

**REVIEW ARTICLE ON CURRENT REGULATORY REQUIREMENTS FOR
REGISTRATION OF NUTRACEUTICALS IN INDIA****Lokesh Mogallpu***

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Article Received on 31/01/2023

Article Revised on 20/02/2023

Article Accepted on 12/03/2023

ABSTRACT

Bioactive or natural chemical components known as "nutraceuticals" are sold in India. Because of the benefits they provide for boosting health and lowering the risk of disease, nutraceuticals have become extremely important. Dietary or food additives with specific physiological impacts are these things. They are known by several names such as dietary supplements, health foods, nutritional supplements, etc. The market for nutraceuticals is growing daily, and so are the product's claims. The regulatory organisation to oversee the registration of manufacturing facilities, import, and export of food is the Food Standard Safety Authority of India (FSSAI). The current paper presents an overview of the existing situation and future growth prospects of dietary supplements in India, as well as the legal framework for dietary supplements and registration process for manufacture, export, and import of nutraceuticals in India.

KEYWORDS: nutraceuticals, dietary supplements, FSSAI, health.**INTRODUCTION**

The terms "nutraceutical" and "pharmaceutical" were combined to form the phrase. Nutraceuticals are foods or dietary components that have health advantages, such as cancer prevention and the treatment of various illnesses, enhancing well-being, prolonging life or postponing the ageing process. The idea of nutraceuticals emerged in areas with better diets rated by customers, then engaged in physical activity to attain a healthy body. Nutraceuticals are substances that are typically ingested in food- or dietary supplement form, such as pills, capsules, or liquids. Nutraceuticals are nutritional supplements with a focus on prevention that are developed from food sources and food ingredients, according to the renowned physician Hippocrates (known as the "father of medicine"). He discussed the idea of "healthy life" dietary intake utilising natural foods, medical conditions, and biochemical substances found in food goods to maintain or treat illnesses and keep people healthy. Nutraceuticals are ingredients that have been taken out of food and are typically offered for sale as medications. Particularly intriguing as a means of lowering the pricey, high-tech sickness are nutraceuticals. Contemporary therapeutic methods used in wealthy nations.

Classification of nutraceuticals

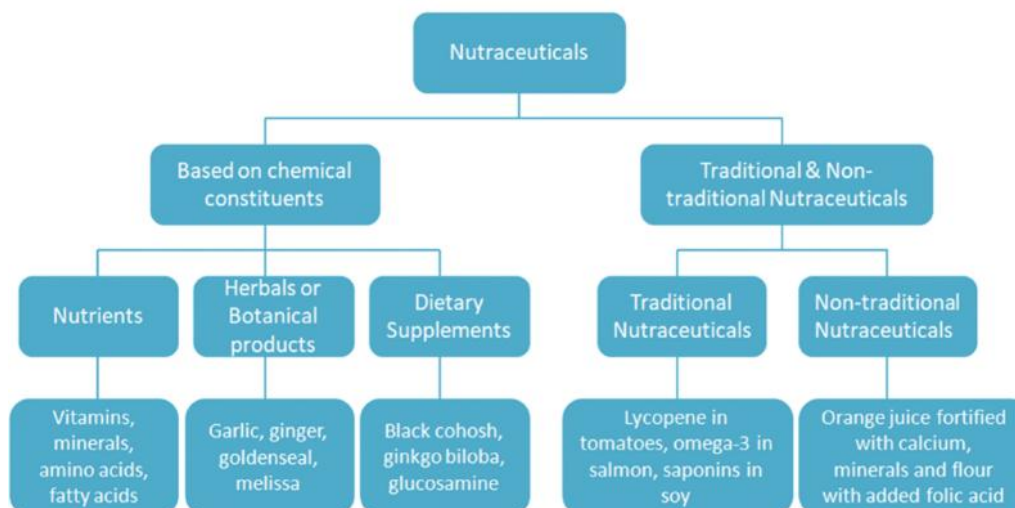


Fig 1: Classification of nutraceuticals.

Discussion: Regulation of nutraceuticals in india:

The rise of the nutraceuticals industry in India has been fueled by rising health consciousness and higher incomes and levels of life, resulting in its being one of the markets with the quickest growth. According to the Indian definition of nutraceuticals, it must include the specified substances and possess the general characteristics indicated. Traditional foods are not included in nutraceuticals. Dietary supplements that contain crucial ingredients having therapeutic effects and being tailored to meet specific dietary needs. These are all the elements that must be different from the requirements in the food products. Indian norms are provided like such, starting with commonplace foods, if any. A food item, then it must include at least one ingredient or composition. These comprise the components that are obtained in the form of liquid extracts, dry powders, and ethanol and hydroalcoholic extracts; they may be combined or added singly from plants, specifically botanicals. Nutrients, proteins, amino acids, and their maximum tolerances for metal components shall not exceed those specified in the Indian laws and regulations, the recommended daily allowance (RDA) is used. The following are the main growth factors for nutraceuticals in India.

1. An ageing population and rising cardiovascular and diabetes mortality rates and overweight
2. Annual Net Amount Available
3. Online users.

