



IJPPR

INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals

ISSN 2349-7203





Human Journals

Review Article

February 2018 Vol.:11, Issue:3

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Regulatory Requirements for Registration, Import, and Manufacture of Dietary Supplements / Nutraceuticals in India

			
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Submission:	25 January 2018		
Accepted:	31 January 2018		
Published:	28 February 2018		

Keywords: Nutraceuticals, Dietary Supplements, registration, import, and manufacture

ABSTRACT

The main aim of this article was to study the various dietary supplements registration processes, regulations on imports and requirements by the Indian Regulatory Authorities. The study emphasizes the challenges faced by stakeholders entering into the Indian market without difficulty by demonstration of strategy arrived from the established guidelines, regulations and expert opinion. The study was undertaken to identify the challenges in dietary supplements and to evaluate the available guidelines and map the general requirements for registration.



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INTRODUCTION

A nutraceutical is a food or food component that claims to have health benefits, including treatment and prevention of disease. In 1989, Stephen DeFelice, M.D., derived the term "nutraceutical" from "nutrition" and "pharmaceutical." Basically, it's used as a marketing term. As defined by Congress in the Dietary Supplement Health and Education Act (DSHEA)¹, which became law in 1994, a dietary supplement is a product (other than tobacco) that is intended to supplement the diet; contains one or more dietary ingredients (vitamins, minerals, herbs, amino acids, and other substances); is intended to be taken orally; and is labeled on the front panel as being a dietary supplement. "The term nutraceutical has no regulatory definition and is not recognized by the U.S. Food and Drug Administration, which uses instead the term 'dietary supplements'. The Merck Manual states, "The most commonly used alternative therapy is dietary supplements, which include medicinal herbs and nutraceuticals." The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries and Departments.

CURRENT SCENARIO

The FMCG (fast moving consumer goods) suppliers and pharmaceutical companies are the key players in the Indian Nutraceutical market. Vitamin and mineral supplements are responsible for the 64% of the total Nutraceutical market in India. The two billion dollars Indian Nutraceutical market² is subdivided into two main categories (i) Functional foods and beverages and (ii) Dietary Supplements.

(i) Functional foods and beverages: This category covers almost 60% of the total market. According to WHO the fortified food is referred to the addition of micro-nutrients to the processed food which includes all the fortified drinks, fortified juices, fortified foods and energy drinks.

(ii) Dietary supplements: This category covers up the remaining 40% of the Indian Nutraceutical market. This class includes Vitamins and Mineral supplement, herbal supplement, protein supplement and Chyawanprash.

The Indian consumer's awareness about conventional nutraceutical ingredients is limited and nutraceutical manufacturers need to take up the cause and spread awareness about their

products to the Indian masses. The global nutraceutical market has seen maximum growth in last decade. In India, beverages and functional food are expected to witness much higher growth rates when compared to dietary supplement over the next five years. The Indian nutraceuticals market which has grown from \$ one billion in 2008 to \$1.8 billion in 2013, has crossed \$ two billion in 2014 and is expected to top \$ four billion by 2018.

IMPORTANCE OF THE PROPOSED WORK

The Food Safety Standards Authority India (FSSAI) is the approving authority which grants the approval for the registration of the food products and food business for the sale of the products in the country. It also promotes the general awareness of the food safety standards in the country. Food safety standard and standards act is laid down in 2006 in order to form the statutory body which regulates the manufacture, storage, distribution, sale, and import, to ensure the availability of the food and food products within the country. Nutraceutical is grouped under the umbrella of foods by the FSS act 2006, rules and regulations 2011. The Food Safety and Standard Authority has issued regulations³ with respect to Licensing and registration of food business, manufacturing, packing and labeling, food product standard etc. The FSSA has 12 chapters with 101 sections and two schedules. The FSSA incorporates the salient provisions of the prevention of Food Adulteration Act 1954 with the aim to establish a single reference point for all matters relating to food safety and standards.⁴ The FSSA establishes the Food Safety and Standards Authority of India (FSSAI) as an apex regulatory authority, consisting of a Chairperson and 22 members. In their endeavor to carry out the provisions of the FSSA, the FSSAI shall be assisted by a Central Advisory Committee (CAC), Scientific Panels (SPs), and a Scientific Committee (SC); each with specific responsibilities.⁴The Food Authority may enlist specific nutraceuticals as approved from time to time after undertaking the proper scientific evaluation. Labeling of Nutraceuticals shall comply with the packaging and labeling requirements as laid down under Food Safety and Standards (Packaging and Labelling) Regulations, 2011.³The Food Safety and Standard act will encourage manufacturers for product Research and Development; develop reliable protocols and carry out clinical studies. Foreign Direct Investment Act will also provide new opportunities for international firms to manufacture and sell nutraceutical products in India.

