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Regulations of nutraceuticals in India & us

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Abstract
Nutraceuticals, defined as any food or part of food which provides health benefits including prevention or treatment of disease, have emerged as a necessity for consumers in developed as well as developing countries. With changing lifestyle and related diseases, functional ingredients such as vitamins, minerals, amino acids, fatty acids and Probiotics, etc. have also become a part of this category. Worldwide regulatory authorities are focusing on the Product Quality and Safety as these products are meant for human consumption. As food products are reaching from one country to another, maintaining safety and quality standards as per various regulatory guidelines set by the respective governments becomes important; which can be a real driver for the industry growth. Foods and food habits in today's lifestyle have lead to the disturbances in an ideally nutritionally balanced body. Therefore in such state if "food be your medicine" then it would be great to achieve a healthy body and mind. This article provides a short review of the Nutraceuticals regulation set out by US Food & Drug administration in USA and in India by Food Safety Standard Authority of India. It mainly focuses on the similarities and differences of nutraceuticals regulatory framework and structure in USA and India, with harmonized technical requirement for registration of nutraceutical product in this market. This article is based on the complete legal requirements that are necessary for the countries that want to register a nutraceutical food or drug product.

Keywords: Dietary Supplement, FSSAI, DSHEA, Regulation of Nutraceuticals, Labelling and Health Claims

Introduction
The term "nutraceutical" was coined from "nutrition" and "pharmaceutical" in 1989 by Stephen Defelice, MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ. According to Defelice, nutraceutical can be defined as, "a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease [1]."

Nutraceuticals, dietary supplements, functional food are sometimes overlapping terms. Over the years the rules and regulations in this area of products have provided distinct definitions and regulations for such products, keeping safety aspects in mind. These standards have evolved more as numbers of products introduced in the market are increasing. Research in the area of food science is providing basis for development of such products. Such products have special health benefit claims or many a times claims for cure for certain diseases or disorders. Regulations in the area of such products vary from country to country and many products have been launched in market [2].

A clear understanding of nutraceuticals in a regulatory system will reduce the confusion in establishing the policy for nutraceuticals. However in current scenario the regulatory position of nutraceuticals is different depending on the country's regulatory framework [3].

Global Market Growth & General Demand Scenario
The global nutraceutical market should reach $285.0 billion by 2021 from $198.7 billion in 2016 at a compound annual growth rate (CAGR) of 7.5%, from 2016 to 2021. The functional beverages market should reach $105.5 billion by 2021 from $71.5 billion in 2016 at a CAGR of 8.1%, from 2016 to 2021. The functional food market should reach $92.3 billion by 2021 from $64.6 billion in 2016 at a CAGR of 7.4%, from 2016 to 2021. By 2020, the world will have 1 billion populations of 60+ ages. While in the initial years, between 1999 & 2002 industry grew at 7% per annum, the next few years up to 2010 saw double that growth at 14% per annum. Currently around $12-15 Bn is being added every year. Nutraceutical demand will grow with increasing risk of diseases such as high blood pressure, obesity, diabetes, and cholesterol is expected to boost product demand over the forecast period. High cost associated

with healthcare treatments has resulted in rising consumer interest in nutraceuticals over the past few years.

U.S. Nutraceutical Market

- The US has been the largest Nutraceutical market so far and almost fully mature. Between 2012 & 2016 it grew from $ 50 Bn to $ 65 Bn, a compounded growth of 10% annually;
- The US market comprises of Functional Food & Beverages (65%) and Dietary Supplements (35%);
- Fast approaching maturity in the dietary supplements segment, while functional food and beverages are quickly catching up;
- US Consumers are extremely health conscious and demand specific ingredients in the nutraceutical products they consume, resulting in a need for customization of nutraceuticals for each target group.
- Currently, companies in the US are looking to diversify their products and are leaning more and more towards natural nutraceutical ingredients in their product offering, mainly due to the increasing consumer demand for all-natural, non-modified functional ingredients [4].

