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RESEARCH ARTICLE

A Short Review on a Comparative Study of Regulation of Nutraceuticals in USA and India

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ABSTRACT

Nutraceuticals are the combination of Nutrition and pharmaceuticals. Every Country has their own guideline and a regulatory requirement which deals with registration process of nutraceuticals. A dietary supplement is a product taken by mouth that contains a dietary ingredient (Vitamins, Minerals, Herbs, Amino acids etc.) Numerous definitions and nomenclature for dietary supplements exist worldwide. 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. Mainly focuses on the similarities and differences of nutraceuticals regulatory framework and structure in USA and India, with stress on global harmonization and harmonized technical requirement for registration of nutraceutical product in this market. A comparative approach was used in this study. The study of the differences and similarities could serve as a measure to find methods for global harmonization, which is currently a vital necessity for regulation. The study is based on the complete legal requirements that are necessary for the countries that want to register a nutraceutical food or drug product.

KEYWORDS

Nutraceuticals, Regulation of Nutraceuticals, Labelling and Health Claims

INTRODUCTION

- Last decades the role of dietary active components in human nutrition has become an important focus of research and has increased the awareness of consumers about diet and proper nutrition. An important product category that has emerged from this focus on dietary active components in human nutrition is ´nutraceuticals´.
- The term nutraceuticals was first introduced by Defelice in 1989 and in 1994 Defelice defined nutraceuticals as "Any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease"

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Regulation of Nutraceuticals in USA: [5-7]

- Nutraceuticals are known as dietary supplements in USA. USFDA defines nutraceuticals, dietary supplements or ingredient. This regulation comes in to force in 1994.
- The regulation includes 1) Vitamins and Minerals 2) Herbs or Phytochemicals 3) Amino acids 4) Probiotics 5) A dietary substance to supplement the diet by increasing the total dietary intake.

- Nutraceuticals are dietary supplements that contain a concentrated form of presumed bioactive substance originally derived from a food but now present in a non-food matrix and used to enhance health in dosages exceeding those obtainable from normal food. eg. Soy protein is a dietary supplement but ipriflavone a synthetic derivative of isoflavone daizein found in soy protein is nutraceutical.
- FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

- The manufacturer of a dietary supplement or dietary ingredient is responsible for ensuring that the product is safe before it is marketed.
- FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market.

- Under FDA regulations at 21 CFR part 111, all domestic and foreign companies that manufacture, package, label or hold dietary supplement, including those involved with testing, quality control and dietary supplement distribution in the U.S., must comply with the Dietary Supplement Current Good Manufacturing Practices (CGMPs) for quality control.
- In addition, the manufacturer, packer or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA all serious adverse event reports associated with use of the dietary supplement in the United States.
- FDA's responsibilities include product information such as labeling, claims, package inserts and accompanying literature. The Federal Trade Commission (FTC) regulates dietary supplement advertising.

Classification of Nutraceuticals [3, 4]

