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NUTRACEUTICAL REGULATIONS AND REGISTRATION PROCESS IN USA

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ABSTRACT

The hybrid for 'Nutrition' and 'Pharmaceutical' is Nutraceutical. In general, nutraceuticals are foods or food components that play an important role in altering and preserving the normal physiological mechanism that maintains healthy human beings. The key factors for the growth of the worldwide nutraceutical market are the current population and changes in health. A value-added growth opportunity both domestically and globally is functional foods and foreign goods. Developing better specified and research-proven goods would help increase consumer confidence in the world's nutraceutical and functional food products.

Keywords: Nutraceuticals, dietary supplements, Regulations, Market scenario

INTRODUCTION

The relationship between the use of appropriate foods for health and their medicinal benefits was conceptualized by Hippocrates (460-377 BC), the well-known father of modern medicine, about 2500 years ago **[1]**.

Theophrastus (370- 285 BC), Cato (234-149 BC), Pliny the Elder (23-79 AD) and Galen (131-201 AD) then cautioned against food items being adulterated. Since 2000 BC Schwann, via the alcoholic fermentation process, microbes (fungus or yeast) were used for product generation in 1837. Funk (1884-1967) conducts scientific research on vitamins and describes them as food components essential to preserve good health **[1]**.

In 1989, the concept 'nutraceutical' was coined from 'nutrition' and 'pharmaceutical ‘Originally, DeFelice was described as 'a food or(part of food) which provides medical or health benefits, including prevention and/or prevention. DiseaseManagement.Naturally, a nutraceutical food can be rich in nutrients such as spiraling, garlic, soya or a particular component of a food such as salmon omega-3 oil. They are also classified as dietary supplements, nutritional supplements and medicinal foods **[2]**.

It differs from isolated nutrients, nutritional supplements, herbal products of genetically modified 'designer' foods, and refined products such as cereals and soups. Due to their presumed safety and possible nutritional and therapeutic effects, they have attracted tremendous attention because of their substantial interest.By supplementation and eating foods that have been formulated / fortified, people can improve their health. Public education, sustainable sources, production and processing, environmental friendliness and local availability are another reason for the increasing trend for neutraceutical **[2]**. The United Kingdom, Germany and France were the first to recognize that diet is more important than exercise or hereditary factors in ensuring good health. Canada described them as 'a food-produced commodity but sold in tablets, powders, (potions) and other medicinal forms not typically associated with food’. Nutraceutical foods in India are food components derived from herbal or botanical raw materials that are used to prevent or treat various forms of acute and chronic diseases **[1-3]**.

NUTRACEUTICAL REGULATIONS [3]

The goal of food regulation is to protect the health of the consumer, increase economic viability, harmonize well-being and generate equal trade in food within and between nations. Two problems are evident for the nutraceutical industries; regulatory ambiguity and labeling claims' credibility. In India, the food sector has been regulated by several laws enacted to complement and supplement each other at various points of time. The

multiplicity of ministries and administrative bodies at both central and state levels has resulted in a complex, poorly organized regulatory framework that increases the burden on the food processing sector. The Food Safety and Standards Act, 2006 (FSSA) was enacted by the government following demand from sectors and stakeholders for a single regulatory body and an integrated modern food law.

Registration of Dietary supplements in US

If the dietary supplements are as specified by the DSHEA, then only that dietary supplement can be reported. According to the regulation provided under 21 CFR 190, which deals with dietary supplements, the active component should also mean that whether it is an active ingredient or an inactive ingredient, it must be noted during registration **[4]**.

When registering, it is important to take note of whether it is an old dietary supplement or a new dietary supplement for registration purposes. If a DS is sold before October 15, it is after the date that it is ODI, and then it is New Dietary Ingredient (NDI). CFSAN shall carry out pre-market surveillance of the protection of the product relating to the NDI products in the US market and all documents shall be sent to the following address **[5]**.

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-820),
Center for Food Safety and Applied Nutrition, Food and Drug Administration,
5100 Paint Branch Pkwy, College Park,
MD 20740.

