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Review Article

Insights and Compliance Challenges for Nutraceutical Regulations in the Indian Market

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ABSTRACT

Nutraceuticals, comprising supplements, herbal medicines, vitamins, and minerals, claim therapeutic benefits in addressing disease causes. Coined in 1989, the term denotes compounds promoting health. Projections suggest India's nutraceutical business will reach USD 18 billion by 2025, necessitating robust oversight. Food Safety and Standards Authority of India (FSSAI), established under Food Safety and Standards Act of 2006, governs approvals. This study aimed to collate data on approved, refused, and withdrawn nutraceutical products and ingredients in India from 2020 to 2023. During this period, 58 out of 110 applications, constituting 52.7%, gained approval. Notably, 20 to 40% of applications related to nutraceuticals faced refusal or withdrawal within the preceding four years. Factors contributing to rejections and withdrawals include sorting S-adenosyl-L-methionine (SAmE) as a pharmaceutical compound, non-compliance with recommended dietary intake, potential drug-like properties, misleading labeling, and insufficient evidence of product efficacy. Withdrawals often result from issues like adulteration, substandard ingredients, and non-compliance with good manufacturing practices (GMP) regulations. To surmount these challenges, FSSAI must establish rigorous regulations and guidelines for nutraceutical promotion, including public notifications for any modifications, with a concurrent expectation for industries to adhere to these guidelines in promoting public health. The collaboration of applicants/nutraceutical industry, and FSSAI would foster stable expansion, as evident in India's CAGR for nutraceutical products and ingredients.

INTRODUCTION

Hippocrates is well known for his statement "Let your food be your medicine and your medicine be your food," highlighting the significance of utilizing food to support well-being and recovery. Ancient Indian medicine known as Ayurveda strongly emphasizes the role that diet plays in both health and disease.^[1] Nutraceuticals are foods or dietary components which are said to provide therapeutic or health benefits, such as avoiding disease or alleviating its symptoms by addressing the underlying source of the issue. The term "nutraceuticals" describes goods made from vitamins, minerals, herbal remedies, and different nutritional components internally used for medicinal purposes or to strengthen resistant to disease. The term "nutraceutical," which combines the words "nutrition"

and "pharmaceutical," was coined in 1989 by Dr. Stephen De Felice. Nutraceuticals are specific formulations that are meant to meet needs and support health prevention.^[2] A nutritional supplement is a food item/component claimed to deliver therapeutic or medical assistance, such as illness treatment or avoidance. Nutraceuticals are "natural" pharmaceutical substances that are refined or derived from food. Research has been done on several traditionally grown foods in an attempt to discover natural remedies that can prevent the illnesses.^[3] Dietary substances may also constitute nutraceuticals, such as fish oil with omega-3, which is obtained from cold-water fish such as salmon, or it can be a food that is naturally high in nutrients or has therapeutic qualities, like garlic or soybeans.^[4,5] Trendy nutraceuticals include omega-3 eggs, ginseng, echinacea, folic acid, glucosamine, cod

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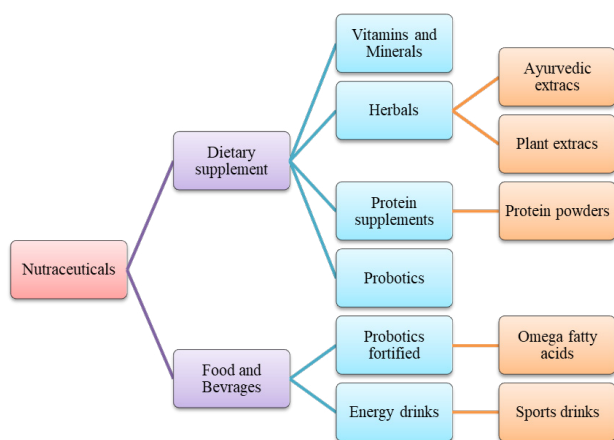


Fig. 1: Classification of nutraceuticals

liver oil, orange juice with calcium added, and green tea, Growol.^[6-8] Nutraceuticals are food-based products with additional health advantages besides their fundamental nutritional value.^[9] They can be categorized according to a number of factors, as illustrated in Fig. 1.

