



Marketing nutraceuticals in India: an overview on current regulatory requirements

Vibhu Yadav, Parijat Pandey, Vineet Mittal, Anurag Khatkar and Deepak Kaushik*

Department of Pharmaceutical Sciences, Maharshi Dayanand University, Rohtak, Haryana (India)-124001.

ARTICLE HISTORY

Received: 10.09.2014

Accepted: 12.10.2014

Available online: 28.02.2015

Keywords:

Nutraceuticals, Dietary Supplements, Food Standard Safety Act, Health Claims, Food Safety Standard Authority of India.

*Corresponding author:

Email : deepkaushik@rediffmail.com

Tel.: +91-

ABSTRACT

Nutraceuticals have gained immense importance due to their health promoting and disease risk reduction benefits. They are food or food ingredients that have defined physiological effects and are recognized by different names like dietary supplements, health supplements, health foods, etc. Availability of large number of foods and nutritive compounds make India a growing source in the international health foods market. Multiple laws, in the past, have existed for regulation of safety for such products. However, implementation of Food Safety Standard Act has strengthened their regulation as well as position in both the international and domestic market. Food Standard Safety Authority of India (FSSAI) is the regulatory body to oversee the registration of manufacturing facilities, import and export of nutraceuticals. The present paper provides an overview on the current status and growth potential of nutraceuticals in India, regulatory framework for nutraceuticals, complete mandatory registration procedure for import, export and manufacturing facility under FSSAI.

INTRODUCTION

Nutraceuticals is a term which describes substances which are not traditionally recognized nutrients (e.g. vitamins, minerals, botanicals) but which have positive physiological effect on human body [1-2]. The term was originally used by Defelice, in 1995 with the definition: "A food or parts of food that provide medical or health benefits, including the prevention / treatment of disease". Nutraceuticals are components that are often consumed in unit dosage form such as, tablets, capsules, or liquids and commonly known as food/ dietary supplements. There is significant growth in nutraceuticals, functional and fortified food sector globally during the previous decade [3]. The health and wellness foods market is currently estimated to be around US\$ 1.6 billion and is expected to reach US\$ 7.5 to 10 billion by 2015 growing at 25 to 30 percent compound annual growth rate [4]. Market demand has increased due to the use of health claim on these products. Recently it has been suggested that there will be 1026% hike in consumption of products with proven health claims, which may translate to a 20% increase in sales. In response to the growing interest in functional foods and nutraceuticals by consumers and food industries, regulatory bodies in a number of countries have developed policies governing issuance of health claims [5-7]. The global nutraceutical market in 2011 was estimated to be \$149.5 Billion, with U.S., Europe and Japan being the largest regional markets, accounting for nearly 93 percent of the global nutraceutical

demand. These markets are nearing maturity, with exceedingly high per capita spends on nutraceutical products (Japan has a per capita spend of \$51/person/year, while U.S. and Europe have \$40 and \$35 each. The global average is only \$21/person/year.) This compels nutraceutical manufacturers to look at developing countries such as India, which have considerably lower per capita spends on these products, as key growth regions [8].

Nutraceuticals in India: Some key facts

The Indian nutraceutical market is mainly dominated by pharmaceuticals and FMCG companies with very few companies that only specialize in nutraceutical products. Increasing health consciousness and improved incomes and standards of living has boosted the growth of the nutraceuticals markets in India, making it one of the fastest growing segments. [9]

The nutraceuticals market in the India is showing a continuous growth trend despite the economic downturn and rising inflation rates. There are several reports which are indicative of huge growth potential of nutraceuticals in India. According to the report released by Netscribes India Pvt. Ltd., the total market of nutraceuticals in India is growing at the rate of 21% per annum. It is currently valued at INR 44 billion, but could be more than INR 95 billion in four years time [10]. In another recent report Frost & Sullivan estimated a growth of 2,731 millions at a CAGR of 13.0 percent [11].

