



Marketing and Regulatory Issues for Functional Foods and Nutraceuticals

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ARTICLE INFO

Keywords: Functional Foods, Natural Health Products, Conjugated Linoleic Acid, Health Canada, Foods and Drug Act, and Regulations

Received : 7 June

Revised : 19 June

Accepted : 20 July

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ABSTRACT

Functional foods and nutraceuticals have gained substantial attention in recent years due to their potential to offer health benefits beyond basic nutrition. These products bridge the gap between food and pharmaceuticals, offering an appealing solution for health-conscious consumers. However, the marketing of functional foods and nutraceuticals is not without its challenges. One primary concern is regulatory compliance. These products often straddle the line between food and medicine, making it crucial to navigate complex regulatory requirements. Marketing claims, such as "heart-healthy" or "immunity-boosting," need to be substantiated by scientific evidence, and companies must ensure compliance with regional food and drug regulations to avoid legal repercussions. Consumer skepticism is another issue. Although functional foods and nutraceuticals are designed to improve health, consumers remain cautious about their effectiveness and safety. Overcoming this skepticism necessitates transparent and credible communication, backed by well-designed clinical studies and endorsements from healthcare professionals. Competitive differentiation is a constant challenge. The market is flooded with similar products, making it challenging to stand out. Companies must invest in branding, innovative product development, and unique marketing strategies to distinguish themselves from the competition. Price sensitivity is a critical factor. Functional foods and nutraceuticals tend to be more expensive than regular foods, which can deter price-conscious consumers. Marketing should focus on the long-term health benefits and value proposition to justify the premium pricing. Distribution and accessibility can be problematic. Functional foods and nutraceuticals are not always readily available in all regions, limiting market reach. Expansion strategies and partnerships with retailers are crucial to ensuring widespread accessibility. Educating both consumers and healthcare professionals is essential

INTRODUCTION

During the 1990s functional foods and nutraceuticals emerged as the dominant trend for the food industry, both in the U.S. and internationally. The concept of foods that could provide health-enhancing and disease-preventing properties was embraced by a growing number of consumers, increasingly documented by nutritionists and scientists, and legally endorsed by public policy and legislative mandates for food and dietary supplement labeling. These developments spawned considerable corporate attention across several industries, from agriculture biotechnology, and life science-based concerns that grow and develop raw commodities to nutritional, food, and pharmaceutical manufacturers that design new products. Bringing these newly developed and newly positioned products to the consumer was the challenge and the value-added opportunity pursued by these industries. Whereas consumer interest in the category continued to grow, 1999 emerged as a year with strong market gains for foods using Nutrition Labeling and Education Act (NLEA)-approved health claims and nutrient content claims as part of their marketing message. Product successes of note included the volume gains reported by Quaker Oats in its third-quarter financial report featuring 7% gains for oatmeal for the summer quarter, a traditional down-period for hot cereal consumption. Ready-to-eat cereals increased by 5% in volume for the period. General Mills, in its mid-year report, highlighted 13% volume gains for Cheerios, using the oat bran and then the whole-grain health claim. Other General Mills whole-grain cereals received similar double-digit volume gains in a food category dependent on population increase (0.6%) for category growth. Campbell Soup The company reported impressive success with its V8 Splash line, rich in antioxidants, which exceeded expected market growth and surpassed its category parent V8 vegetable juice

Evolution of a Marketing Environment for Functional Foods and Nutraceuticals

Early in the new decade the Office of Dietary Supplements at the National Institutes of Health (NIH) and the U.S. Department of Agriculture (USDA) funded a variety of research projects and established numerous university research centers to address the science needed for U.S. Food and Drug Administration (FDA) reviews and approval of health claims on food labels. The advances in scientific documentation coincided with legal challenges to the regulatory structure and science criteria. Prompted by case law, the FDA went through a series of positions to establish criteria for review and approval of "Qualified Health Claims" on food labels. At mid-decade, the process is still evolving.

