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Statement Of

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And

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The Legislative Context of the New Dietary Ingredient Provisions

In order to understand the proper interpretation and application of the new dietary ingredient provisions in Section 413 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), it is essential to review both the events that precipitated the enactment of the Dietary Supplement Health and Education Act (DSHEA) of 1994 and the specific statutory language used in Section 413 as contrasted with the statutory requirements enacted years earlier for conventional food.

In congressional testimony presented in July 1993, FDA Commissioner David Kessler launched a strong attack on all aspects of the labeling and safety of dietary supplement products.[1] In the months that followed, FDA threatened, and in some instances took, regulatory action against dietary supplement products that both the regulated industry and the consuming public feared would threaten the continued existence of many dietary supplement products and perhaps the manufacturers as well. The regulated industry launched a congressional counter-offensive, arguing that new legislation was needed to prevent FDA from declaring numerous dietary supplement ingredients to be illegal food additives. This battle continued for more than a year, culminating in the enactment of DSHEA in October 1994. The sole purpose of Congress in enacting this legislation was to repudiate what Congress concluded to be the excessive regulation of dietary supplement products sought by FDA and, in particular, to require new and different safety standards for dietary supplement ingredients and products. In short, Congress ordered FDA to stop its enforcement campaign aimed at dietary supplements and to adopt a more tolerant

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[1] "Regulation of Dietary Supplements," Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, 103d Cong., 1st Sess. 63 (1993).

approach toward consumer freedom of choice, within the new statutory provisions established under DSHEA.

The legislative language used in DSHEA was designed to implement this new congressional mandate. All dietary ingredients were exempted from the food additive provisions of the law, in order to assure that FDA would not carry out its threat to sweep major dietary ingredients from the market as illegal unapproved food additives.

The following examples will suffice to illustrate the congressional intent. Section 409 requires that a food additive must be proved to be "safe" before a regulation can be promulgated authorizing its marketing. In implementing that statutory requirement, FDA defined "safe" to mean "a reasonable certainty" that the substance is not harmful under its intended conditions of use.[2] In contrast, Congress determined under Section 413(a)(2) of DSHEA that it was sufficient that a new dietary ingredient "will reasonably be expected to be safe." The food additive provisions rely solely upon scientific testing to develop adequate proof of safety. In contrast, the new dietary ingredients provisions allow reliance upon "a history of use or other evidence of safety." Whereas the food additive provisions require promulgation of a regulation before marketing may begin -- premarket approval -- the new dietary ingredient provisions do not require any response from FDA before marketing begins -- only premarket notification, at least 75 days prior to marketing. In short, the provisions incorporated by Congress into DSHEA, to assure the safety of new dietary ingredients, were deliberately and explicitly drafted to require a more flexible and general approach to safety than FDA had threatened to impose under the food additive provisions of the FD&C Act.

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[2] 21 C.F.R. 170.3(i).

It is in this context that the provisions relating to FDA regulation of new dietary ingredients under the statutory provisions added to the FD&C Act by DSHEA in 1994 must be approached.

The Definition of a New Dietary Ingredient

The definition of a new dietary ingredient is very broad in scope. A dietary ingredient is defined in extremely general terms under Section 201(ff) of the FD&C Act, to encompass any dietary substance that is used to supplement the diet. A dietary ingredient becomes a new dietary ingredient under Section 413(c) of the Act if it was not marketed in the United States prior to October 15, 1994.

It is clear that Congress intended this to be an extremely broad definition. Changes in manufacturing processes do not convert an old dietary ingredient into a new dietary ingredient. New salts and esters of pre-1994 dietary ingredients do not create new dietary ingredients. Nor do new sources of old dietary ingredients become new dietary ingredients. Neither would the use of new claims, new labeling, new formulations, and other new conditions of use result in a determination that an old ingredient has become new.

The Exclusion of Dietary Ingredients Present in the Food Supply

Congress determined that not all new dietary ingredients need be the subject of a submission to FDA at least 75 days before marketing. Section 413(a)(1) was included in DSHEA to exclude new dietary ingredients present in the food supply as long as the food in which the ingredient is found has not been chemically altered. Once again, this is an extremely broad and flexible exclusion. Any substance found naturally in the food supply -- at any level, and regardless of prior safety evaluation -- is excluded from the requirement of a 75-day notice.

Synthetic or recombinant nature-identical versions of these ingredients are also excluded. The only limitation is that the ingredient must not have been produced by chemically altering the food in which it was found.

The Appropriate Content of a 75-Day Notice for a New Dietary Ingredient

FDA has promulgated regulations in 21 C.F.R. Part 190 that fairly and adequately describe the contents of a 75-day notification as set forth in Section 413(a)(2) of the FD&C Act. There is no need for further regulations or guidance on this matter.

In the event that FDA does conclude that regulations or guidance would be advisable, it is important that the agency incorporate the more flexible and general approach intended by Congress rather than the more rigid approach applied to food additives. An appropriate model might be the approach used by the Federation of American Societies for Experimental Biology (FASEB) for its landmark review of GRAS food ingredients during the 1970s. FASEB evaluated the existing scientific data in a practical and commonsense way, without imposing rigid "cookbook" checklists like those in the Red Book or set forth in the Federal Register notice announcing this meeting. In enacting DSHEA, Congress specifically rejected a rigid Red Book approach, and substituted a much broader standard.

If raw agricultural commodities were to be subjected to the type of checklist analysis set forth in the Federal Register notice, few, if any, would pass. The same would be true of botanical ingredients used for centuries throughout the world but not brought to the United States before 1994. Applying the Red Book or any other checklist to new dietary ingredients would frustrate the congressional intent and violate the words of the statute.

Conclusion

FDA is at a crossroads in the regulation of dietary supplements. Beginning with the enactment of DSHEA, FDA decided not to enforce compliance with the law in the vain hope that Congress would repeal it. That strategy has proved to be self-defeating. Fortunately, the Bush Administration has now stepped up to the task of implementing DSHEA.

In implementing the new dietary ingredient provisions of the statute, FDA has two alternative approaches to consider. The first approach would be for the agency to return to the 1993 approach by interpreting the statute in a way that restricts dietary supplements the greatest.[3] FDA could, for example, interpret the definitions of dietary ingredient and old dietary ingredient very narrowly, interpret the definition of new dietary ingredient very broadly, and then apply a rigid checklist standard for food safety, similar to the Red Book, that very few, if any, new dietary ingredients could pass. That is one alternative. It would violate both the intent and the terms of DSHEA. It would provoke enormous new regulatory, legal, and legislative battles. It would be a major disservice to the consuming public.

The second approach would be to attempt to reflect the congressional intent as faithfully as possible. It would recognize the broad scope of the definitions of a dietary ingredient and an old dietary ingredient, the breadth of the exclusion for dietary ingredients present in food, and the flexible safety evaluation intended with respect to new dietary ingredients for which a 75-day notice is required. This would allow FDA to focus on real safety issues, not on rigid adherence to a checklist, and thus closely follow the intent of Congress.

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[3] 139 Cong. Rec. 31144-31156 (November 20, 1993); S. Rep. No. 103-410, 103d Cong., 2d Sess. (1994).

I strongly encourage FDA to apply practical and real-world standards for food safety rather than unrealistic and impractical requirements -- and thus to provide the type of public health protection that Congress mandated. By respecting the intent of Congress in rejecting a food additive approach, FDA has the opportunity to establish a less rigid and more practical system that will nonetheless adequately protect the public.