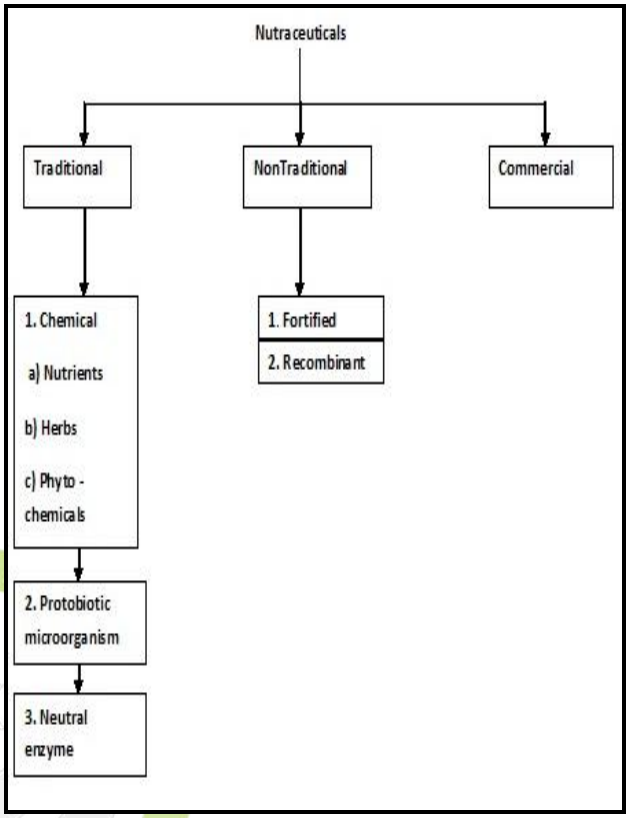

Figure 1: Classification of Nutraceuticals

Health Claims in USA

Health Claims: Health claims are claims made on food or food product or dietary ingredient that they will reduce the risk of developing disease or condition.

Nutrient Content Claims

This describe directly or by implication the level of a nutrient or dietary substance in a serving

They are limited to those authorized by FDA regulation.

- ***Absolute nutrient content claims***

These are direct statements about the level of a nutrient in the product.

- **Relative nutrient content claims**

Compare the level of nutrients of one product to another

- ***Implied nutrient content claims***

Claims not explicitly stated but implied by association with an ingredient known to contain a particular nutrient or be free of that nutrient.

Health Claims

These health claims are pre-authorized by FDA.

- ***SSA Claims (Significant Scientific Agreement)***

These claims can be used for conventional foods and dietary supplements. FDA authorizes SSA claims based on the Agency's extensive review of the scientific literature. 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 at this time. 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.

Structure/Function Claims

Describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function or general well-being.

Cannot describe or imply that a nutrient or functional component affects a disease or health-related condition via diagnosis, cure, mitigation, treatment or prevention (a claim doing this is an unauthorized drug claim).

Regulation of Nutraceuticals in INDIA: [8-10]

- 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" as:

A. foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist and may contain one or more of the following, namely:

a) Plants or botanicals or their parts in the form of powder, concentrate or extract in water, Ethyl Alcohol or Hydro Alcoholic extract, single or in combination;

b) Minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);

c) Substances from animal origin;

B. A dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

a) A product that is labeled as a "Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of Powders, Granules, Tablets, Capsules, Liquids, Jelly and other dosage forms but not parenterals and are meant for oral administration;

b) Such product does not include a drug as defined in clause (b) and Ayurvedic,

Sidha and Unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made there under;

c) Does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under FSSA.

d) Does not include a narcotic drug or a psychotropic substance as defined in the schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945.

Health Claim

1. Nutrient content claim

2. Reduction of disease claim

3. Structure/Function claim

Nutrition Claim

A nutritional claim suggests a food has beneficial nutritional properties, such as "low fat", "no added sugar" and "high in fibre".

A claim is a statement that suggests a relationship between food and health for instance that 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.

Registration Process in USA[11]

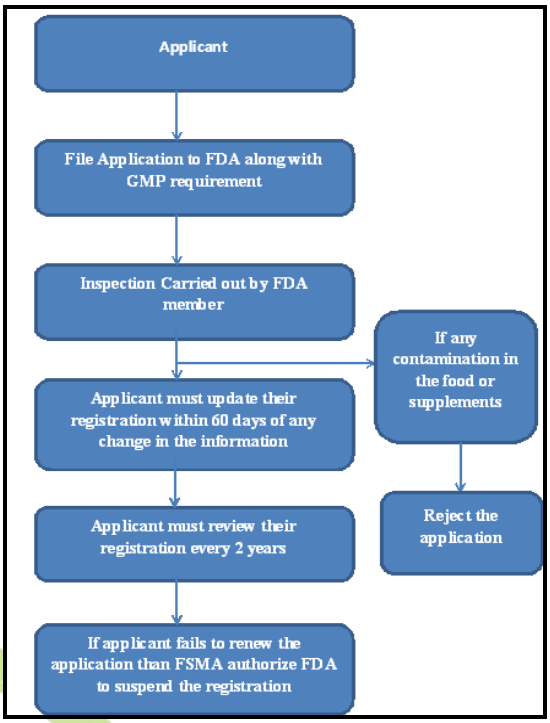

Figure 2: Registration Process of USA

Registration Process in India[12]