From the 1970s onwards, food has taken on major connotations of being "good for you" or "bad for you," the latter types of foods, such as saturated fats and sodium, to be avoided or ingested in moderation. The good-for-you foods increasingly include foods and food components shown to lower the risk of cancer, heart disease, and other chronic diseases of aging. Since then, numerous

studies and research reports have been published documenting the association between diet and health. In response, public health goals were reoriented from the prevention of diseases associated with nutritional deficiencies to an emphasis on nutrition for decreasing risks for chronic disease. Early attention focused on preventing, among others, coronary heart disease, stroke, high blood pressure, cancer, diabetes, obesity, osteoporosis, dental diseases, and diverticulum disease, as pursued in the Surgeon General's landmark document on nutrition and health published in 1988. During the first Bush administration, two major initiatives dominated consumer nutrition policy.

The FDA, acting under Congress's directive, wrote new regulations governing health claims on food labels. The Nutrition Labeling and Education Act (NLEA) of 1990 was implemented in 1993. With the assumption that the food label is a primary nutrition education vehicle for the consumer, the NLEA carefully restricted what can be claimed on the label as well as what nutritional information must be disclosed.

The second parallel consumer nutrition education thrust involved the redefinition and reissue of the USDA Five Food Groups from 1979 as the initially controversial Food Guide Pyramid was released in 1992. The new Food Guide Pyramid recommended the number of servings for six food groups. This initiative was refined and reintroduced in 2005 as My Pyramid. In this environment emphasizing the role of diet in preventing disease and in promoting good health, a marketing, consumer, and regulatory crisis began to surface. A market for products with food components that prevent disease and prolong good health was created by consumer interest and education in such products. This was accompanied by publicized technological advances and scientific studies isolating food components such as antioxidants and carotenoids whose presence in food delivers these prophylactic benefits. These products are referred to by many terms such as nutraceuticals, functional foods, designer foods, and other labels from the corporate and scientific community. Interested consumers seek and respond to marketing claims that identify and elaborate on these components. Such claims, particularly as presented on the product label, created a growing dilemma for the FDA in the mid-and late-1980s

Regulatory Background

Since 1973, FDA regulations have stated that a food whose label represents that the food is adequate or effective in "preventing, curing, alleviating or curing any disease or symptom" is considered "mislabelled". These regulations were amended in 1993 to exempt FDA-approved health claims (21 C.F.R. 101.9(i)(1) (1992 ed.; re-codified and expanded in new NLEA regulations on 21C.F.R. 101.9(k)(1), 58 Fed. Regis. 2533, 23 January 1993).

Appearance of Permissive Health Claims on Food Products

Contrary to the strict pre-1993 provisions, in the mid-1980s the FDA pursued a policy of selective non enforcement, permitting an acceleration of explicit health-related and disease-related claims on food products that the FDA felt were justified and benefited public health. The frequently cited "watershed" was the 1984 promotion of All Bran cereal by Kellogg's Company with labels that explicitly claimed preventive benefits of fiber concerning cancer: "... eating the

right foods may reduce your risk of some kinds of cancer ... eat high fiber foods ... bran cereals are one of the best sources of fiber.

This promotion was jointly conducted with the National Cancer Institute (NCI) which, in the 1980s and 1990s, was ahead of other government agencies in promoting to the consumer the use of diet and, specifically, foods rich in certain nutrient properties. The NCI launched the well-publicized Designer Foods Program specifically to address and document the role of these phytochemicals in cancer prevention

Other permitted claims in the late 1980s included claims concerning lowered blood serum cholesterol and the reduced risk of chronic heart disease for oat-based breakfast cereals and other products containing oat bran; claims that calcium helps reduce the risk of osteoporosis promoted on dairy products and dietary supplements; and vegetable oil products posting a variety of claims from “cholesterol-free” to “better for your heart than ... ” to specific claims regarding “lower blood serum cholesterol” and “reduced risk of chronic heart disease.” By 1990, it was reported that “... 40 percent of all new food products introduced in the first half of 1989 bore general and specific health claims.”{16} Besides the exploding number and variety of health claims promoted by food marketers – which the FDA chose to ignore, thereby informally condoning them – the FDA also officially exempted several food categories from drug status and accountability while permitting explicit health and disease-related labeling claims. These food product categories included “medical foods,” hypoallergenic” foods, diabetic foods, sugarless foods that “will not promote tooth decay,” and foods that are qualified for special dietary uses (21 C.F.R.).