The documents required are as follows:

1. Applicants name and address
2. Product name even the botanical name can be included.
3. Statement of whether it is an ODI or NDI type of dietary supplement.
4. Evidence of safety measures if any
5. Signature of the manufacturer and the distributor

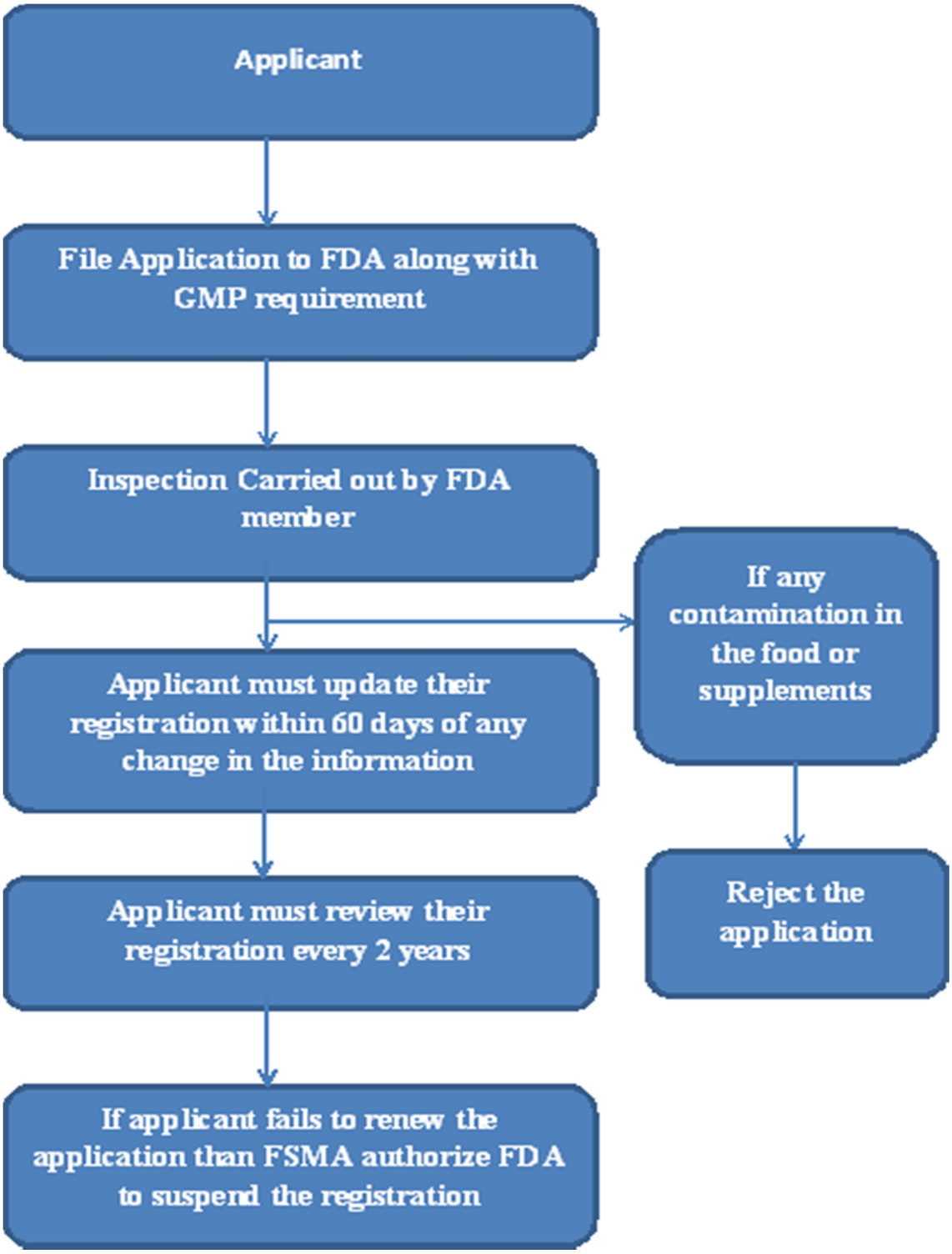

Figure 1: Registration process in USA [11]