Since most nutraceuticals have several therapeutic effects, much work has been done to decentralize them within the current study according to their primary indication for a particular condition. The illnesses listed below were all connected to nutraceutical benefits (and/or found to act as): (a) cardiovascular agents; (b) anti-obesity agents;^[10] (c) antidiabetics; (d) anticancer agents; (e) immune system boosters;^[11] (f) chronic-inflammatory disorders; and (g) degenerative diseases. Nutraceuticals were suggested to improve the body physiologically or guard against certain illnesses.^[12]

Due to lifestyle choices and insufficient dietary intake, health disorders like obesity, anxiety, depression, coronary artery disease, high blood pressure, diabetes, cancer, and compromised immunity remain on the rise.^[13] To mitigate this, demand from consumers indicates that food will not only satiate their appetite but also protect them from illnesses and maintain their physical and mental well-being. Consumers are suspicious of exaggerated health claims and require clarification over whether to see nutraceuticals as food or medicine due to a lack of knowledge. The development of this sector is impacted by the variations in regulations pertaining to nutraceuticals.^[14,15]

Nevertheless, these hesitations, the world market for supplements and nutraceuticals has expanded rapidly over the last ten years, with estimates for 2019 value approaching \$353 billion USD. The pandemic of coronavirus 2 (SARS-CoV-2) that began in November 2019 and continued towards the completion for the fiscal year caused the use of nutraceuticals and nutritional supplements to increase even more in the early part of 2020. Global nutraceutical demand has surged on account of the COVID-19 pandemic.^[16] Because consumers are now more aware of the growing expense of prescription

drugs, the ineffectiveness of conventional medications, and the increased likelihood of side effects, nutraceuticals are emerging at a rapid pace. The dearth of effective treatments and prevention options for chronic illnesses, the impersonal nature of interactions with healthcare professionals, the need for customized medications, the aging patient population, and the renewed emphasis on preventive medicine have all contributed to the trend toward alternatives to pharmaceuticals.^[17]

India's nutraceutical business, valued at USD 4-5 billion, is expected to lead the world. According to reports and experts, it is anticipated to rise to over USD 18 billion by 2025. According to studies, the dietary supplements market in India is anticipated to arrive at an approximate value worth USD 10,198.57 million by 2026, from USD 3924.44 million in 2020. Based on the information provided the industry is experiencing a growth rate of 22%. Since the acceptance of preventative healthcare and rising consumer awareness, the Indian nutraceutical industry has grown quickly, with a compound annual growth rate (CAGR) of 21% over the previous five years.^[18,19]

Demand for complementary therapies and rising consumer knowledge of traditional substances found in nutraceuticals provide an emerging market to the nutraceutical industry.^[20,21] Consequently, rigorous, and efficient laws are needed to regulate the import, production, distribution, and marketing of nutraceuticals, given the extent of Indian market, which is expected to increase. Under Food Safety and Standards (FSS) Act - 2006, the Indian government formed Food Safety and Standards Authority of India (FSSAI) to ensure sufficient availability of safe and efficient food ingredients. The regulatory system governing foods, functional foods, and dietary supplements started to evolve and advance at fair pace with the founding of the FSSAI. The FSSAI's primary objectives are to supervise food manufacturing, processing, transportation, marketing, and imports while establishing science-based food standards to guarantee that food is safe for human consumption. FSSAI, that was formed under the FSS Act of 2006, is the authority in India that authorizes nutraceuticals. The FSS Rules of 2011 were published in the Indian Gazette on May 5 2011, and entered into effect on August 5, 2011.^[22] According to the regulations known as FSS (Nutraceuticals, Functional Foods, Special Nutritional Use Foods, Medicinal Purpose Foods, and Novel Foods) which were established in 2016, there are health supplements and nutraceutical standards. The eight types of functional foods covered by these laws are: novel foods, prebiotics, probiotics, foods containing plant or botanicals, special dietary use, special medical purposes food.^[23,24]

The investigation's goal was to obtain information regarding the approved, rejected, and withdrawn Nutraceutical products and ingredients in India under the FSSAI regulations over the course of the preceding four years (2020 to 2023).



