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Current Regulatory requirements for Registration of Nutraceuticals in India and USA

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ABSTRACT

There is growing recognition of the potential role for nutraceuticals and dietary supplements in helping to reduce health risks and improve health quality. Pharmaceutical and nutritional companies are aware of the monetary success taking advantage of the nutraceuticals and dietary supplements. Nutraceuticals has proven health benefits and their Consumption will keep disease at bay and allow humans to maintain an overall good health. Functional foods and internationally products represent a value added growth opportunity both domestically and internationally. Development of better characterized and research proven products will help enhance consumer confidence in nutraceutical and functional food products in the world. Regulatory aspects of such products were in a state of confusion in 20th century. Till date the regulations are not harmonized for the globe and change from country to country. But now it is clearly understood that the regulations for clinical evidence and safety of such products cannot be less stringent than rules for modern medicines and thus the science of nutraceutical is progressing. The global nutraceutical market will reach $285.0 billion by **2021** from $**198.7** billion in 2016 at CAGR of **7.5%** from 2016-2021. The present research has been devoted towards better understanding of the nutraceuticals and its regulation in India and USA.

Keywords: Nutraceuticals, dietary supplements, Regulations, Market scenario

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1. Introduction

Plants are one of the most important resources of human foods and medicines. Rapidly increasing knowledge on nutrition, medicine, and plant biotechnology has dramatically changed the concepts about food, health and agriculture, and brought in a revolution on them. By increasing technological uses there is vast increase in the production of various new nutraceutical molecules which are very helpful in promoting the public a healthy lifestyle has a result the use of nutraceutical has become a trend by which the quality life can be maintained, no need of additional therapy of nutrition and vitamins are required after the access of nutraceuticals, these type of nutraceuticals does not only enhance life style by promoting good health but also prevent us from upcoming disease, and it has very less side effects compared to other pharmaceutical product hence a long period of life can also be obtained (1 – 4).

"Let food be thy medicine and medicine be thy food". Referred to the functional food, dietary supplements, these products have been defined as "any food substance that may be considered a food or part of a food and provides medical and health benefits including the prevention and treatment of disease. Perhaps the most descriptive term used to refer to this part food/part dug products is "nutraceuticals". This name was coined by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine, located in Cranford, New Jersey (5).

1.1. Types of Nutraceuticals

Nutraceutical are associated with the treatment or prevention of many diseases as following and they provide treatments in terms of:

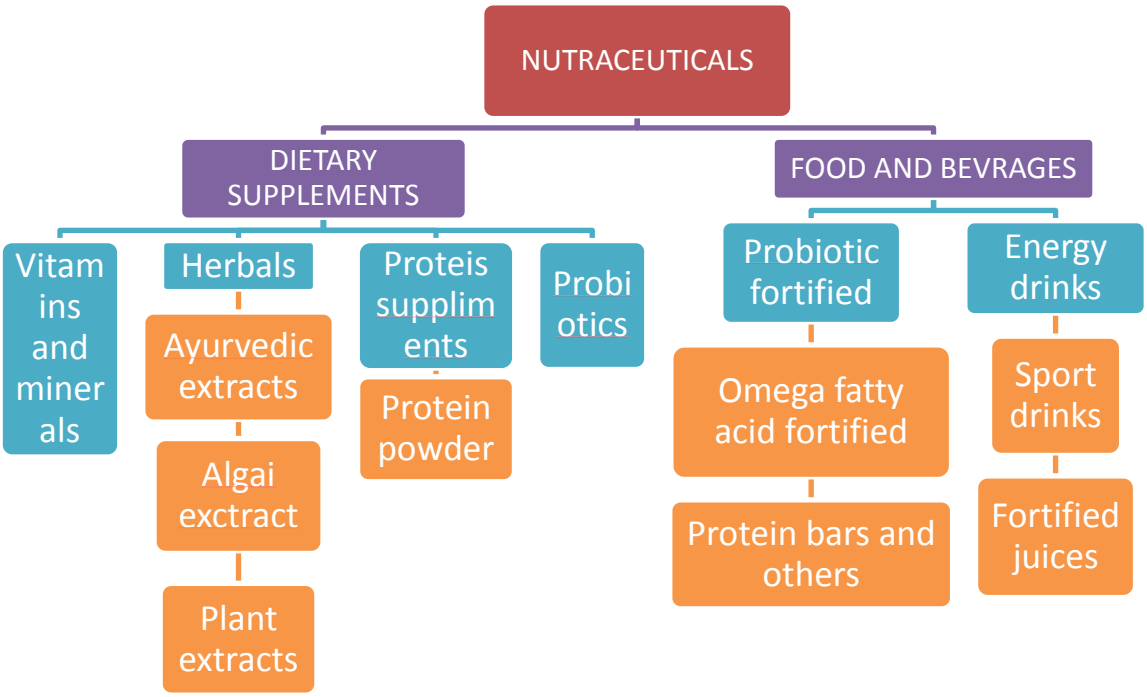
- Anti-diabetic
- Anti-cancer
- Chronic heart disease
- Anti-hypertensive
- Hypertension
- Arthritis