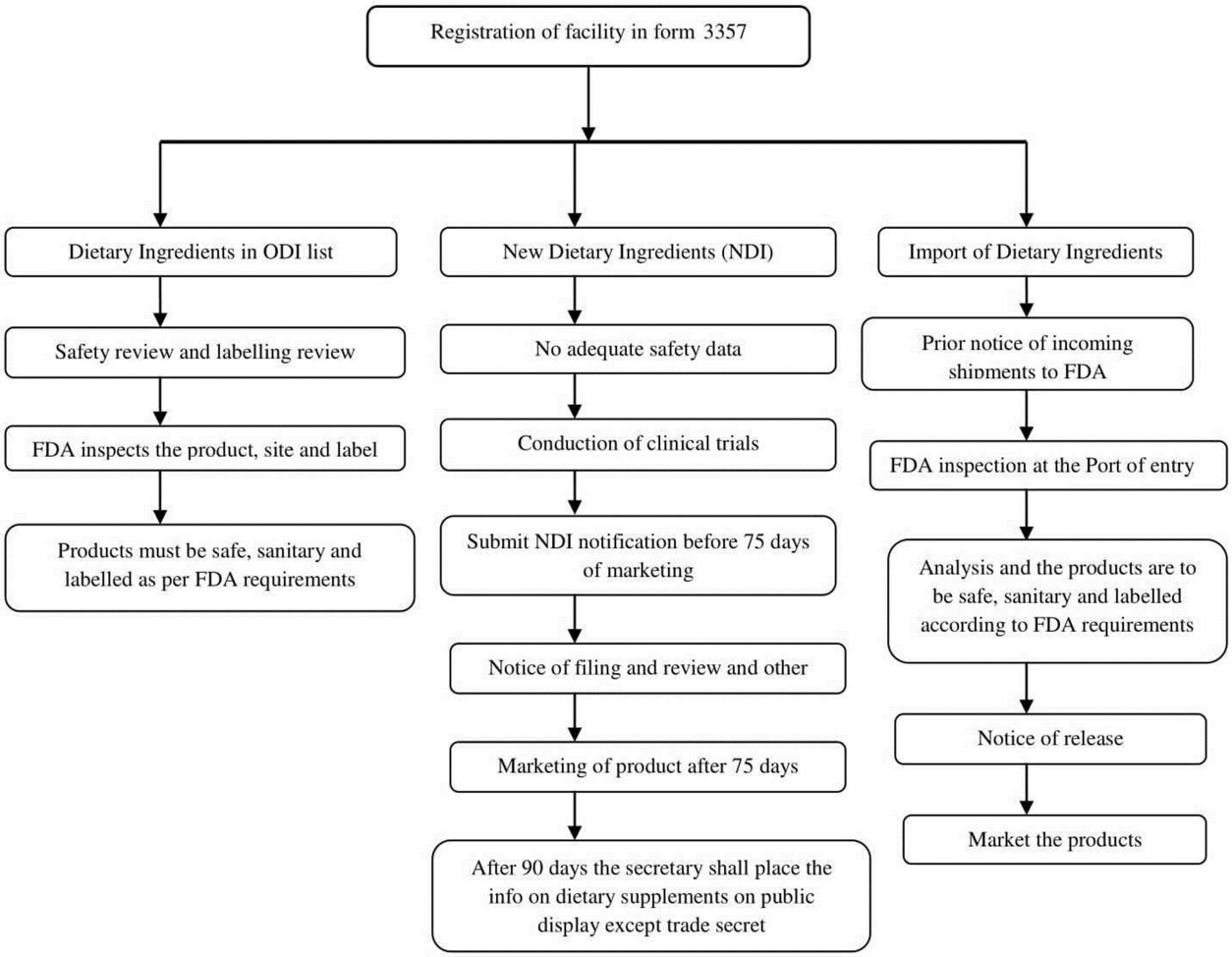

Figure 2: Regulatory process clearance in USA [12]

Nutrition Labeling and Education Act [6, 7]

Under the Federal Food, Drug, and Cosmetic Act and its amendments, these FDA Food Labeling web pages discuss the labeling criteria for foods. For most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, beverages, etc., food labeling is required. Nutrition labeling is optional for raw food (fruits and vegetables) and fish. We refer to these items as foods that are "conventional" See "Dietary Supplements." for more information on dietary supplements, a special category of products that falls under the general food umbrella but has different labeling criteria.

Terms such as "functional foods" or "nutraceuticals" are widely used in the marketplace. Such foods are regulated by FDA under the authority of the Federal Food,

Drug, and Cosmetic Act, even though they are not specifically defined by law.