The major growth drivers for nutraceuticals in india are:

- ◆ Aging Population
- ◆ Increasing mortality rate due to cardiovascular, diabetes and obesity
- ◆ Annual Disposable Income
- ◆ Internet Users
- ◆ Healthcare Spending
- ◆ Spending habits of the urban population of the country

Food Standard Safety Act

In 2006, the Indian government passed Food Safety and Standard Act to integrate and streamline the many regulations covering nutraceuticals, foods and dietary supplements. The act calls for the creation of the Food Safety and Standards Authority (FSSAI). The FSSAI role is to draft rules and regulations for companies in the food sector to be licensed by local authorities, and a system of checks and balances, including product-recall procedures enforcements and penalties [12]. The Food Safety and Standard Rules, 2011 have been issued, effective from 5th of May, 2011. According to this FSS Act, it is mandatory to register food/nutraceuticals facility under FSSAI. Online procedure is available for registration of import, export and manufacturing of food and nutraceuticals facility. Earlier there were multiple laws to regulate nutraceuticals in India and conforming to so many laws was a very difficult task for the manufacturers. As a final point, in 2005, a number of committees, including the standing committees of parliament on agriculture submitted its 12th report in which the need for a single regulatory body and integrated law was emphasized. The Indian Food Safety Standard Bill 2005 was signed into law, promising a major impact on Indian food processing industry [13]. Under this Food Safety and Standards Act, 2006, 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. were repealed after commencement of the FSS Act, 2006. The Act also aimed to establish a single reference point for all matters related to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command [14].

FSSAI: The New Ray of Hope

To make effect of Food Standard Safety Act, an independent statutory authority was established the Food Safety and Standard Authority of India (FSSAI) with head office at Delhi. The FSSAI came into existence in 2008 [15]. This authority enforces various provisions of the act and consolidates various acts & orders that have hitherto and 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. The Food Safety and Standard Authority have also issued regulations about licensing and registration of food business, packing and labeling, food products standard and additives, etc. These acts, rules and regulations have been implemented from 5th of August, 2011 [16]. Thus, now there is one single legislation and specified authorities to regulate manufacture, sale and distribution of nutraceuticals, functional

food and dietary supplement in India [15-19].

Licensing/Registration System under FSSAI

Everyone in the food sector is required to get a license or a registration that would be issued by the local authorities. Temporary stall holders are exempted from the license, but need to get their businesses registered with the local municipality or panchayat. Import licensing, manufacturing licensing and other national level clearances/licenses required from the regulatory side need to be taken care of before launching these products in India. The FSSAI promises to simplify the licensing and registration processes for nutraceuticals since the actual process varies with a number of parameters. For product registration in India, a number of licenses (almost 4 - 5) might be required, depending on the actual product status like:

- ◆ Whether the company wants to sell bulk drug or finished formulation
- ◆ Whether the company is importing finished product or bulk goods
- ◆ Whether product to be imported is with or without India specific label
- ◆ Will the claims be developed in India
- ◆ Whether the company has a packaging license
- ◆ Whether it requires manufacturing license
- ◆ Whether it requires marketing license

A number of documents have to be furnished by the food importer/ exporter/manufacturer to the government authority along with registration application dossiers

Registration of Manufacturing Facility under Central Licensing System

Food Safety Standard Authority of India has created an online procedure for registration of food facilities (import, export, and manufacturing) which is illustrated by Figure 1. The application should be submitted to the State Authority/Regional Office of Food Safety and Standards of India, within fifteen days from the date of submission of application online. The fees and supportive documents are required to be submitted as part of the application. The list of documents required for nutraceutical registration is given in Table 1.

Claims on Nutraceuticals

According to Food Safety and Standards Act- (packaging and labeling) regulations, three types of claims are defined namely health claim, nutrition claim and risk reduction claim [16]. *Health claim* means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health and include nutrition claims which describe the physiological role of the nutrient in growth, development and normal functions of the body, other functional claims concerning specific beneficial effect of the consumption of food or its constituents, in the context of the total diet, on normal functions or biological activities of the body and such claims relate to a positive contribution to health or to the improvement of function or to modifying or preserving health, or disease, risk reduction claim relating to the consumption of a food or food constituents, in the context of the total diet, to the reduced risk of developing a disease or health related condition. *Nutrition claim* means any representation which states, suggests or implies

Table 1. : Documents required for registration of nutraceuticals in India.

