Current Status of Functional Foods in the United States

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Functional foods, also known as nutraceuticals, are foods or food supplements designed to deliver a specific health benefit. The presentation will summarize the current status of the field and discuss both current and potential regulations with emphasis on those features that differentiate nutraceuticals from drugs. Examples will be discussed concerning current practices in development of nutraceuticals and the types of problems that limit their marketing and acceptance. The marketing of herbal and plant products in the United States will also be described, and both the permissible process and the current strategies employed will be described in comparison with on-going activities in the nutraceutical field. Finally, conclusions will be derived concerning the current status, changing focus and future directions for nutraceuticals in the United States.

The claims made for benefits from nutraceuticals determine how they are regulated. If a claim is made that a food can prevent or cure a disease, it is considered to be a drug and is regulated in the same manner, with clinical trials for safety and efficacy, documentation and approvals required by the FDA. However, the increased effort and expense incurred by this process is not usually merited in the present system because, in contrast to a novel drug entity, a functional food lacks the exclusivity that permits patent protection. Thus, a similar return on money invested is less feasible.

Currently, a compound marketed as a nutraceutical can make structure/function claims, with FDA approval. For example, the claim can be made that diets low in fat and high in fiber can reduce risk of heart disease. However, disease treatment claims cannot be made without full documentation. Thus, it cannot be claimed that the nutraceutical can prevent or cure heart disease.

Historically, the FDA was originally authorized to approve and regulate any
substance making disease-related claims. Compounds not eligible for approval as
drugs were severely restricted in the type of health-related claims that could be made.
However, in recent years, additional legislation has modified the regulatory process for
nutraceuticals. The Nutritional Labeling and Education Act (1990) permitted
companies to make health claims on food labels if the FDA determines that claims are
supported by "significant scientific agreement". Subsequently, the Dietary
Supplement Health and Education Act (1994) established limits to intervention by the
FDA specifically to situations arising from unsafe or toxic products. In this legislation,
structure/function claims were defined and were limited to description of functions
and/or effects of the substance in the body (and not on the disease).

Considerable current efforts are being expended to liberalize these regulatory
requirements. Pending and proposed legislation focuses on other ways of making
scientific or clinical data available to the public. Since these proposed approaches
are generally designed to bypass FDA oversight and permit less rigorously regulated
claims, many are controversial and it is not clear what modifications will actually
emerge. However, due to the increasingly high cost of drug research and
development as well as the need to establish a basis of exclusivity and profitability for
nutraceuticals if they are to be marketed successfully, these efforts are bound to
continue.

Efforts will also continue to differentiate and define properties of individual
nutraceuticals so that unique and potentially patentable properties can be identified.
Biotechnology approaches may help in these efforts by developing novel production
methods and enhancement of existing and transferred properties. Examples of these
approaches and strategies will be discussed.

The marketing of herbal and plant products in the United States can be
compared with that of nutraceuticals. The latter substances generally are supported
by more scientific data, whereas the former are based upon traditional usage and
custom. Herbal and plant products are generally accepted as safe by regulatory
authorities if there is a history of use or other evidence of safety in the recommended
use. In their labeling, they are permitted to (a) claim benefits related to a classical
nutrient-deficiency disease prevalent in the United States, (b) describe a role in
affecting structure and function in humans, (c) describe a documented mechanism by
which an ingredient acts on structure or function, and (d) describe the general well-
being resulting from consumption. Manufacturing standards for herbal and plant
products can be set by the FDA. Since these preparations are usually mixtures, purification and standardization of active ingredients as well as standardization of the preparation present particular problems.

The marketing of herbal and plant products in the United States also differs significantly from the process in Europe. In Germany, particularly, many herbal and plant products have been licensed based upon published information and are sold and prescribed as reimbursable drugs with corresponding labels and package inserts. As public interest in alternative medicine continues to increase in the United States, some of the approaches used in this field in Europe may prove of value not only for herbal and plant products but also for nutraceuticals.

In summary, the regulatory environment in the United States for nutraceuticals continues to be restrictive, though considerable pressure exists for more moderate legislative approaches. Utilization of biotechnology to enhance and otherwise modify properties of nutraceuticals promises to contribute significantly to product development and differentiation in the future.


Current and potential regulations of functional foods (nutraceuticals) will be discussed with emphasis on those features differentiating nutraceuticals from drugs. Current practices in nutraceutical development and limitations on their marketing and acceptance will be summarized. Comparisons between development and marketing strategies used for herbal and plant products and those used for nutraceuticals will be outlined. Finally, conclusions will be derived concerning the status and evolving future prospects for nutraceuticals in the United States.