METHODOLOGY

Through the use of the authorized FSSAI website, a review regarding the products and ingredients authorized by the regulatory body in India between 2020 to 2023 was performed. An investigation has been done on the list of applications under the regulations known as the FSS (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 that are approved, rejected, closed, withdrew, or in another status as of January 4, 2023. With a particular focus on ingredients and items associated with nutraceuticals, the evaluation involves classifying them according to data from the FSSAI's business section's Food Safety Compliance System (FoSCoS). The information acquired made it possible to determine India's percentage of nutraceutical applications. Subsequently, a thorough evaluation of accepted, denied, and withdrew applications was carried out for comparative purposes.^[25,26]

Registration Process

To enter the Indian market, one must register as a nutraceuticals with the FSSAI authority. The Food and Safety Authority of India (FSSAI) has several procedures to be followed to register as a dietary supplement in India. The stringent regulations and laws are making it increasingly challenging for businesses to get their nutritional supplements certified. However, adherence to all rules and regulations pertaining to registration

procedures is necessary for the appropriate protection of public safety. To put their products on the market, they must fill out and get approved a number of forms, such as FORM A and FORM B. The examination of an application typically takes seven days from the date of receipt. Fig. (2) describes the specific steps associated with registering nutraceuticals in India.^[27]

Statistical Findings and Discussion

Initial reports indicate that the FSSAI had received 110 applications regarding authorization of nutraceutical products and ingredients during 2020 to 2023. These applications are divided in to three categories according to the specifics of approval: products and ingredients that were accepted, refused, and withdrawn.

The percentage of applications that the FSSAI or the applicant authorized, denied, or withdrew between 2020 and 2023 is represented in Table 1. Over the course of these four years, 58 applications or 52.7% of the 110 applications, received approval. Of the 110 applications, 20 to 40% pertaining to nutraceutical products and ingredients turned out to be amid the applications that were refused and withdrawn within the preceding four years (Table 1). Fig. 3 gives specific information about the proportion of applications throughout India were subsequently accepted, refused, and withdrawn from 2020 to 2023.

Table 2 shows detailed information regarding the number and percentage of applications submitted for approval to

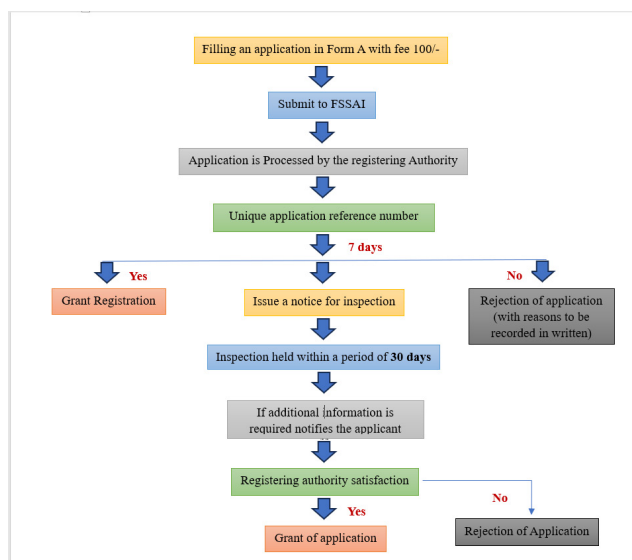


Fig. 2: Registration process of nutraceuticals in India

Table 1: Applications for nutraceutical products and ingredients

	All	Approved	Rejected	Withdrawn
Total (n)	110	58	38	14
Percentage (%)	110	52.7	34.5	21.7

n – number of applications, % - percentage of applications.