Reaction and Institution of the Nlea

The incipient loss of control by the FDA with its official and unofficial exemptions encouraged a flood of health claims from entrepreneurial marketers and created a consumer marketplace rife with confusion and skepticism. Adding to the loss of control and embarrassment on the FDA level was the ambitious behavior of several state attorney generals who very publicly invoked their authority in this arena, on behalf of consumer protection, opposing fraudulent and misleading food labeling claims and seizing the products. An early attempt to regulate this type of imitative and ambitious marketing behavior was an FDA proposal in 1987. This set of permissive guidelines never took effect and ultimately was replaced by the restrictive 1990 NLEA proposals. The strict separation of the definition of food and drug returned. A food product could make a health- or disease-related claim “only if (FDA) determines, based on the totality of publicly available scientific evidence (including the evidence from well-designed studies ...) that there is a significant scientific agreement, among experts ... that the claim is supported by such evidence” (21 U.S.C. 343(r)(3)(B)). Though the overall regulations were quite stringent, more restrictive, more inclusive, and set high standards for qualification, the FDA did address and rule on ten claims that the agency examined for authorization. The authorized claims were approved for use as generic health claims on foods that qualified.

The implementation of the NLEA in 1993 quickly prompted concerns about ambitious enforcement from the FDA. In hindsight, two results are easily documented. The industry's adherence to the new legislation dramatically reduced the number of claims used in food product advertising (Figure 1). The concerns of the dietary supplement industry that the FDA would aggressively apply the new regulations to their growing industry prompted separate legislation in the area. The quick and unanticipated passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994 created a separate set of label criteria for the ancillary dietary supplement industry that was distinct from the regulations required on food labels. It also created a separate and distinct regulatory category for dietary supplements with separate marketing standards for label claims and advertising statements

Utilization of the FDA Modernization ACT to Establish Health Claims

The regulated market for health claims on foods and claims on dietary supplements continued to evolve in the late 1990s as claims were approved and challenged, and as various legal precedents occurred in this area. The Food and Drug Modernization Act (FDAMA) of 1997 permitted the consideration of authoritative statements as a source for health claims on foods. This led to the approval of the whole-grain health claim addressing the risk of heart disease and cancer, as cited in a National Academy of Science report on diet and health. This report also sourced the potassium and risk of high blood pressure and stroke claim.

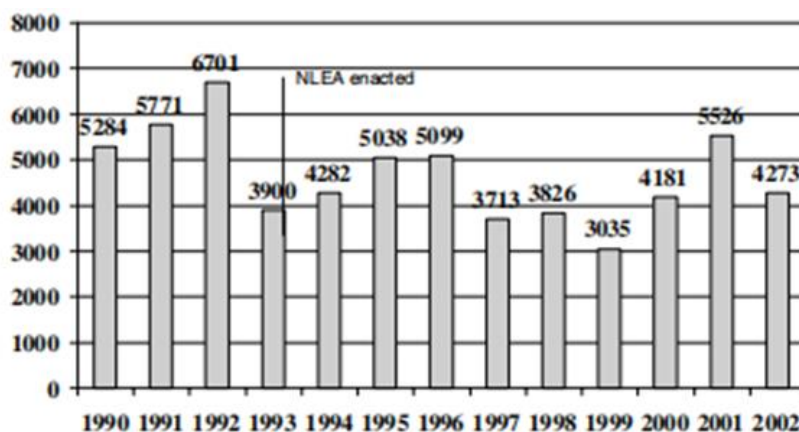


Figure .1 Use of Nutrition Messages on Food Labels 1990–2003: Nutrient Content Structure/Function - Health Claim

Pursuit of Qualified Health Claims for Food Products

Legal developments during 1999 triggered a significant revamping of FDA claim regulation, which is still evolving at mid-decade. The new qualified health claim criteria are still under review and expand the possibility that manufacturers may be able to bring more “emerging” science to the label as they present their data in unbiased terms. The qualified health claim format permits discussion of a nutrient–disease connection in qualified terms, depending on the FDA’s assessment of the strength of the relationship based on the presented dossier of research. This is a complex and lengthy assessment that includes multiple considerations. These include the number of studies.