Regulations of Nutraceuticals in India

Nutraceuticals are known as "Foods for special dietary uses" in India. Food Safety and Standards Authority **(**FSSA), defines "foods for special dietary uses or functional foods or nutraceuticals or health supplements" [5]. The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 in India which consolidates various acts and orders that were in existence to handle food related issues in various Ministries and Departments. FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. Thus it applies to products like dietary supplements and nutraceuticals too. Various central Acts like Prevention of Food Adulteration Act, 1954, Fruit Products Order, 1955, Meat Food Products Order, 1973, Vegetable Oil Products (Control) Order, 1947, Edible Oils Packaging (Regulation) Order 1988, Solvent Extracted Oil, De- Oiled Meal and Edible Flour (Control) Order, 1967, Milk and Milk Products Order, 1992 etc. have been repealed after commencement of FSS Act, 2006 [6].

Health Claim [7] "Health claims" means a relationship between a food or a constituent of that food and health. Health claims can further be grouped into:

1. Nutrient content claim
2. Reduction of disease claim
3. Structure/Function claim

Nutrition Content Claim: A nutritional claim suggests a food has beneficial nutritional properties, such as "low fat", "no added sugar" and "high in fiber". A Claim is a statement that suggests a relationship between food and health. For instance a Food can "help lower cholesterol", "help reinforce the body's natural defenses" or "enhance learning ability"

Reduction of Disease Claim: Any claims states or implies that the consumption of dietary supplements or one of its constituents significantly reduce the risk factor in the development of human disease.

Structure/Function Claim: Structure claim is a statement on label of a food or dietary supplement about how that product affects the human body structure.

Regulatory Requirements in India

1. **Product Evaluation**: Examination of each active ingredients & additive.

Various steps in the product evaluation include:

- Developing extracts of documents
- Sample collection (in the presence of witnesses)
- Sample dispatch to the concerned authority (different processes for bulk package and single package)
- Food analysis
- If analysis is not complete within the stipulated period of time, further action plan by the designated officer
- Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)

2. **Licenses:** To get Product registered in India, number of licenses (almost 4 - 5) might be required which include:

- Import licensing
- Manufacturing licensing
- Marketing licensing and
- Other state and national level clearances/licenses required from the regulatory side, which need to be taken care of before launching these products in India.

3. **Health and label claims:** "Health claims" means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health. This includes:

- India specific labeling and packaging requirements
- Packaging of the consignment composition of the consignment and approach to market the same
- Need for sample material and declaration for registration
- Label content and claim
- Structure - function claim

Registration Process in India [8]