For the better understanding of the updated requirements for Imports, Exports and Registration of Dietary Supplements/Nutraceuticals with FSSAI in detail and to ensure the regulatory compliance in India, this project work is initiated.

Role of nutraceutical agents in cardiovascular diseases:

Nutraceuticals like carnitine, N-acetylcysteine, creatine, glutathione, selenium, resveratrol, beta-sitosterol and flavonoids are used in cardiovascular diseases⁵. L-carnitine has a beneficial effect on cardiac function and it was postulated to be cardioprotective due to its antioxidant effects.

Documents Requirement for FSSAI Food License

The FSSAI required documents for Food License depends on the kind of registration – simple Registration Form A or Food License Form B which depends on annual turnover. For tiny FBO only registration with food, authority is required.

Annual Turnover	Registration / License
Below 12 Lakhs	Registration FORM
12 – 20 Lakhs	State License FORM B
Above 20 Lakhs	Central License FORM B

Basic Registration is required for small Food Business Operators (FBO) having an annual turnover less than 12 Lakhs.

Documents required with Form A⁶

- Passport size photograph of Food Business Operator
- Document for Identity proof like ration card, voter ID card, Pan card, Driving License, Passport, Aadhar card, Senior citizen card, Department issued ID
- Supporting documents (if any): NOC by Municipality/Panchayat, Health NOC

State License is required for FBO having an annual turnover of 12 – 20 Lakhs

Documents required with Form B (State License)⁶

- Form B must be appropriately completed and signed (in duplicate) by the proprietor or partner of the authorized signatory

- It is mandatory for manufacturing and processing units to provide a blueprint plan of the processing units which shows the dimensions in meters or squares and operation wise area allocation along with name, list of equipment and machinery with their number, installed capacity and horsepower used.
- It is mandatory for companies to furnish the list of Partners/Proprietor/Executive Members of society with complete address and contact details.
- Address proof and photo ID issued by Government authority
- In case of manufacturers, list of food category desired to be manufactured
- Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, the collection of samples, packing and dispatch. (for manufacturers / processors)
- Analysis report (Chemical and Biotechnological) of water to be used as the ingredient in food from a recognized/public health laboratory to confirm the portability (mandatory only for manufacturing and processing units only)
- Proof of possession of premises (Sale deed/ Rent agreement/Electricity bill etc.) (optional)
- Partnership Deed/Affidavit of Proprietorship/Memorandum & Articles of Association towards the constitution of the firm. (optional) – For MoA – Three pages need to be uploaded (First page – Certification of incorporation, Second page – Authorization of food business activity and Third page – list of directors with addresses)
- Copy of certificate obtained under Co-Op Act – 1861/Multi State Co-Op Act – 2002 in case of Co-operatives. (wherever applicable)
- NOC & Copy of License from the manufacturer (mandatory for re-labelers and re-packers only)
- Food Safety Management System plan or certificate (if any)

- Source of milk or procurement plan for milk including the location of milk collection center's etc. in case of Milk and Milk Products processing units.(wherever applicable)
- Source of raw material for meat and meat processing plants. (wherever applicable)
- Pesticide residues report of water in case of units manufacturing packaged drinking water, packaged Mineral water and/or carbonated water from a recognized/ public health laboratory
- Recall plan wherever applicable, with details on whom the product is distributed. (optional)
- NOCs from Municipality or local body. (optional)
- Form IX: Nomination of Persons by a Company along with the Board Resolution.
- Certificate provided by Ministry of Tourism (HRACC) (Applicable to Hotels only)
- For Transporters-Supporting documentary proof for Turnover or self-declaration of number of vehicles
- Upload Production unit photograph
- Declaration form