• Form B duly signed by the authorized signatory body
• Blueprint/Layouts plan of the processing unit
• List of Directors with full address and contact detail
• Name and list of equipment and Machinery
• Photo I.D. with Address Proof issued by government
• List of food category desired to be licensed
• Water analysis report
• Proof of possession premises
• Food Safety Management System Plan
• NOC From Manufacturer
• Food Recall Plan
• DGFT registration certificate of Importer Exporter
• NOC's From Municipality / Local Body

that a food has particular nutritional properties which are not limited to the energy value, but include protein, fat carbohydrates, vitamins and minerals. *Risk reduction claim* in the context of health claims means significantly altering a major risk factor for a disease or health-related condition. However, due to lack of clarity in specific regulations for registration of nutraceuticals and permitted additives, entrepreneurs intending to launch nutraceuticals in India are still facing the following challenges:

- ◆ Drugs defined under Section 3 (b) (i) of the Drugs and Cosmetics Act, 1940 and also Ayurvedic, Siddha and Unani drugs are specifically excluded from the scope of the definition of Nutraceutical, Health Supplement, etc. under Section 22 of the Act. The definition of drug under Drugs Act is very exhaustive. Taking recourse to the definition of drug, regulatory officers are categorizing nutraceuticals, especially manufactured and marketed in tablet, capsule or liquid oral dosages form containing vitamin and minerals as drugs on the basis of even structure function claims.

- ◆ The regulatory officers also take a view that as empty gelatin capsule itself is covered by the definition of drug, any product marketed in capsule form will also be considered drug.

- ◆ Some commonly used colors and additives such as binding agents, granulating agents used in formulating tablets do not find place in the list of permitted food additives under the regulations.

- ◆ Though the structure function claims are permitted, there is no clarity as to the permitted structure function claims for nutraceuticals and dietary supplements. To overcome these difficulties, it would be necessary to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to provide for specific

exemption to nutraceuticals, dietary supplements, health supplements from the scope of Drugs and Cosmetics Act, 1940 and Rules, 1945.

Conclusion and future outlook for nutraceuticals in India:

After implementation of Food Safety Standard Act, 2006, nutraceuticals safety and quality has been increased up to a large extent and also confusion due to multiple laws has been prevailed. The formation of Food Safety Standard Authority of India (FSSAI) has shown positive outcomes in successful online registration of the food facilities. Thus, any new applicant entering Indian nutraceuticals market should comply with the regulatory framework for smooth running of his business. Nutritionists and food scientists have the possibility through the development of nutraceuticals to offer beneficial opportunities related to the well being and health and reduction of risk to diseases. There should be new retailing programmers, increased validation and clinical research, heightened awareness due to media and government focus, and greater corporate responsibility, innovation R&D and product development skills. The manufacturers should increase their research strategy to evaluate more and more therapeutic ingredient regarding nutraceuticals so that consumers consider them not only OTC (over the counter) drugs, alternative or complementary medicines but to ensure their health benefits beyond basic nutrition.

Considering the various alternative trends in the added value food and drinks market, it has been estimated that the right marketing strategy is even more crucial for manufacturers. Consumer acceptance of the concept of nutraceuticals has been widely recognized as key success factors for market orientation, consumer-led product development, and successfully negotiating market opportunities. Acceptance, however, is determined by a host of factors such as primary health concerns, consumers'