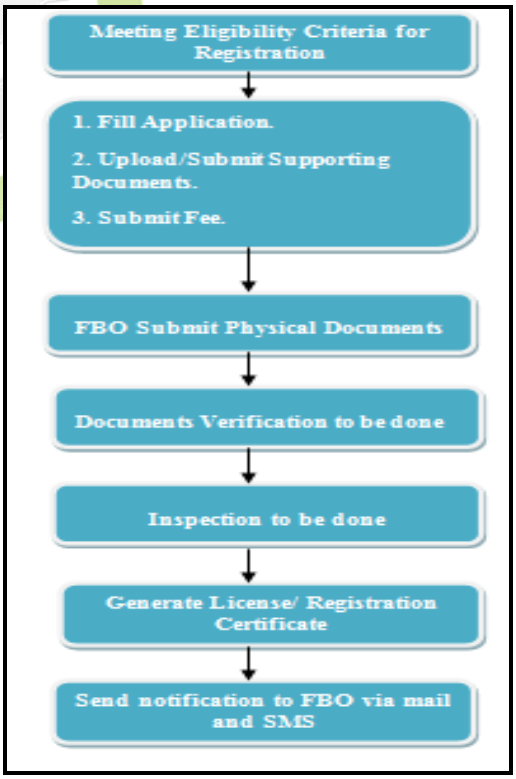

Figure 3: Registration Process of India

Table 1: Comparison of Regulatory Guidelines of USA and INDIA

	USA	**INDIA**
Definition	US Food & Drug Administration defines Nutraceuticals as "Dietary Supplements" Under Dietary Supplements & Health Education Act	Food Safety and Standards Authority **(**FSSA) defines Nutraceuticals as "Foods for special dietary uses" in India.
Rules/Regulations for licensing and registration	USFDA	FSSAI
Regulations came into force in year	1994	2011
Responsible Regulatory authorities for Registration of Nutraceuticals	Dietary Supplements and Heath Education Authority	Food Safety and Standard Authority of India
Form For Registration	Form 3537	Form A , B & C
Regulatory Requirements for Registration	A. Product licensing B. Evidence requirements for safety & efficacy C. Labelling D. Heath claims E. GMP F. Adverse Reaction Reporting G. Clinical Trials	A. Product evaluation B. Licenses C. Health & label claim
Fees for registration	Currently no Required	25000
Guidance Documents	• Current Good Manufacturing Practice • Warning Letter & Safety Alerts • Labelling and Regulation • Health Claims • Adverse Events Reporting • General Compliance & Inspection Information	• Administrative Data • Technological Data • Information on dietary exposure, nutritional impact on the consumer • Efficacy-Health Claim/ Nutritional Claim/Risk Reduction Claim • Details of fees to be enclosed
Claims	Nutrient Content Claims • Absolute Nutrient content Claims • Relative Nutrient content Claims • Implied Nutrient content Claims Health Claims • SSA Claims(Significant Scientific agreement) • FDAMA (FDA Modernization act) Qualified Health Claims Structure/Function Claims	• Nutrient Content Claim • Reduction of disease Claim • Structure/Function Claim

CONCLUSION

Nutraceutical products are nowadays widely used for the treatment of various diseases and hence it is necessary to enlighten the requirements that a filing country should follow. Hence, the study on regulatory requirements on nutraceutical products would help in focusing on the areas that are not yet clear for the same. 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. From the above study concluded that the registration of nutraceuticals in USA is easier then India because in USA there is more specific documents and less time consuming than India.

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