1.2. Based on Chemical Constituents

A. **Nutrients:** Nutrients are substances with established nutritional functions, such asvitamins, minerals, amino acids and fatty acids.
B. **Herbals:** These products also known as botanical products are used as concentrates and extracts.
C. **Dietary Supplement:** These are the products which are administered through mouth which contains a dietary ingredient which can be added to the food in the diet. Some of dietary supplements are in menopausal symptoms black cohosh is used, in memory loss gingko biloba, and for in arthritis glucosamine /chondroitin. Other than this there are some major uses such as weight-loss supplements and meal replacements sports nutrition. Some of such ingrediants may contain vitamins, minerals, herbs or other botanicals, amino acids, enzymes, organ tissues, gland extracts, or other dietary substances. They are available in many dosage forms such as tablets, capsules, liquids, powders, extracts, and concentrates.

1.3. Traditional and Non- Traditional nutraceuticals

Wide variety in category of traditional foods and non traditional foods in name of nutraceuticals are available in market (6–8).



Figue 1. Types of Nutraceuticals (6-8)

1.4. Dietary Supplements

Using some criteria DSHEA has defined dietary supplement as a dietary supplement is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients an herb or other botanical, an amino acid, :a vitamin, a mineral, a these are just the supplements which are added in the diet resulting in this there is just increase in the food intake of a person per day these may be in the form of extracts, liquid concentrates, metabolic constituent or any combination of the dietary components.

- Intended for ingestion in pill, capsule, tablet, or liquid form.
- Not represented for use as a conventional food or as the sole item of a meal or diet.
- Labeled as a "dietary supplement."
- Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval,

- License or its certification obtained from the secretary of health and human services waives this position.

Dietary supplements can also be extracts or concentrates, they are found in many forms such as:

- Tablets
- Capsules
- Soft gels
- Gel caps
- Liquids
- Powders

"DS no need to get approved by the USFDA before marketing. But safety efficacy has been tested by the FDA and there are proper provision foe labeling that is a label claim which assures that this is nit indented to diagnose or cure any disease. High cost of pharmaceuticals drugs like allopathic drugs as resulted in production of nutraceuticals and resulted in increase in global market (8 – 11).

2. Discussion

2.1 Regulation of Nutraceuticals in India

In Indian market Nutraceutical is a new word. Nutraceuticals has a spectacular annual growth rate of there is 25 % annual growth of nutraceuticals in India which is same as Japan.

According to Indian definition of nutraceuticals it must have the listed ingredients and also must have the general given properties. Nutraceuticals do not include traditional foods. Nutraceuticals which contain some important component having therapeutic activity or formulated to satisfy particular dietary requirement.

These are notified in such a way that all the required ingrediants in the food stuffs must differ from the rules of Indian standards presented as such, from the ordinary food stuffs if though there exist any kind of food stuff then it must containg one or more than one of the following composition or ingredients. These has been defined in the following such as:

These include the parts which are obtained in type of liquid extract, dry powder, or extract in the way of ethyl alcohol and hydro alcoholic thee may in the form of combination or singly added from the plants and namely botanicals.

Enzymes which not be more than the limits. Vitamins, minerals, proteins and amino acid or thier components of metals should not exceed more than the limits which has been mentioned in the recommended daily allowance (RDA) for the Indian rules and regulation.