Label Claims for Food & Dietary Supplements

Three types of claims that are specified by law and/or FDA regulations are among the claims that can be used on labels for food and dietary supplements: health claims, claims for nutrient content, and claims for structure/function. Learn more from Product Statements for Organic Foods and Dietary Supplements regarding these types **[6]**.

The FDA urges the submission of petitions and notices in electronic form.

Types of Claims

1. FDA Modernization Act of 1997 (FDAMA) Health and Nutrient Content Claims
2. Health Claims That Meet Significant Scientific Agreement (SSA)
3. Qualified Health Claims
4. Nutrient Content Claims
5. Structure/Function Claims for Dietary Supplements and Conventional Foods

1. FDA Modernization Act of 1997 (FDAMA) Health and Nutrient Content Claims [9]

Companies may not use a health claim or nutrient quality claim in food labeling prior to the Food and Drug Administration Modernization Act of 1997 (FDAMA), unless the Food and Drug Administration (FDA) issued a regulation approving such a claim. Two new provisions of FDAMA (specifically sections 303 and 304 amending, respectively, sections 403(r)(3) and 403(r)(2) (21 U.S.C. 343(r)(3) and (2) of the Food, Drug, and Cosmetic Act, referred to as the Act) will also authorize distributors and manufacturers to use claims if such claims are based on actual, written, authoritative statements of certain federal scientific bodies as well as those of certain federal scientific bodies These provisions are meant to speed up the process by which the scientific basis is laid down for such statements.

In order to evaluate the most suitable method for the application of these new provisions, the FDA has been analysing both the legislation and the associated legislative history since the enactment of FDAMA. Due to the pace at which the provisions of the FDAMA became successful, during the initial phase of implementation of these new provisions, the Agency has decided to issue this guidance paper.

2. Health Claims That Meet Significant Scientific Agreement (SSA) [10]

Authorized health claims in food labeling are claims that have been reviewed by the FDA and are permitted to demonstrate in food products or dietary supplements that a food

or food ingredient can reduce the risk of a disease or health condition. These arguments are backed by empirical evidence and can be used to describe the association between a substance (a particular food ingredient or food) and a disease or health-related condition in traditional foods and dietary supplements (e.g., high blood pressure). The 1990 Nutrition Labeling and Education Act (NLEA) directed the FDA to issue legislation allowing for health statements to be used. All health statements must be subject to the FDA's scrutiny via a petition process.

In order to be accepted by the FDA as an authorized health claim, substantial scientific agreement (SSA) must be reached among qualified experts that the claim is supported by the entirety of scientific evidence available to the public relating to a substance/disease relationship. The SSA standard is intended to be a strong standard which provides a high level of trust in the relationship between substance/disease validity.

3. Qualified Health Claims

Qualified health claims (QHCs) are backed by scientific evidence, but do not comply with the more stringent requirement of "significant scientific agreement" required for an approved health claim. They must be accompanied by a disclaimer or other qualifying language to adequately convey to customers the extent of scientific evidence supporting the claim, in order to ensure that these statements are not deceptive.

For the use of a qualified health claim, food manufacturers may require the agency to consider exercising enforcement discretion. Qualified health claim petitions are not "approved" by the FDA.

The FDA provides a Letter of Enforcement Discretion for a QHC petition with reliable scientific evidence, providing clear argument terminology that represents the degree of supporting scientific evidence and information of all enforcement discretion conditions under which the FDA will not object to the use of the QHC. Rulemaking is not involved in the process.

4. Nutrient content claim

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 **[7]**.

5. Structure / function claim

On the labels of conventional foods and dietary supplements as well as medications, structure/function statements have historically appeared. Some basic regulatory

criteria and procedures for structure/function claims and two related forms of dietary supplement labeling claims, claims of general well-being, and claims related to a nutrient deficiency disease were developed by the Dietary Supplement Health and Education Act of 1994 (DSHEA).

The role of a nutrient or dietary ingredient intended to influence the normal structure or function of the human body can be defined by structure/function statements, such as "calcium builds strong bones." They can also characterize the means by which a nutrient or dietary ingredient acts to preserve such structure or function, such as "fiber maintains bowel regularity," or "antioxidants maintain cell integrity."

General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient. Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), but such claims are allowed only if they also say how widespread such a disease is in the United States.