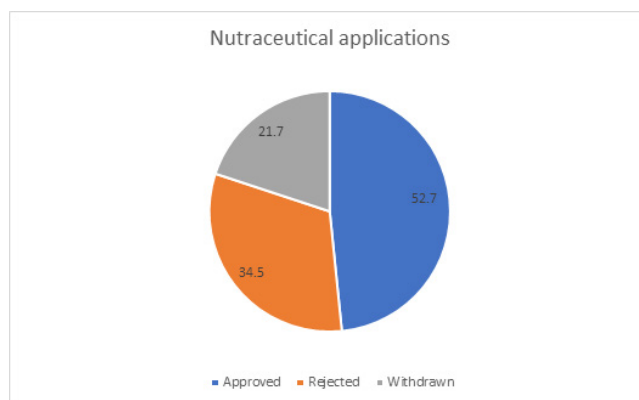


Fig. 3: Applications for nutraceutical products and ingredients (2020-2023)

Table 2: Percentages of applications that were regulated during the years 2020 to 2023

Types	Total 2020		2021		2022		2023	
	n	%	n	%	n	%	n	%
All applications	110	15	34	30.9	37	33.6	24	21.8
Approved	58	8	17	29.3	20	34.4	13	22.4
Rejected	38	6	11	28.9	10	26.3	11	28.9
Withdrawn	14	1	6	42.8	7	50	0	0

n – number of applications, % - percentage of applications.

the FSSAI related to nutraceutical products and ingredients from 2020 to 2023. Out of 110 applications, 15 applications were submitted in 2020, in which only 8 (14%) applications were approved, and percentage of applications that were rejected and withdrawn in the year 2020 were observed to be 6 (16%), and 1 (7%) (see Table 2). The quantity of applications filed in the following years was determined to have considerably increased in comparison to the amount filed in 2020, i.e., the percentage of applications submitted in the year 2021 to 2023 were 17 (29%), 20 (35%), and 13 (22%). Figs 4-7 shows the percentage of all the applications that were approved, rejected, and withdrawn within the span of four years (2020–2023).

Since 2016, the Indian nutraceutical industry has experienced significant transformation, and the market has steadily expanded. Consumption of nutritional supplements and nutraceuticals increased considerably more in the initial months of 2020 as a consequence for the SARS-CoV-2 pandemic that began in November 2019. Amidst the catastrophic worldwide pandemic, people looked for supplementary safeguards against viral infections and illnesses, believing that ingesting supplement products would have positive impacts on health or “immune-boosting” properties. The demand for supplements and nutraceuticals has shown strong growth tendencies, but such trends are unlikely to last. This devastating Covid-19 pandemic wave is predicted to significantly impact the nutraceuticals business in India, which is anticipated to increase at an estimated CAGR of up to 35%, from \$4 billion in 2019 to \$18 billion in 2025. Nutraceuticals are becoming essential in today’s world for managing certain health conditions as well as general well-being. This condition has allowed nutraceutical firms to better serve consumers by offering more accessible, high-quality, and customized supplements and nutrition to meet their unique needs. Nevertheless, there are further concerns about the industry’s regulatory control in terms of effectiveness, safety, and consumer exploitation, all of which have an immense impact on the well-being of consumers.^[28]