The Substances which has been obtained from animal origin

Or any of the substance which are added as the dietary supplements in the diet which in result increase the intake of diet in the form of food.

2.2. FSSAI

In 2006 parliament passed food safety and security ACT. Then in 2008, FSSAI came into existence. For implementation of FSSAI Act process of prepublication consultation in 2006 has been conducted where various rules and regulation are drafted. So that by the end of September 2010 these drafted regulations will be sent for notifications.

a) As framed in the FSSAI act, 2006 various rules and regulations related to nutraceuticals has been framed.
b) Food obtained from processing of organic production and their standards considering the proprietary and novel food which are not safe but also not mentioned in the act. are also included rather than the Food ingredients composed of or containing obtained through from modern biotechnology the food obtained like, genetically modified or engineered organisms which may also contain the same has also been included in the act.
c) This FSSAI act consists of twenty-one chapters and in that the fourth article that means 22 of the act says about nutraceuticals, dietary supplements and various functional foods, and these products can be produced/manufactured, marketed that means sold or distributed that means imported can be done by any of the company. And these products may include nutraceuticals, dietary supplements, functional food, organic food, unprocessed food, can food, novel foods, irradiated foods.
d) Packaging and labeling of nutraceutical and their claims including restrictions in advertisement about the nutraceuticals has been addressed in the article 23 and 24.
e) This kind of nutraceuticals can be permitted by the regulations made under this Act; which do not claim to cure or mitigate any specific disease, disorder or condition.
f) Rules which are made under the act that's the substances listed in Schedules E and EI of the D&C Rules, 1945; it 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.
g) The FSSAI Authority would also have to come up with the hilarious task of putting in place the various minimum levels of compliance of food laws,
h) Rules and regulation which are made under the new regime by the food safety commissioner of each state will be very difficult to control both the claims as well as the quality and their force role should be expedited.
i) Food ingredients composed of or containing obtained through from modern biotechnology the food obtained like, genetically modified or engineered organisms which may also contain the same has also been included in the act.
j) **"food for special dietary uses"** these kind of labels are meant for functional food or nutraceutical dietary supplements that is not mainly for obtaining as conventional food such products may be formulated in the form:
    - powders,
    - granules,
    - tablets,
    - capsules,
    - liquids,

- jelly and other dosage forms but not parentarals.

k) There may be provisions of various testing and tracing the origin of the food products right back up to farm level are done with the help of drafted guidelines.

- Standardizing the Manufacturing Process, Validation and Intellectual property protection
- It Define the various list of permitted health claims and the required quantity of such ingredients to make the claims.
- Resulting in the formation of a Regulatory Framework and their standards.
- Active involvement of Government and Private Agencies in educating consumers on the benefits of nutraceuticals.
- The industry is waiting for revised RDA levels to make them applicable for Indian population's current lifestyle.
- Recognize list of nutritional ingredients with proven health benefits.
- Increased collaboration among Indian manufacturers on R&D (12).

2.3. Registration and Licensing requirements:

- A manufacturer cannot start his/her business until he/she is registered or is been licensed in a valid manner
- The inspection of premises has been done after the issue of ID number in the way which is ordered by the act of FSSAI by the safety officer.
- Under this regulations the license which is granted shall be valid and subsisting, unless it is not specified, for a period of fifteen years.
- Manufacturers have to register with the state office commissioner and those manufacturers whose turnover is greater than 12 lacks to have to validly get a license from FSSAI office. Even the same goes for petty food manufacturer
- An application for the grant of a license shall be made In form B of schedule 2 a application should be filled so that the licence can be granted. And this license shall be issued within 60 days from the date of issue of application ID number

2.4. Requirements for the entry in India:

In India various nutraceutical related regulations are evolving these has been resulted in chaos and difficulty for manufacturers of nutraceuticals. But though to outline the regulations properly it is very needed to put in force by all the company though if they are feeling it very stringent. As these nutraceuticals are very growing in the Indian market the development and the claims enhancement is very required.

Licenses: The new regulations given by FSSAI promises to simplify the licensing and registration procedure for nutraceuticals, but the areal process differs significantly. To register product in India, various licenses has to needed which depends on actual product status like which requires many documents to report to the government officer by the person who imports they also need to interlink the dossiers of the product with the licensing procedures.

