, and the Meat Food Products Order of 1973 Order 1966, Milk and Milk Products; Order 1988, Solvent Extracted Oil; De-
oiled Meal and Edible Flour (Control) Order Order, 1992, etc., were revoked with the implement ation of the FSS Act in 2006.

Health Claim:

[20].Health claimsrefer to associations between a f ood or a dietary ingredient and well-being.
One can further categories health claims into:

a) Claim on nutrient content
b) Decrease in illness claims
c) The Structure/Function assertion

a) Nutrition Content Claim: A nutritional claim denotes that a food item has certain advantageous nutritional characteristics, like being "high in fiber," "low fat," and "free of added sugar." A claim is a declaration. It implies a connection between nutrition and well-being. For example, food can "enhance learning ability," "help reinforce the body's natural defenses," or "help lower cholesterol."

b) Reduction of Disease Claim: Any assertion that suggests or declares that using dietary supplements or any of their components dramatically lowers the risk factor in the emergence of human illness.

c) A structure/function claim: is a statement found on the label of a food product or dietary supplement that describes how the product affects the structure of the human body.

INDIA'S REGULATION REQUIREMENTS:

1. Product Evaluation: Analysis of each additive and active ingredient.
Several phases in the assessment of the product consist of:

•Generating document extracts
•Gathering samples (with witness's present)
•Sending samples to the relevant authority (various procedures for single and bulk packages)
•Food examination
•If the analysis is not finished in the allotted time, the assigned officer will take additional action.
•Proceedings for adjudication (conducting hearings, appeals, holding inquiries, etc.)

2. Licenses: Several licenses (almost four to five) may be needed in order to register a product in India. These licenses include:
•Licensing for imports
•Before releasing these items in India, the following regulatory approvals and licenses must be obtained: Manufacturing licensingMarketing licensing and additional state and national level clearances and licenses

3. Health and label claims: Any statement that ind icates, implies, or suggests a connection between a food and its component is referred to as a "health cl aim." food and well-being.
This comprises:

- Requirements for packaging and labelling uniq ue to India
- The packaging used for the cargo contents
- Shipment and marketing strategy are identical
- Requirement for declaration and sample materi al for registration
- Content and claim labelling
  Claim for structure-function.

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Process in India: (Fig. 07)

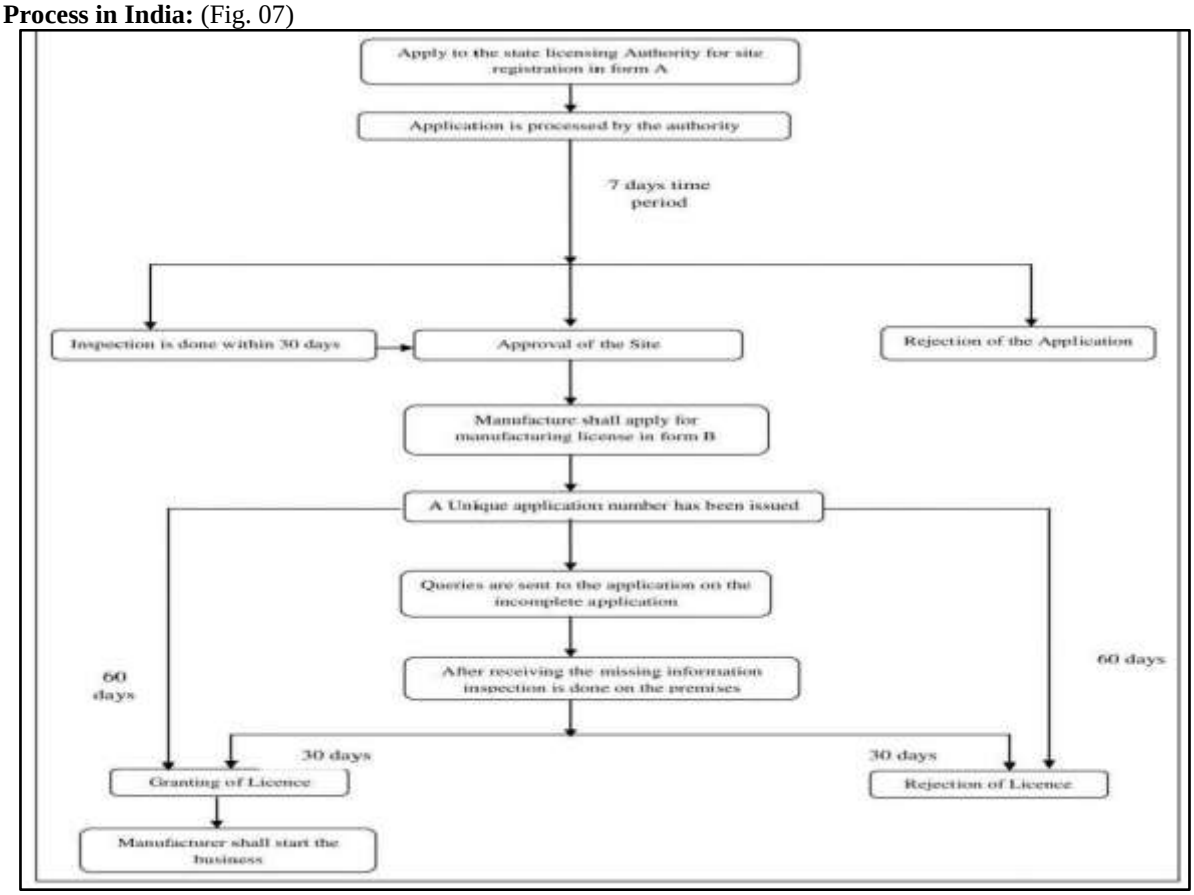

Fig .07: Registration process in india

II. CONCLUSION:

In 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." The term "nutraceutical," coined by Stephen DeFelice in 1989, encompasses a spectrum of products with health benefits, emphasizing the intersection of pharmaceutical and nutritional realms. The global nutraceutical market's substantial growth, coupled with diverse regulatory landscapes, underscores the need for standardized practices. The adherence to Good Manufacturing Practices (GMP) ensures the consistent quality of these products. Region-specific regulations, such as the Dietary Supplement Health Education Act (DSHEA) in the U.S. and the Food Safety and Standards Act (FSSA) in India, illustrate the dynamic regulatory environment. As nutraceuticals continue to play a pivotal role in global health, harmonizing regulatory frameworks becomes paramount for fostering innovation and ensuring consumer well-being.

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