Issues and Implications for Investment

An applicant has two key concerns when approaching the FDA regulatory environment in pursuit of claim approval. These are the amount of documentation and time required for approval, the type of claim, and the structure of the communications message permitted. For a health claim to be approved on a food product, the claim must be submitted to the FDA with scientific documentation. All materials enter the public domain. After a lengthy review and public comment, the claim study type, and size, the strength of study findings, relevancy of the studies to the intended claim statement and target population, and consistency of findings across studies, may receive generic approval for use by all products that meet the qualification of the claim. It remains a concern for the existing qualified health claim protocol that the time necessary for review and approval, the presentation of data in the public domain, and the generic availability of the resulting claim will deter private investment in documenting and developing products with functional advantages for health. Private sector situations that benefit under the existing generic claim protocol include agricultural co-ops and ingredient suppliers who can either patent or brand their functional ingredients in a way that grants them some advantage to provide a return on their investment in research to document the functional ingredient.

Future Issues: Nutrigenomics and Food Nanotechnology

The development and commercialization of next-generation functional foods and nutraceuticals will be influenced by the fields of genomics and nanotechnology. There is a growing understanding that certain food components activate genetic-based responses in body cells and that these responses vary on an individual level. With broader access to DNA typing and gene testing, it is expected that individually customized diets can be prescribed to prevent disease when susceptibility is identified on an individual cellular level. Called nutrigenomics, this nascent field holds promise for customized preventive healthcare. Nanotechnology application in food delivery also promises a high-tech patentable research field that can enhance and deliver functional benefits in food forms through micro encapsulation and nano processing, among other applications. Difficulties in extracting, standardizing, and delivering benefits in the botanical arena may be ameliorated through advances in food nanotechnology. Both fields are aggressively pursuing intellectual property protection, though policymakers are uncertain how to regulate these processes and products. There also is preliminary debate on whether proprietary discovery will impede new product development and dissemination of healthier foods on the widest level in the future.

Good Taste is Necessary

Most successful new food products in the late 1990s demonstrated three criteria: taste, convenience, and nutritional advantage. The taste remains paramount of the three and is the dictating factor for repeat purchases. Although nutrition or convenience may generate trial purchases, neither will sustain repeat purchases without good taste. Not only should nutraceutical products provide good taste, but they must also promise good taste in their advertising and

reinforce the consumer's curiosity for good taste. This is critically important for new products without the benefit of familiar brand heritage.

Brand Name Connects to Functional Advantage

The brand name of the product should connect to the health benefit of the product and offer insight into the unique functional value of the food, as well as not connote a taste concern. An exception would be a preexisting product like oatmeal re-positioned for its functional health value, where the preexisting brand equity is retained. The early psyllium cereals demonstrated the communication strength of the more straightforward Heart wise brand offered by Kellogg's vs. the more vague implications of General Mill's Benefit brand moniker. Again, the Nabisco Brand Nutra Joint product communicated with consumers but the recent Kellogg's psyllium line Ensemble did not equate the beneficial purpose of the product. Tropicana has succeeded in communicating its functional orange juice line, first under the banner Pure Premium Plus and later Essentials, with the identification of the specific functional ingredient(s) and purpose. This was dramatically successful with their Healthy Kid's introduction is based on a nutrient bundle adding health benefits specific to children's nutrition needs and dietary deficiencies.

Consumer Education Required

The more specific the nutrient and its benefit, the more consumer education on the disease state and health condition that is needed. Cardiovascular disease, cancer, and osteoporosis seem to be reasonably well-communicated health concerns, but many of the more specific health issues are not. Complementary, the consumers have varying levels of understanding of the benefits of the nutrients. Popular antioxidant vitamins are readily accepted for their health value, whereas newer antioxidants such as lycopene and xanthan are less familiar and not readily identified with the health condition they sustain. Levels of consumer education appear to follow public health campaigns, and to the degree that approved health claims receive rapid exposure in the commercial and public health media, consumers quickly appreciate new nutrient benefits.