- Import
- License for manufacture
- license for marketing
- Other state and national level clearances/licenses required from the regulatory side, which need to be taken care of before launching these products in India.

Health claims and label claims: It is very required to know the regulatory frames of nutraceuticals which is very different from the other countries. All the health as weel as label claims should be notified and followed very carefully.

Whenever the personnel from different country wants to get their product register they have to follow the norms of Indian regulation. While doing this a foreign person has many chaos and answers for them can be the following points.

- India has its specific packaging as well as labelling requirements
- Packaging also need to show up their components of the consignment along with same need of the sample product to get it packed according to indiam specification.
- Content which has to be included in the claim
- Structure claim
- Following functional claim

India has discovered to maintain their own content of the label claim with various claims. Based on the regulatory assessment of the product, India-specific label content and claims needs to be developed. New entrant should also consider the requirements to be met, to make specific product claims regulations about such products in India.

In India FSSAI ac has been created which consolidates various rules and regulation related to the food are made to come in existence to maintained the standards and qualities by the various departmental ministers.

This FSSAI do not only regulate the process starting from the production till it reaches the consumers but also maintain the quality of the food. Hence the safety of public is been taken care by the departments of the FSSAI.

IT is not only applied to the normal food components but also implies to their nutraceuticals and dietary supplements (13-15).

2.5. Nutraceuticals and Dietary supplement scene in US

Many evidences show that after consuming dietary supplements most of Americans including ladies and mens and even kids are falling sick as these dietary supplements were promising to provide a better and energetic life. These dietary supplements were consumed in the form of juice, snacks, meals, and other supplements. And these has created a storm in the government has it failed to keep

the public health in safe. Resulting to this various regulation were created in the forward years

2.6. The Regulation of Dietary Supplements in US

The U.S. Food and Drug Administration (FDA) is responsible for regulating dietary supplements in US is been regulated by the USFDA through its various centre of food sector .later food and drug cosmetic act regulated or amended a DSHEA that is dietary supplement health education act 1994. And this DSHEA create many standards which a dietary supplement must accomplish.

The safety of the dietary supplements has been taken care by the USFDA but their approval by USFDA is not required.

- Before producing or selling their products. Dietary supplement manufacturers do not need to register with FDA, or obtain FDA approval,
- Prior to marketing a product, manufacturers are responsible for ensuring that a dietary supplement (or a new ingredient) is safe before it is marketed. FDA has the authority to take action against unsafe dietary supplement products.
- Manufacturers must ensure that their product label information is truthful and not misleading.

2.7. Registration of Dietary supplements in US

If the dietary supplements is according to the definition given by the DSHEA then only it can be registered as dietary supplement. The active component should also imply according to the regulation given under 21 CFR 190 which deals with Dietary supplements while registration two things has to be noted that whether it is a Active ingredient or Inactive ingredient.

While carrying out the registration it has to be taken care that whether it is old dietary supplement or new dietary supplement for the purpose of registration. If a DS is marketed before15 October than it is ODI are it after the date then it is New Dietary Ingredient (NDI). CFSAN carry out the pre market surveillance for the safety of the product in the US market related to the products of NDI and all the documents are needed to be submitted to the following address.

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 a ODI or NDI type of dietary supplement.
4. Evidence of safety measures if any
5. Signature of the manufacturer and the distributor (16-18)

2.8. Registration of Dietary supplement in India:

Registration for dietary supplement from the FSSAI authority is mandatory to get entry in the market of India. There are various procedure which is given by the FSSAI to follow to get registered as a dietary supplement in India. Because of the stringent rules and regulation its becoming very difficult for the companies to get approved their dietary supplement. But for the proper public safety it is required to follow all the guidelines and regulation of registration procedures. Various forms like FORM A and FORM B has to be filled and get approved to place their product in the market. Following is the chart of procedure to get the approval:

There are various rules given by the FSSAI tpo be followed for the registration and licensing of food products like nutraceuticals and dietary supplements. They also have given various claims regarding the label and packaging and various standards and their limits of additives are also mentioned. Hence all the standards has to be maintained to get their product approved. Hence there are various departments from the production to distributors.