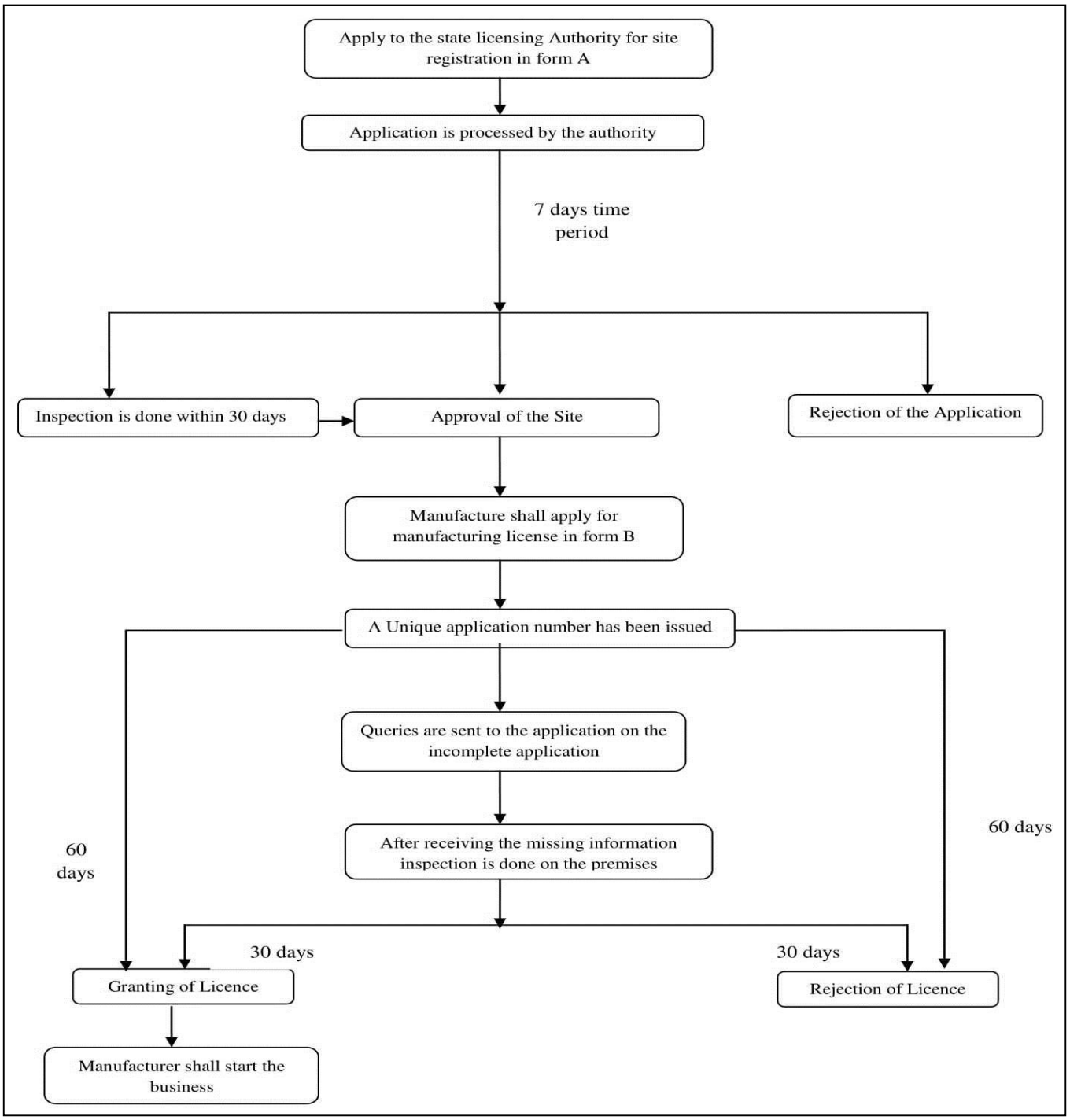

Fig 1: Registration Process of India

Regulation in United State

USFDA defines nutraceuticals as dietary supplements and the regulations came in 1994. FDA regulates dietary supplements product and dietary ingredients under a different set of regulations. Under the Dietary Supplement Health and Education Act (DSHEA):

- Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.
- FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.

Health Claims in USA

Health Claims can be of three types: a) Health claims, b) Nutrient content claims, and Structure/function claim.

1. **Health claims:** Health claims, was authorized under the NLEA of 1990. Health claims describe a relation between a food, food component, or dietary supplement ingredient and reducing risk of a disease or health-related condition **[9]** Health claims can further be grouped into:

- **SSA Claims (Significant Scientific Agreement):** These claims can be used for conventional foods and dietary supplements. The Significant Scientific Agreement (SSA) standard is used to determine that the nutrient/disease relationship is well-established.
- **FDAMA (FDA Modernization Act):** These claims can be used only for conventional foods and cannot be used on dietary supplements. FDA authorizes the use of an

FDAMA claim as a result of the notification from a stakeholder.

- **Qualified Health Claims:** These claims can be used for conventional foods and dietary supplements. Any interested party may petition FDA to issue a regulation regarding a health claim (see 21 CFR 101.70). FDA evaluates the petition according to the SSA standard.

2. **Nutrient Content Claims:** Such claims are about the content of certain nutrients or substances in a food, such as low in fat or good source of calcium and are used to describe the percentage of a nutrient in a product relative to the daily value.

3. **Structure/Function Claims:** This claim was authorized under the Dietary Supplement Health and Education Act of 1994. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Registration process in USA [10]