Avoid Information Overload

Consumers do not easily process complex quantitative information about nutritional benefits and do not readily understand comparative mathematical relationships as validation of nutritional benefits. While this information may be provided on a product's label and in marketing materials, it should not be essential to positioning and advertising the product. This information is useful to medical audiences and informed consumers, and its presence adds value to these purposes.

Competitive Set Determined by Health Issue

One of the most common core marketing errors encountered with Functional Foods and Nutraceuticals is the tendency to target the product category competitive group rather than the alternative competitive group defined by a health condition. Cholesterol-lowering foods, whether oats, soy, or stanol ester lubricants, directly compete with ethical drugs for this purpose and elicit a strong competitive response from the pharmaceutical industry. These defensive responses are intended for consumers and the medical community.

Food manufacturers rarely anticipated this out-of-category or even out-of-sector rally. Floor

Importance of Nonverbal Messages

The Importance of Non-Verbal Messages The use of non-verbal messages is an important method of conveying taste, quality assurance, and function. By displaying active and satisfied users, the functionality of the product can be suggested in different ways. The taste guarantee is communicated to satisfied users who like the product. Non-verbal information may also be used to represent target market consumers, and product quality, and lend a "natural" aura to a product through fields, growing plants, botanical graphics, or other imagery reassuring.

Usage Occasion

Seeing satisfied users and products consumed within a use case is reassuring and provides context for consumers. The occasion of use is an important factor as it advises the consumer on ways to incorporate the product into their daily life so that dosage requirements are met. It also suggests the possibility of product substitution, increasing the likelihood of product adoption.

Avoiding Negative Publicity

Advertising that emphasizes fear of disease and messages that address the loss of health have not resonated with consumers so far. Consumers are hesitant to avoid information and prefer and accept "more" and "better" information and general promises of good health. Functional Foods is a great source of information on which products are "better" and "good for you", and is easily positioned to highlight these positive benefits. This approach to good health is also less demanding on the regulatory structure

Niche Markets

Almost by definition, as bioactive ingredients are better understood, they are promoted for specific use by specific populations and represent niche market opportunities. As the category matures, competition increases, and the medical community becomes more interested in products, the niche market specificity will become more important. These specifics are necessary to communicate product differentiation, superiority, and credibility.

Exploit Corporate Heritage

Many food and pharmaceutical companies hold enviable brand equity positions, such as Quaker Oats Oatmeal mentioned earlier and enjoys corporate images of trust and expertise with the consumer. McNeil Consumer Health holds such trust with the consumer as does Kellogg's with its healthy fiber cereal dominance. Kellogg's Heartwise cereal was able to secure ready consumer acceptance as a high-fiber cereal because of Kellogg's heritage in the category. For General Mills' Cheerios brand and Tropicana's Pure Premium Plus and Essentials line, the existing equity of taste and quality were powerful foundations for their transformations to functional food positionings. The existence of a product line or portfolio allows the nutrition message and health claim to be directed at one product in the line, but the health "halo" covers the entire line, even the items that are sugar-frosted, marketed to children, or otherwise inappropriately positioned to be consonant with targeted health claim marketing.

Dosage and Standardization

As the category for functional foods continues to mature, the regulatory environment, the educated consumer, and the medical community will be asking for levels of bioactive presence to fulfill efficacious dosage levels. Standardized products will be an important factor in assessing product quality, and perhaps meeting required product certification in the future.

Packaging

The use of individual-serve packaging suggests dosage and the delivery of multi-packs in sleeves can suggest and monitor weekly usage. Individual service also offers the opportunity to market the product in multiple outlets including vending, convenience store, and food service formats, which are popular functional food channels in Japan and Europe. Individual serve packaging is particularly popular with beverage and bar product forms. For products to convey functionality, they are better presented in smaller portions. They are not meant to be refreshing beverages or meal substitutes. Lower caloric content also increases the likelihood that the products can be incorporated into a daily diet without a major impact on preexisting dietary habits.