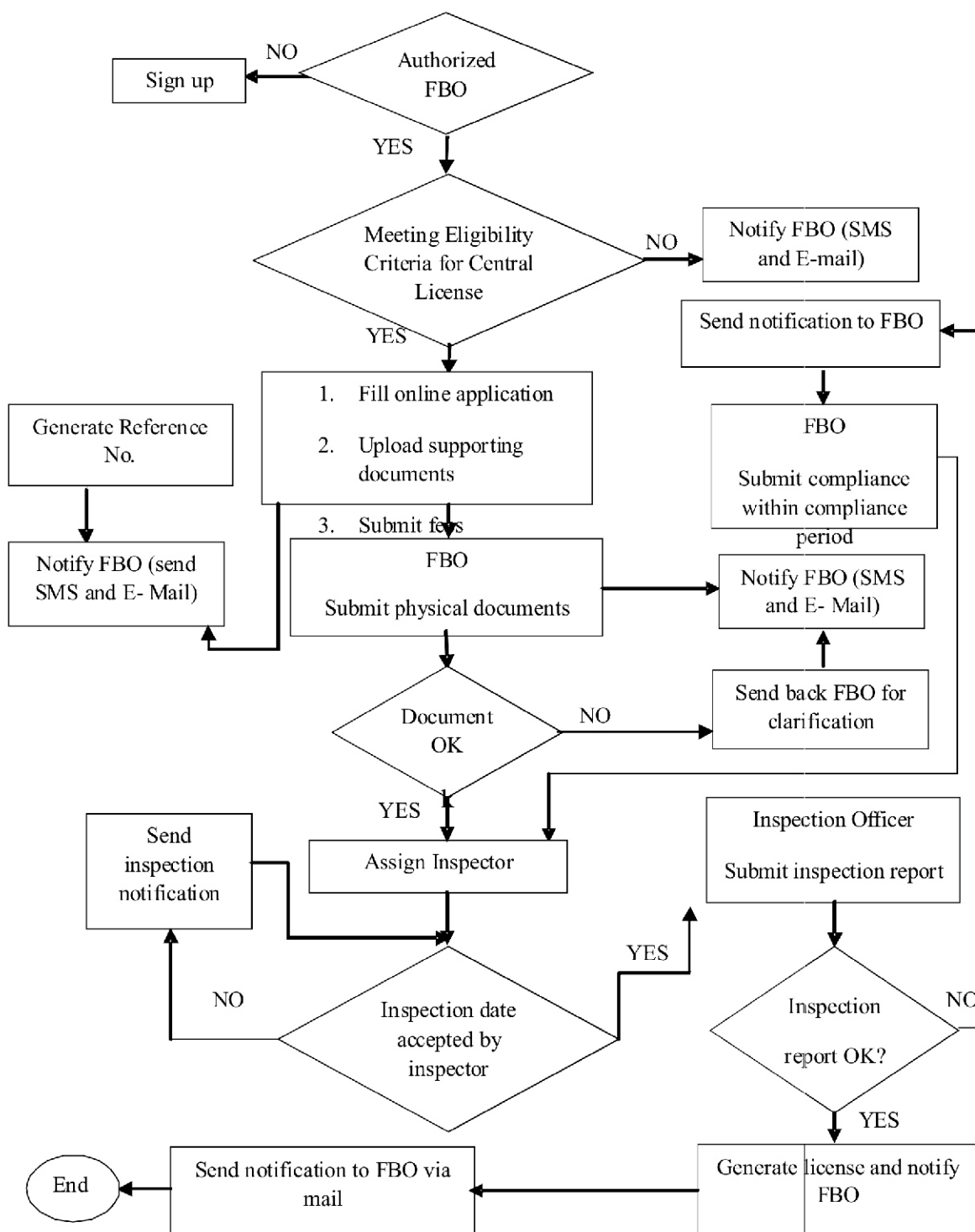


Figure 1: Online procedure for registration of food facilities (import, export, and manufacturing).

familiarity with the nutraceutical concepts and with the functional ingredients, the nature of the carrier product and the manner of health effect communication. However, despite all the encouragement for functional food, nutraceuticals, or food for special dietary use, there is no health claim approval procedure defined in the act for nutraceuticals as it is necessary to treat this segment as an independent and unique entity under the Food Safety Standard Act, 2006.

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