Central License is required for FBO having an annual turnover of above 20 Lakhs

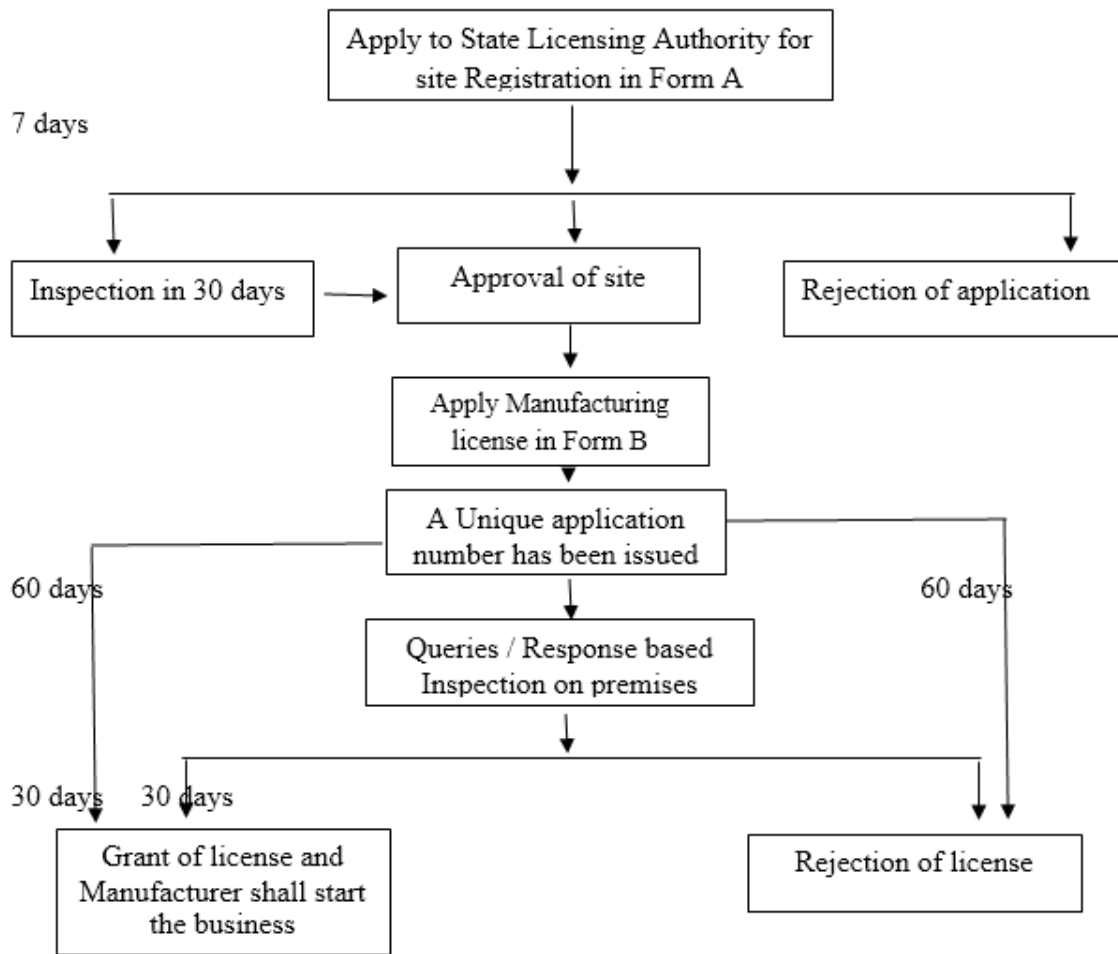
Documents required with Form B (Central License)⁶

- Blueprint/layout plan of the processing unit showing the dimensions in meters/square meters and operation-wise area allocation (mandatory for manufacturing and processing units only).
- List of Directors with full address and contact details (mandatory for companies only)
- Name and List of Equipment and Machinery along with their number, installed capacity and horsepower used (mandatory for manufacturing and processing units only).
- Photo ID and address proof issued by Government authority of Proprietor/Partner/Director(s)/Authorized Signatory. (optional)

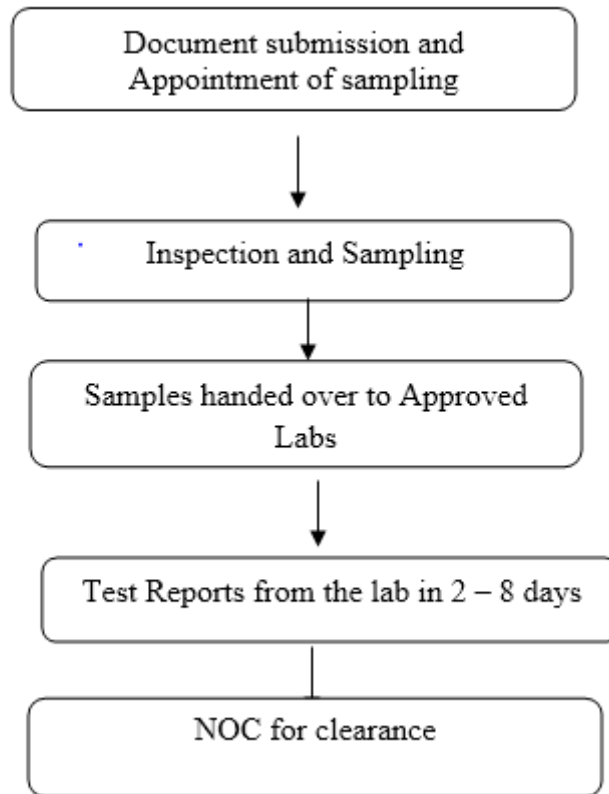
- List of food category desired to be manufactured. (In case of manufacturers).
- Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, the collection of samples, packing & dispatch. (Mandatory for manufacturing and processors).
- Analysis report (Chemical & Bacteriological) of water to be used as an ingredient in food from a recognized/ public health laboratory to confirm the portability (mandatory only for manufacturing and processing units only).
- Proof of possession of premises. (Sale deed/ Rent agreement/ Electricity bill, etc.) (optional).
- Partnership Deed/Affidavit/Memorandum & Articles of Association towards the constitution of the firm. (Optional).
- Copy of certificate obtained under Co-Op Act – 1861/Multi State Co-Op Act – 2002 in case of Co-Operatives. (Wherever applicable).
- NOC from the manufacturer (mandatory for Re-labellers and Re-packers)
- Food Safety Management System plan or certificate (if any).
- Source of milk or procurement plan for milk including the location of milk collection center's etc. in case of Milk and Milk Products processing units.(wherever applicable).
- Source of raw material for meat and meat processing plants. (wherever applicable).
- Pesticide residues report of water in case of units manufacturing packaged drinking water, packaged Mineral water and/or carbonated water from a recognized/ public health laboratory
- Recall plan wherever applicable, with details on whom the product is distributed. (Optional).
- NOCs from Municipality or local body. (optional).
- Supporting document proof for turnover