Potential Product Positioning

Consumers interested in functional foods and nutraceuticals have four categories of product functions that are desired. These are therapy, prevention, performance, and particularly in the U.S., weight loss. The therapy, prevention, and performance categories have varying foci, depending on the respondent's sex and age. Consumer studies repeatedly indicate there are segments in the population that have attitudes and lifestyles more consonant with the concept of healthy foods. Typically, consumer research can segment about 40 million consumers who are "health active," meaning they act today to ensure good health when older, are concerned about family nutrition, regularly eat fruit, accept medications, and exercise twice a week. In addition, research recognizes a somewhat similar group of consumers titled "health aware," who are like the former "active" group except they do not exercise twice a week. This group, also comprising consumers over age 18, is estimated to include 13 million consumers. These are sizable consumer markets. Of notable interest is that these "health active" and "health aware" consumers also differ from the remaining "health uninvolved" population of 137 million people by their advanced interest in the continuum of food-nutrition-health. They are far more likely to have moved farther along the continuum to food-nutrition-health-wellness-well-being. Their concept of health has a totality about it that is likely to encompass community, self-enhancement, religion, personalization, rituals, and the environment. These factors can be addressed as physical, emotional, spiritual, social, and financial dimensions. Not surprisingly, people who are willing to believe what they do and eat today may potentially impact their health far in the future have some distinguishing beliefs that can become the foundation for functional food positioning, advertising messages, promotional opportunities, and product ingredients.

LITERATURE RIVIEW

Physical Components

Functional food and nutraceutical positionings, regardless of product function or product form, exist along each of the five dimensions identified in the following sections. The physical dimension is the most obvious and is clustered around attention to nutrition, exercise, and medicine. Functional foods can be positioned along a continuum of nutrition to medicine depending on their scientific credibility and purpose for therapy, prevention, or performance. Any products that complement or enhance the health benefits of physical exercise offer strong positioning opportunities.

Emotional Components

The emotional component involves the need for nurturing, self-knowledge, and stress management. Functional food and nutraceutical positioning are compatible with a need for nurturing one's health as well as that of one's family. The woman's proclivity for functional food products encourages her, as a primary shopper, to respond to a position that nurtures and protects her family. This consumer's interest in self-knowledge, which will include genome vulnerabilities and environmental exposure, as well as the individual's need for stress management, will heighten consumer interest in products, particularly customized products that address these concerns. Self-knowledge and customized/personalized/individualized products offer a potentially powerful match. Test kits and other measurements and "surrogate markers" or biomarkers (such as cholesterol for cardiovascular disease) become valuable vehicles for recognizing individual needs for protection, restoration or enhancement of performance, and recovery. These vehicles will document the need for a specific disease-associated functional food, and thereby encourage its use.

Well-Being Components

The consumer's dimension of well-being, or spirituality, encompasses meditation, prayer, energy, and nature. The two latter components directly relate to the performance purpose of functional foods (energy) and the desirability of natural ingredients for such products (nature). The term natural takes on many dimensions of purity from the desirable organic stricture to being naturally sourced, or simply being plant-derived rather than a laboratory-sourced synthetic substitute. Consumers' first preference, by a wide margin, is to obtain nutraceutical substances through the consumption of fruits and vegetables. This underscores their desire for familiar and natural sources of these active ingredients. Natural connotations can be conjured from the product name, label graphics, and advertising setting. In Japan, where the culture harmonizes rather than separates food and health, FOSHU (Foods for Specified Health Use) products are required to be of natural origin.

Social Components

The social component includes three factors of large and familiar promise for functional food positioning. These are family, community, and philanthropy. The first two provide reasons as well as occasions for functional food consumption. So long as nutraceuticals remain a functional food – an edible or drinkable product – they have the potential to be a part of the most social and routine parts of our lives, namely, daily sustenance. The philanthropy connection

is an important insight for marketers as it indicates that relationship marketing should be a powerful tool. Tying products in with preexisting disease foundations and fund-raisers, such as the breast cancer annual "Run for the Cure" event, should carry strong credibility to these consumers. Foundation endorsements, seals of approval, and spokespeople offer potential marketing and positioning tactics. Many may offer opportunities for exclusivity, which could become a powerful product point of differentiation in an arena of generic claims.

