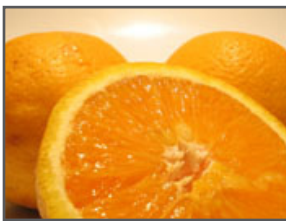




Nutraceutical: A combination of “Nutrition” and “Pharmaceutical”

By Dr. Ashoka Ghosh

This article assesses the changing regulatory scene in addition to changes in leading ingredients that food, drinks, and pharmaceutical companies adhere to in the new consumer health marketplace.



Dr. Stephen DeFelice, MD and Chairman of Foundation for Innovation in Medicine, has defined nutraceutical as, “Food, or parts of food, that provide medical or health benefits, including the prevention and treatment of disease.” The term was invented

in the 1990’s to give an identity to a highly promising area of health and medicine. It defines all categories of foods that help in preventing and controlling diseases. It also includes genetically modified foods, functional food, or processed food which contains additives (pharma food). The FDA defines nutraceuticals as products that “have the basic attributes of traditional foods—taste, aroma, or nutritive value—and that have been proven to provide an additional health benefit.”

Nutraceuticals Categories

Nutraceuticals are prepared from herbs or plant raw materials. The *Institute of Nutraceuticals Research* at Clemson University has established the following list of nutraceutical categories:

- Dietary Supplements: consists of vitamins, minerals, co-enzyme Q, carnitine, and multi-mineral formulas
- Botanicals: comprises of ginseng, ginkgo biloba, saw palmetto, and other plant-based supplements
- Functional Foods: these are oats, bran, cereals, and grains, yogurt, and other probiotics; Omega-3-rich products; canola and other oils with lowered triglycerides; and plant stanols present in fruits, vegetables, and nuts; and supplemented food products.
- Medicinal Foods: includes transgenic plants.

Market for Nutraceuticals

As per 4th Nutraceutical Summit held in Mumbai, India from February 21-23, 2008, it is estimated that value of global nutraceutical market is at over \$80 billion. A significant

share (35%) in world nutraceutical market is captured by US followed by Japan (25%). European Union has captured a share of 10% of nutraceutical market and the size is estimated to be US \$ 8 billion. According to a report, “World Nutraceuticals industry forecasts to 2010 & 2015,” there is a worldwide demand for nutraceutical ingredients and it will reach \$15.5 billion in 2010.

Nutraceutical industries are very fast growing (7-12% per year). In US more than 100 million people are using these natural products. These products are already marketed in supermarkets with nutraceutical weight-loss products being the highest sold—according to the *Nutrition Business Journal*. Major pharmaceutical, biotechnology companies, and food companies are good contenders in the nutraceutical market. More pharmaceutical companies are seen partnering with herbal companies.

Consumer Concerns

Consumers love buying food, especially fresh, attractive, and rich foods. The rising cost of healthcare is the reason consumers are turning to self-care and prevention. Supermarkets are today full of packaged products with guaranteed makeover of your personality. “Low fat,” “all natural,” “trans-fat free,” “organic,” and “calcium-enriched” are a few words listed in brilliant colors on attractive boxes. However, these claims are extremely confusing to consumers. Most consumers do not understand the effects of the thousands of so-called “nutritional supplements.” Some consumers feel secure after having these products. While some believe that eating such food with a few added nutrients really improves their diet, others think that eating such food will suffice their required diet.

Demand for Regulation

The US FDA regulates dietary supplements under a different set of regulations. The FDA does not formally screen and



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regulate nutraceuticals and only takes action against any unsafe dietary supplement product after it reaches the market. Manufacturers of nutraceuticals don't have to seek drug approval from the FDA to market their products under the Dietary Supplement Health and Education Act (DSHEA) of 1994. They can sell the product after submitting safety information to the FDA. As for efficacy claims, DSHEA allows without FDA authorization firms to make statements about classical nutrient deficiency diseases and use the so-called "structure and function" of the body or the "well-being" achieved by consuming the dietary ingredient. Foundation for Innovation in Medicine has proposed Nutraceutical Research and Education Act (NREA). If it enacts, it will review, approve, and regulate the new products and its claims.

Conclusion

Today, consumers are more concerned about their health and are taking a more proactive approach towards their lifestyle. They are managing their health judiciously and trying to prevent diseases- obesity, diabetes, cardiovascular, and bone and joint diseases-which are more diet-related. An extensive scientific study of nutraceuticals is required to prove "their effects with reduced side effects." The clinical benefits of such products should be developed by industries to supplement their claims.

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