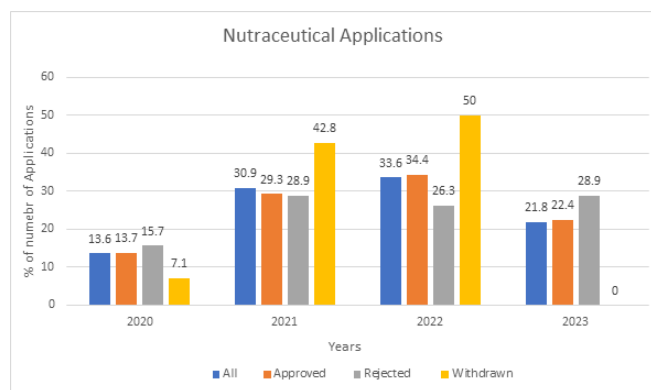


Fig. 4: Percentage of applications regulated by FSSAI during 2020-2023

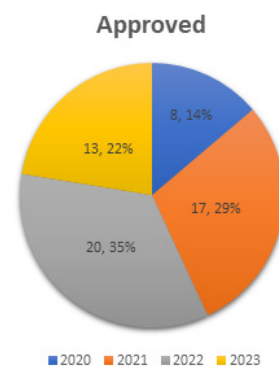


Fig. 5: Percentage of approved products and ingredients during 2020-2023

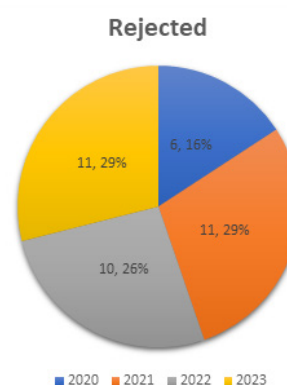


Fig. 6: Percentage of rejected products and ingredients during 2020-2023

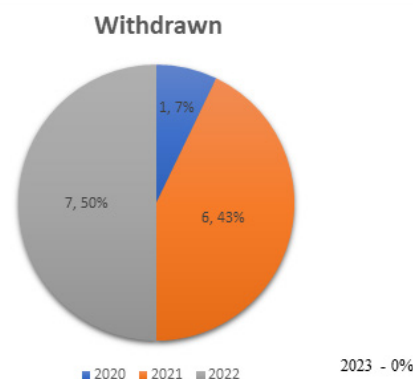


Fig. 7: Percentage of withdrawn products and Ingredients during 2020-2023

The current report presents a thorough overview of the issues concerning the FSSAI’s oversight of India’s nutraceutical rules, outlining which ingredients and products are permitted, rejected, and removed from sale between 2020 and 2023. 52.7% of the authorized nutraceutical applications submitted for marketing in India between 2020 and 2023 are shown statistically



by the FSSAI, whereas the percentage of applications that had been withdrawn and refused within that same period were found to be between 20 and 35%. The statistical evaluation was presented *via* Fig. 3 and Table 1. A number of considerations were noted through a variety of sources in relation to the FSSAI's and applicant's refusal and withdrawal of nutraceuticals. The use of an ingredient known as S-adenosyl-L-methionine (SAME), reiterated as a pharmaceutical compound, serves as one of the most prevalent explanations for FSSAI to reject applications for nutraceutical products. The industry's reluctance to consider doses that have been mentioned as being higher than recommended dietary intake, exhibiting drug-like properties, misleading labelling, and advertising, and due to the absence of sufficient evidence to support a product's efficacy were other common reasons for application rejection. Factors for withdrawal were observed to be associated with adulteration, use of substandard ingredients, and non-compliance with good manufacturing practices (GMP) regulations.

To overcome these challenges, the FSSAI must establish more rigorous rules and guidelines for marketing of nutraceutical supplements in India. Additionally, it must notify the public through official gazette notification of any changes pertaining to the prohibition or removal of particular ingredients. According to the CAGR % for nutraceutical products and ingredients indicated above, the applicants or nutraceutical industry and FSSAI collectively contributed to a steady growth that characterizes the nutraceutical market in India. In order to conduct this study, data from the official FSSAI webpage was evaluated. This article relies on what the FSSAI has published in the given list since it cannot access the complete data. As a result, this evaluation might not accurately reflect the statistical analysis on the total number of nutraceutical applications that the FSSAI in India granted, refused, or withdrawn.

CONCLUSION

In conclusion, there is a lot of room for expansion in India's nutraceutical sector, which is expected to become the world's largest. Based on application acceptance and rejection statistics, the FSSAI contributes to a critical regulatory role in this rapidly growing business. While FSSAI has approved a substantial percentage of applications, concerns linger regarding the effectiveness, safety, and consumer protection within the industry. Addressing these challenges is imperative to ensure the consumers well-being and consistent expansion of India's nutraceutical market. Therefore, it is recommended that FSSAI fortify its regulatory framework, introducing more comprehensive rules and guidelines for marketing nutraceutical supplements. Transparent communication of any regulatory changes through official notifications will further enhance consumer awareness and confidence

in the nutraceutical products available in the market. By doing so, India can better harness the potential of its nutraceutical sector, fostering a healthier and more robust industry landscape.

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