Financial Components

The fifth dimension is financial, and its clusters into four drivers: concerns and preparations for comfort, retirement, maintaining independence from one's children, and for contingency planning. Though obviously, no functional food is a financial investment instrument, brand positionings, nonverbal advertising messages, and promotions that focus on the enjoyment and attainment of these goals give a credible context and purpose for preventive functional food products.

This is evident in the advertising campaigns for Quaker Oats Oatmeal using the health claim language in a venue of active seniors enjoying breakfast on the golf course; Tropicana Pure Premium Plus presenting active seniors hiking under the headline, "Leave the Grand kids in the Dust" inclusion of the health claim; and in Ensures active senior advertising. Ensures campaigns have focused on two of the above elements: elder parent and grown child enjoying the product together and toasting "to our health," and implicit independence. More recently, a campaign for active seniors was introduced, again emphasizing the comfort and fun opportunities offered by healthy retirement.

METHODOLOGY

This study combines a comprehensive literature review of existing research on marketing and regulatory issues in the functional foods and nutraceuticals industry. Data were collected from various sources, including government reports, academic articles, and industry publications.

Marketing Issues:

Functional foods and nutraceutical companies often grapple with intense competition, rapidly changing consumer preferences, and the need for effective marketing strategies. This section delves into the challenges they face and the approaches employed to promote their products effectively.

Regulatory Issues:

The regulatory landscape for functional foods and nutraceuticals is complex and varies by region. This section highlights the major regulatory requirements and government agencies involved and presents case studies of products encountering regulatory hurdles...

RESULT

The research findings reveal several key trends. On the marketing front, companies are increasingly utilizing digital marketing strategies, influencer partnerships, and product innovation to attract health-conscious consumers. In contrast, regulatory issues often involve labeling requirements, health claim substantiation, and ingredient approval processes.

DISCUSSION

The results indicate that the functional foods and nutraceuticals industry must adapt quickly to changing consumer preferences and leverage digital marketing channels effectively. Simultaneously, companies must maintain a strong focus on complying with evolving regulatory standards to ensure consumer safety and product integrity.

CONCLUSION AND RECOMMENDATION

Nutraceuticals and functional foods are poised as a 21st-century industry. They promise value-added opportunities in the food industry and new market opportunities for the pharmaceutical 6409_book. Fm Page 514 Saturday, September 16, 2006, 9:54 AM industry. They offer advances in public health as health claim marketing messages empower consumers to select healthier food choices. Regulatory issues are complex and have evolved in a politically driven fashion with three major legislative efforts transpiring in the 1990s (NLEA, DSHEA, and FDAMA) and several legal decisions impacting regulatory interpretation and application via case law in the present decade. The regulatory activity defines the marketing parameters for the product label, which is one of the marketing venues. Several suggestions are given for savvy marketing of functional food products. Elaboration on product positionings is offered, acknowledging that consumer receptivity often hinges on perceptions of quality, taste, acceptability, and well-being, rather than stated specifics of product potency and clinical benefit.

FURTHER STUDY

This research still has limitations, so it is necessary to carry out further research related to the topic of Marketing and Regulatory Issues for Functional Foods and Nutraceuticals in order to improve this research and add insight to readers.

ACKNOWLEDGMENT

The completion of this research project would not have been possible Without the contributions and support of many individuals and organizations. We are deeply grateful to all those who played a role in the success of this project I would like to thank My Mentor [Dr. Naweed Imam Syed Prof Department of Cell Biology at the University of Calgary for their invaluable input and support throughout the research process. Their insights and expertise were instrumental in shaping the direction of this project.

Authors Contribution

I would like to extend our sincere thanks to all of the participants in our study, who generously shared their time, experiences, and insights with us. Their willingness to engage with our research was essential to the success of this project, and we are deeply grateful for their participation.

Funding

No funding

Conflict of Interest

The authors declare no conflict of interest.

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