- NOC/PA document issued by FSSAI
- IE Code document issued by DGFT
- Form IX Nomination of persons by a company along with the board resolution
- Declaration form

The licensing process is done in two steps (i.e.) site registration and product registration².



Food Import Clearance Process



Web-based Food Import Clearance System

- It facilitates CHA's / Importers to:
 - To Register online
 - Apply for NOC without visiting any FSSAI Office and make payments for testing
 - Track status of their application
- It facilitates FSSAI Authorized Officers / Inspectors to:
 - Process applications for NOC
 - Ensure timely sampling and inspection
 - Generate No Objection Certificate (NOC)
- It facilitates Labs to:

- Update test results in the system
- Invoice FSSAI for payment
- Communicate with other labs
- It facilitates FSSAI HQ to:
 - To monitor the overall operations of the ports
 - Analyze the risk associated with importing countries
 - Generate MIS reports

Clearance of Imported Food by the Food Authority⁷

Upon arrival of the food consignments at the port, the importer or Custom House Agent shall file an Integrated Declaration Form as specified by the Customs. The Form forwarded from Customs to the Food Import Clearance System of Food Safety and Standards Authority of India shall be processed in the following manner, namely:-

- (a) the Authorised Officer shall scrutinize the Form and may seek clarification if required
- (b) upon satisfactory scrutiny, the applicant shall pay the fees as specified by the Food Authority for scrutiny of documents, visual inspection, and drawing of the sample
- (c) where a single bill of entry is made up of articles of food consignment consisting of multiple categories of articles of food, inspection fee shall be paid for each category of articles of food
- (d) the Food Authority shall specify and review the inspection fee from time to time
- (e) on receipt of the fees, the Authorised Officer shall intimate the details of date and time of inspection to the Food Importer to facilitate the presence of the Food Importer or his Customs House Agent/Authorised representative at the time and place of inspection.

The Food Importer or his authorised representative shall remain present at the customs area at the appointed time to participate and facilitate visual inspection, assist in drawing of samples, if required, assist in the import clearance proceedings as instructed by the Authorised Officer

or his representative and witness proceeding, sealing of samples by the Authorised Officer or his representative and affix his countersignatures on the sealed samples.

If the Food Importer or his Customs House Agent is not present to facilitate the inspection and sampling in spite of two opportunities having been granted, the Authorised Officer may refuse to grant further opportunity for inspection and sampling of the food consignment : provided that any further opportunity in this behalf may be granted by the CEO or his authorised representative after levy of suitable fee on the Food Importer as may be specified by the Authority from time to time.

The report of the visual inspection shall be submitted in FORM – 1.

CONCLUSION:

The nutraceutical is an emerging business in the world of pharma and the growth of the business in the forthcoming years are huge. In India, Food Safety and Standard Authority of India [FSSAI] is the only single authority to regulate production, distribution, and marketing of nutraceuticals in India. Various Indian companies have entered their place in case of plant extracts and phytochemicals as supplier both locally and globally, which will help in flourishing nutraceuticals sector in near future. Globalization of the nutraceutical and functional food industries present significant challenges to stakeholders, not the least of which is the regulatory variance between countries active in the marketplace. Hence, when any new participant wants to enter the Indian nutraceutical market, it is very important to comply with the regulatory framework, so that the business will run smoothly.

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