FSSAI: The FSSAI was established in 2008. This authority consolidates different acts and orders that are related to the act's enforcement of various provisions formerly handled food-related concerns in a variety of Ministries and departments. The FSS legislation of 2006, rules, and regulations of 2011 classify nutraceuticals under the general heading of foods. Foods for particular dietary needs, functional foods, or nutraceutical health supplements are defined as follows in Section 22(1) of the FSSA: a) Food produced using organic methods, with

requirements that take into account the proprietary and unique foods that are not only unsafe but also not specified in the act. Are also included in the act, in addition to dietary components made of or containing elements derived through contemporary biotechnology, such as genetically modified or engineered organisms that may also include the same. b) a product that is advertised as a "Food for special dietary uses or functional foods or Nutraceuticals or health supplements or similar such foods" and is not intended for consumption as a conventional food. Such products may be formulated as powders, granules, tablets, capsules, liquids, jelly, and other dosage forms, but not parenterals, and are intended for oral administration.

Registration and licensing requirements of nutraceuticals in india: Several licences (about 4–5) may be necessary for product registration in India, depending on the specific product status, such as: Whether the business aims to sell finished formulation or bulk drugs.

Whether or not the business is importing finished goods or bulk products

Whether the product being imported will include or exclude India particular label

Will India be where the claims are developed?

The existence of a packaging licence for the business.

Whether a manufacturing licence is necessary Whether a marketing licence is necessary.

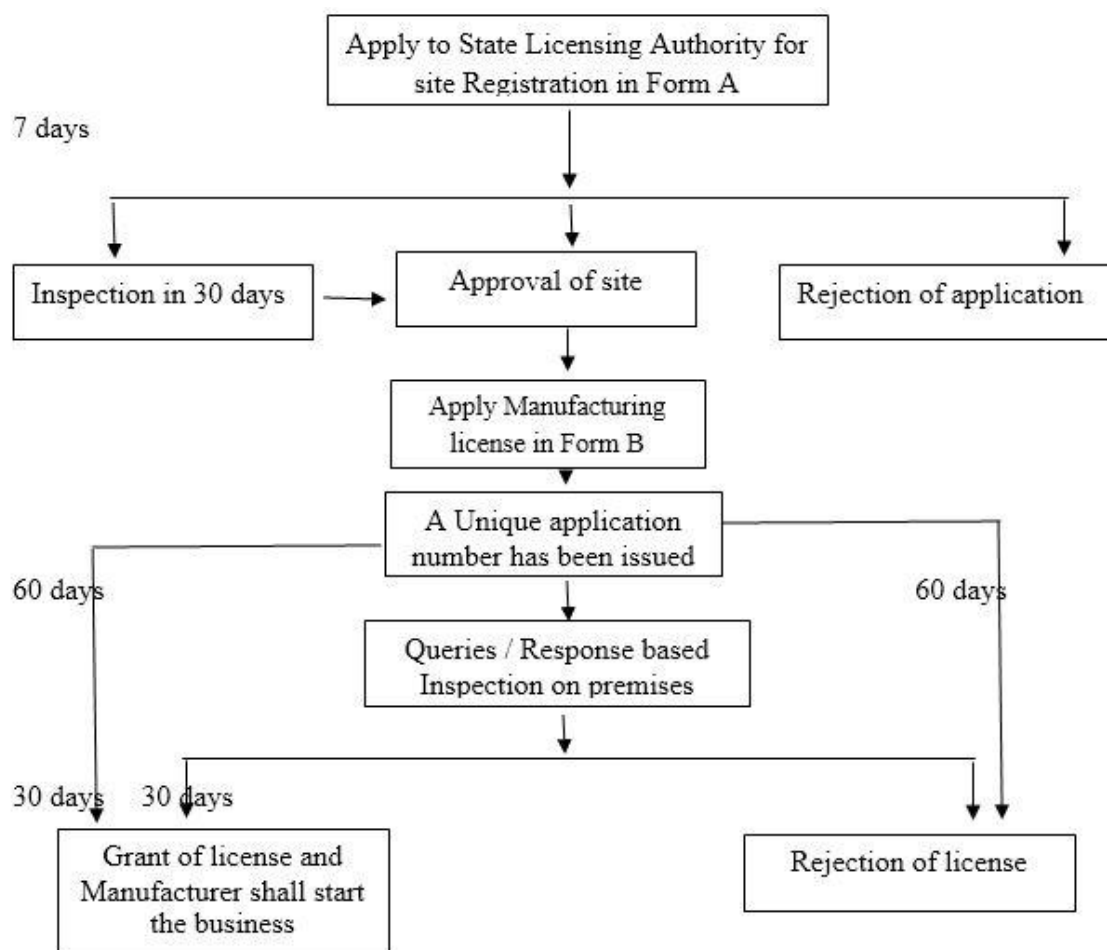


Fig 2: Registration process of nutraceuticals in india.

Licenses: Depending on the status of the actual product, different licences are required for the registration of nutraceutical products in India. The importer is also required to submit product dossiers in accordance with the licencing requirements, and many documents must be reported to the appropriate government official.

the import

License for production

Permission for marketing

Before launching these items in India, additional regulatory permissions and licences at the state and federal levels must be obtained.

CONCLUSION

In the pharmaceutical industry, the Nutraceuticals sector is still in its infancy, but it is expected to grow significantly over the next several years. Even if the market has a greater capacity and the business is growing, no precise regulations have been established to control large corporations. Knowing the most recent nutraceuticals legislation in India is crucial for market owners. The company must meet a number of requirements in the specified guidelines in order for the product to be approved.

ACKNOWLEDGMENTS

We take this opportunity to express deep sense of gratitude to WJPMR Journal for publishing my article.

Conflict of interest

The author declare that there are no conflicts of interest.

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