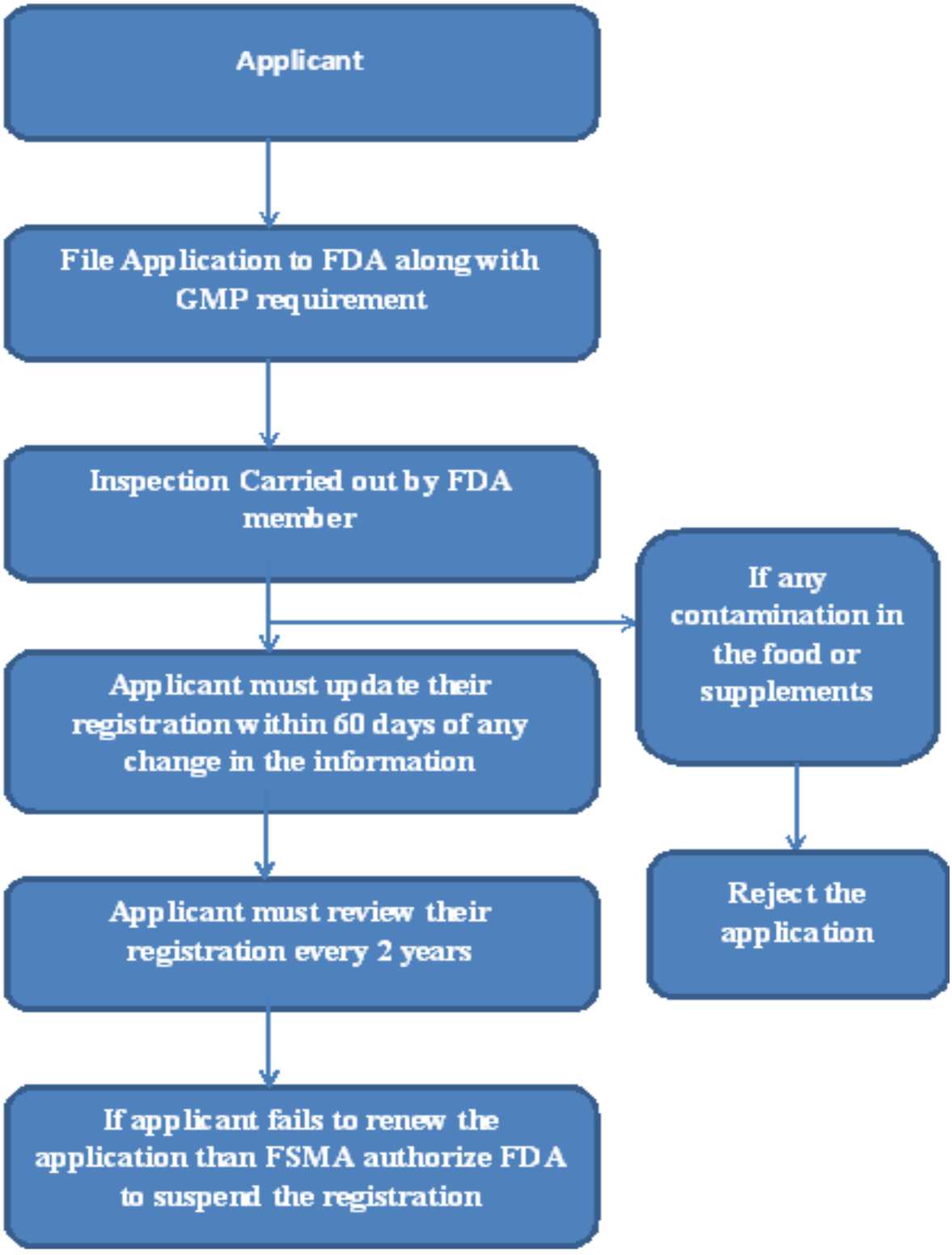

Fig 2: Registration process in USA

Regulatory Process for the Clearance in USA

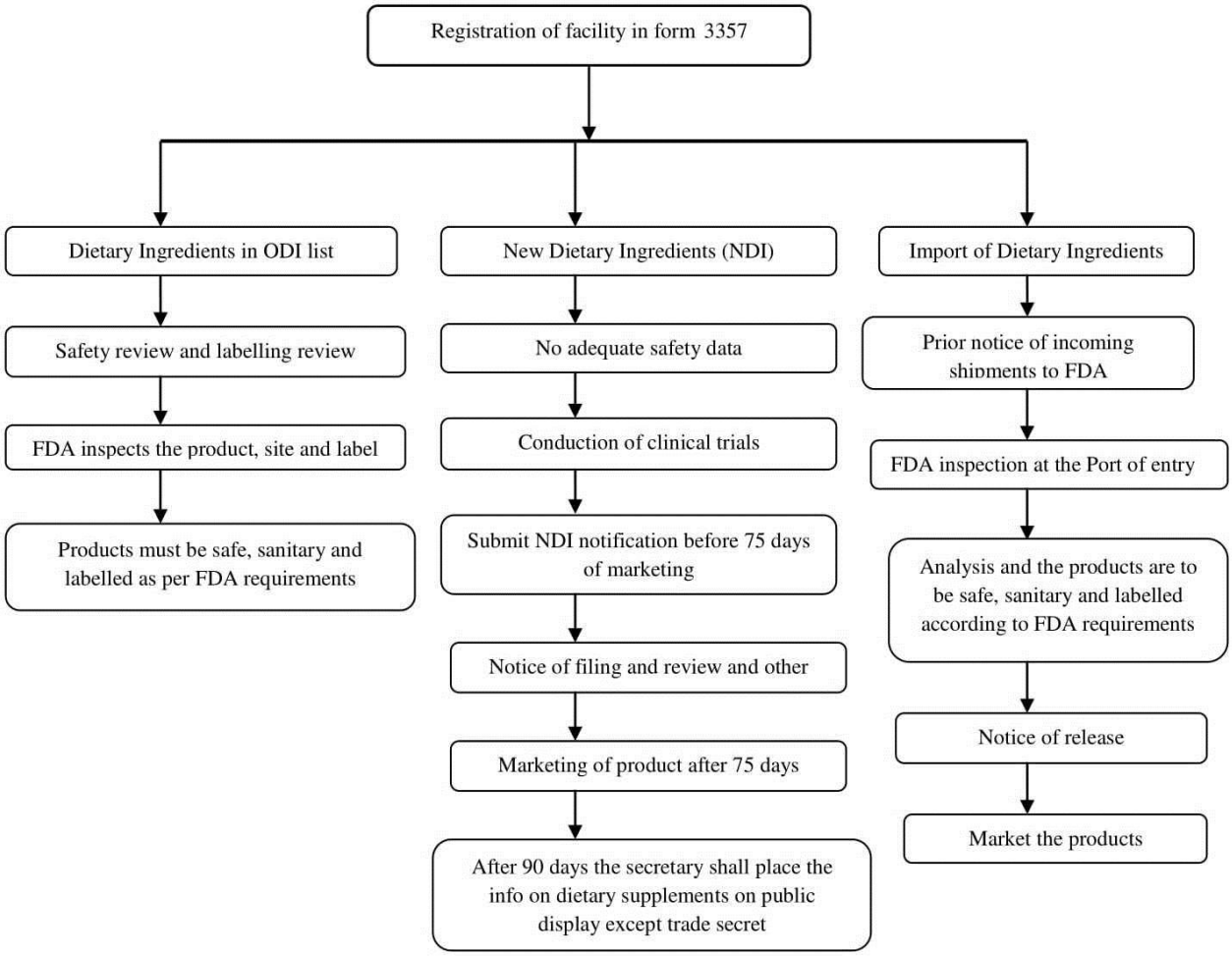

Fig 3: Regulatory Process for the Clearance

Comparison of Regulatory Guidelines of USA and INDIA

	USA	**India**
Regulation for licensing and registration	By United States Food, and Drug Administration (USFDA)	By Food Safety and Standard Authority of India (FSSAI)
Definition	USFDA defines Nutraceuticals as "Dietary Supplements" Under DSHEA	FSSAI defines Nutraceuticals as "Foods for special dietary uses".
Act/Regulatory authority for registration of nutraceuticals	Dietary Safety and Health Education Act	Food Safety and Standard Authority of India
Regulations w.e.f	1994	2011
Regulatory requirements for registration	Product licensing, evidence requirements for safety & efficacy, labeling, health claims, GMP, adverse reaction reporting and clinical trails	Product evaluations, licenses, health and label claims
Form for registration	Form 3537	Form A, B. and C

Conclusion

The Nutraceutical is an emerging business and the growth of the business in the forthcoming years is huge. The United States has amended the Dietary Supplement and Health Education Act (DSHEA) in 1994 which gives the roadmap for the registration of the Nutraceuticals/Dietary supplements in the country for the marketing purpose. In India, Food Safety Standards Act 2006, and Food Safety Standard Rules and Regulations 2011, are implemented to avoid the grouping of Nutraceutical product either into food or drug. The Nutraceuticals in India are called by the name "Functional Foods for special dietary uses". When any new Product/entrant wants to enter in the Nutraceutical market of particular country, it is very important to comply with the regulatory framework of that country but it depends on the control of purity, efficacy and safety. The nutraceutical industry is growing at a rate far exceeding expansion in the food and pharmaceutical industries. In coming years, the most successful nutraceutical players are likely to be those companies in which functional product are just a part of a broad line of goods satisfying both conventional and health value point. Future demand of nutraceutical depends on consumer perception of the relationship between diet and disease.

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