FSS regulations, 2011, frames that:

a) For the registration form A/B has to be filled for the manufacturing in india according to sch-1

b) If personnel need import license then it has to be issued from the Central Licensing Authority.

Following documents are needed for the approval:

- Form A
- Declaration form which has to be self attested
- Manufacturing/ import license –
- Form B and form C
- Declaration form which has to be self attested
- and the below document copies

Documents to be enclosed with new application for license / import license to State / Central Licensing Authority

- Form-A, Form-B, Form-C
- Layout of the manufacturing unit even blueprint can be submitted. Blueprint/layout plan of the processing unit
- List of Directors
- List of the machines which are used in manufacturing with its name.
- Photo I.D with the proof of address
- List of food category which is to be manufactured.
- Authority letter with name and address of responsible person
- NOC & Copy of License from manufacturer
- Food Safety Management System plan or certificate (if any)
- Source of milk or procurement plan for milk including location of milk collection centres
- Source of raw material

- Pesticide residue report of water
- Recall plan
- Form IX
- Certificate provided by ministry of tourism
- For transporters-supporting documentary proof
- Declaration form (14, 15, 19-22).

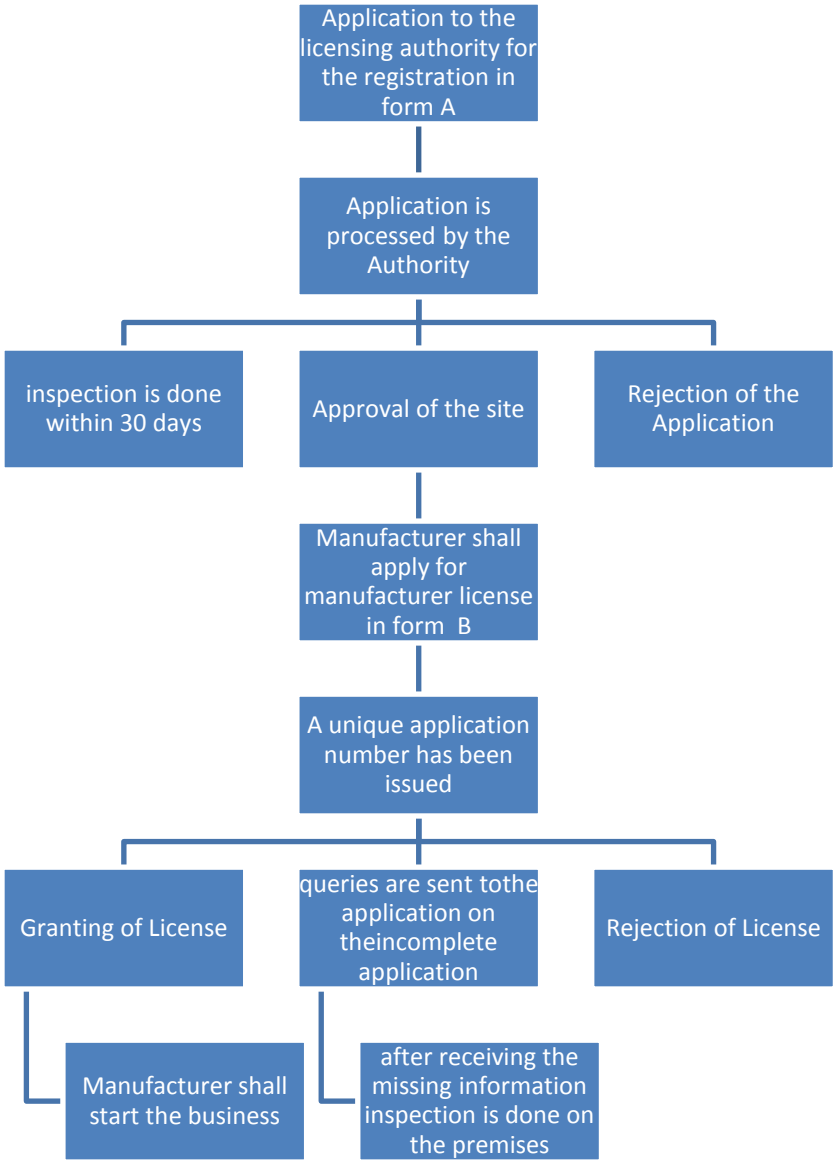


Figure 2. Registration process of nutraceutical in India (14, 15)