These three forms of statements are not pre-approved by the FDA, but the manufacturer must provide evidence that the claim is valid and not deceptive and must inform the FDA of the text of the claim no later than 30 days after the dietary supplement has been put on the market. If the label of a dietary supplement contains such an argument, it must state in a "disclaimer" that the claim has not been assessed by the FDA.

The disclaimer must also state that the substance of a dietary supplement is not intended to "diagnose, treat, cure or prevent any disease," since such a claim can be made legally only by a medication. See 21 CFR 101.93, entitled 'Some Types of Statements for Dietary Supplements,' and the final rule of the FDA of 6 January 2000, entitled 'Regulations on Statements Made for Dietary Supplements Concerning the Impact of the Substance on the Structure or Function of the Body,' for more detail on the distinction between structure/function claims and disease claims

Dietary supplement health and education act

The 1994 Dietary Supplement Health and Education Act ("DSHEA") is a 1994 statute of federal law in the United States that describes and controls dietary supplements. Under the Act, under 21 CFR Part 111, supplements are effectively controlled by the FDA for Good Manufacturing Practices **[6]**.

DSHEA describes the term 'dietary supplement' as meaning a substance (other than tobacco) intended to supplement a diet containing or carrying one or more dietary

ingredients, including vitamins, minerals, herbs or other botanical ingredients, amino acids, dietary ingredients intended for human consumption to supplement a diet by raising total dietary intake, or a concentrate, metabolite, constituent, extract or c-component.

Food safety and modernization act

The Food Safety Modernization Act of the FDA (FSMA) is changing the food safety system of the nation by shifting the emphasis from responding to preventing food borne illness. In reaction to drastic changes in the global food system and in our perception of food borne disease and its effects, Congress adopted FSMA, including the recognition that preventable food borne disease is both a major public health problem and a challenge to the food system's economic well-being **[10]**.

Seven key rules for the implementation of FSMA have been finalized by the FDA, acknowledging that maintaining the protection of the food supply is a mutual obligation at several different points in the global supply chain for both human and animal food. The rules of the FSMA are intended to make clear concrete steps that must be taken to avoid contamination at each of these stages.

The Food Safety Modernization Act of the FDA (FSMA) gives the FDA a new mandate for public health. It directs the FDA to develop standards for those who produce, process, transport, and store food to follow modern food safety prevention practices. It also provides the FDA with new mandates, authorities and oversight instruments aimed at providing clear guarantees that these activities are being carried out on a consistent, on-going basis by the food industry.

In order to establish the new prevention-oriented standards, the FDA is in the midst of the regulatory and guidance creation process needed, and FSMA implementation teams have established several ideas about how the FDA can better supervise the food industry, reinforce the global food safety system, and improve public health security **[13]**. Planning has already started for the next step of implementation of FSMA, which includes the operationalization of the new requirements for public health prevention and the implementation of the strategic and risk-based industry oversight system at the core of FSMA on the ground **[14]**.

This strategy document is intended to guide the next step of implementation of FSMA by outlining broadly the drivers of change in the approach of the FDA to food safety and the

operational strategy, as mandated and empowered by FSMA, for the implementation of that change. The appendix sets out guiding principles for how the plan should be applied with regard to food and feed installations, safety requirements and regulation of imports. The work of the teams responsible for developing the particular strategies, capacity building, training and operational plans required to implement FSMA in these areas will be driven by this document.

CONCLUSION

In particular, in the prevention and/or treatment of acute and chronic human diseases, nutraceuticals may have major health benefits. However, its growth depends on its consistency, protection, long-term adverse effects and toxicity, as well as on human supplementation studies and clinical trials. Nutraceuticals are used in the form of vitamins, probiotics and fortified diets to combat genetic diseases. In order to have a beneficial effect on the health of a person, commercial nutraceuticals have to pass through strict regulatory controls.

In addition, a dietary supplement must be classified as a dietary supplement and intended for consumption and must not be represented for use as a conventional food or as a single meal or dietary supplement. Additionally, a dietary supplement may not be licensed or permitted for examination as a novel drug, antibiotic or biological unless it has been advertised as a food or dietary supplement prior to such dietary supplement. Under DSHEA, and for the purposes of the drug specification, dietary supplements are considered to be food.

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