2.9. Checklist of registration requirements:

INDIA

1. Form-B Duly completed and signed

2. Layout of the manufacturing unit or it can also be in the form of blueprint.

3. Directors name and their list

4. Equipments and Machinery used in the manufacture's list with their names

5. Photo I.D and with the proof of address

6. The productds which has to be manufactured are listed

7. Authority letter

8. report of analysis

9. Premises owning proof.

10. Affidavit of Proprietorship

11. Copy of certificate obtained under Coop Act – 1861 /Multi State Coop Act - 2002 in case of Cooperatives

12. NOC & Copy of License from manufacturer

13. Food Safety Management System plan or certificate (if any)

14. Source of milk or procurement plan for milk including location of milk collection centres etc. in case of Milk and Milk Products processing

15. Source of raw material

16. Pesticide residue report of water

17. Recall plan

18. Form IX

19. Certificate provided by ministry of tourism

20. For transporters-supporting documentary proof

21. Declaration form

US

The documents required are as follows:

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

Others

(a) The type of the new dietary ingredient present in the dietary supplement with its name should be recorded

(b) Notification receipt made under section 413 that is D&C act will submit the acknowledge

(c) the submission of the new dietary ingrediants must be done for the approval in gazette officer to the given addressed ahich has been mentioned before in the given research work, their labeling should also be according to the regulations.

(d) Manufacturer's signature or the signature of the distrubuter

(e) Manufacturers name with the address proof has to be senrt to the gazette officer fot thee approval of the new dietary ingredient.

(f) Dietary ingredients name with the botanical name need to be submitted.

(g) A dietary supplement which has to be placed in the market should be commenced before seventy five days that it contains a new dietary ingredient that has not been recorded earlier in the article and the chemical ingredient should not be altered (23).

Comparision between India and US (16, 17, 23-25):

Table 1 Comparision between India and US (16, 17, 23-25)

US	INDIA
In USA food and drug administration **(FDA)** regulates nutraceutical under different set of regulation. According **DSHEA** (1994) manufacturer should ensure that nutraceutical is safe before it is marketed.	In India **FSSAI** regulates nutraceutical.
FDA take action against unsafe products but FDA **approval is not required** for registration	FSSAI has been established to maintain standard and safety of food for humans consumption thus it applies to products like dietary supplement and nutraceutical. FSSAI **approval is required**
In USA market share growth is mostly contributed by diertary supplements.	Indian market share growth is not expected to come from dietary supplements. However functional food and beverages are expected to drive growth throughout subcontinent
In United states 80% of agricultural products are processed as nutraceuticals	India is second largest producer of fruits and vegetables but only a small amount of perishable agricultural products are processed (approximately 2%) in comparison to United states.
Dietary supplement: Any food and food ingredients that may provide health benefit beyond the traditional nutrition than it contains.	**Dietary supplement**: A new ingredient has been added to a food and the new product has additional function (often related to often related to health promotion or disease prevention
Products include: products of biotechnology	Products include : herbal extracts spices foods and nutritionally improved foods
United states claims and labeling regulation are more restrictive.	Indian claims and labeling regulation are less restrictive.
Claims implying medicinal and therapeutic functions **are permitted**.	**Not permitted**
Disease risk reduction claims such as SSA claims and qualified claims are permitted	Disease risk reduction claim are prohibited. Structure and functional claims are not prohibited.

3. Conclusion

With the increasing demands of nutraceutical in the global market, the regulations of nutraceuticals are now toughened. Regulations are amended constantly whenever needed. It is very important for the market owners to know the recent regulations of nutraceuticals. And rules which a company should follow to get their product approved.

Different country has different rules and regulation for a company to follow and I have discussed about India and

US. FSSAI in India and DSHEA in US amend various law according to the market need. Various guidelines have been provided which states various norms which should satisfied by the company for the product approval.

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Conflict of interest

The authors declare that there are no conflicts of interest.

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