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**Effective Regulation of Dietary Supplements**

Presentation of

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NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

Good morning. I am grateful for the opportunity to present NFPA's views on regulating dietary supplements.

The National Food Processors Association (NFPA) is the principal scientific trade association representing the \$430 billion food processing industry.

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Today, I will briefly discuss issues related to the safety of dietary supplements, and to labeling claims available for dietary supplements, and will offer suggestions regarding the regulation of this class of foods vis-à-vis other types of foods regulated by FDA. We intend to file written comments at a later date.

NFPA is interested in dietary supplements because they are foods. NFPA supports a regulatory policy which is consistent for all foods with respect to safety and label claims.

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NFPA is aware that the law makes different provisions for the burden of proving safety of ingredients for dietary supplements and other foods. While by law dietary ingredients of dietary supplements are no longer deemed to be food additives, NFPA believes that this does not absolve the dietary supplement industry from responsibility for safety of their products and ingredients. Dietary supplement companies should continue to assess the safety of their products and ingredients prior to market, monitor safety after market introduction, and have procedures in

99N-1174

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place in the event a recall is necessary – dietary supplements are not exempt from voluntary recall provisions.

To assist the dietary supplement industry in assuring the safety of its products, NFPA believes that FDA should proceed promptly with the rulemaking on Good Manufacturing Practices (GMPs) for dietary supplements. The experience of the food industry is that GMPs serve as a useful outline for those production and processing procedures which result in safe and high quality food products.

The dietary supplement industry should also be encouraged to notify FDA that key dietary ingredients in their products are Generally Recognized as Safe (GRAS) – especially dietary ingredients with some history of use. Using GRAS notifications for dietary ingredients with a history of use would complement the current pre-market notification procedures for new dietary ingredients of dietary supplements. GRAS substances are not food additives, by legal definition, so dietary supplement ingredients would not be excluded from consideration under GRAS provisions. Ingredients of dietary supplements should be held to the same GRAS standard as conventional food ingredients. Consideration under GRAS provisions should address current levels of consumption and conditions of use for dietary ingredients, including herbals and botanicals; current uses may be very different from historical uses. We note that some botanical ingredients have utilized the new GRAS notification process (albeit as flavors). To assist the dietary supplement industry – indeed, all sectors of the food industry – in filing GRAS notices, FDA should promptly finalize its proposal on GRAS notification procedures. The supplement industry should be encouraged to use this provision, to assure users of supplement ingredients, including herbal and botanical ingredients, that there is no question of the safety of these substances.

NFPA believes that the dietary supplement industry should carry the burden of ensuring its products are safe, and FDA should provide a regulatory environment – through GMPs and GRAS – to assist the industry in its endeavors.

Regarding label claims of health benefits, conventional foods and dietary supplements enjoy similar, if not always identical, regulatory approaches. In the area of health claims, both conventional foods and dietary supplements should be subject to the same provisions – and this includes extending provisions for health claims made under the FDA Modernization Act to supplements. NFPA believes that the recent court decision in *Pearson v. Shalala* ultimately will exert equal force on claims labeling rules for both dietary supplements and conventional foods.

With respect to structure-function claims, NFPA commented last year that FDA's unfortunate proposed rule would have as much an adverse effect on claims for conventional foods as it would on dietary supplement claims. The proposed

redefinition of “disease” would adversely effect health claims and structure-function claims for both foods and supplements. NFPA has urged FDA to withdraw this proposal, and we repeat our request today. We also ask FDA to take to heart the arguments we put forward with respect to “nutritive value” for food components which are the subject of structure-function claims.

It is imperative that all types of claims on dietary supplements, and other foods, be well-substantiated or very carefully and explicitly qualified. NFPA believes that FDA needs to be aggressive in its enforcement posture against any poorly substantiated, poorly qualified, or otherwise misleading claims. Again, this approach should help assure a level playing field between dietary supplements and other sectors of the food industry. Furthermore, NFPA encourages FDA to undertake this activity in close coordination and cooperation with the Federal Trade Commission.

All these reforms – safety and claims – are needed not only to ensure a level playing field between dietary supplements and conventional foods, but to prepare a positive environment for new types of foods being designed to provide health benefits beyond those of basic nutrition. Whether these novel foods are dietary supplements in the form of conventional foods, or traditional foods enhanced with properties or components associated more with dietary supplements; whether they have increased levels of classical nutrients achieved through genetic modification, or herbal and botanical ingredients added to their formulation – NFPA believes that the course to a barrier-free regulatory environment lies in correcting the flaws in current rules, and a strong enforcement approach, rather than in embarking on an entirely new regulatory scheme.

NFPA urges FDA to consider carefully the impact on the conventional food industry caused by dietary supplement rules. NFPA believes that all regulations affecting dietary supplements will also make an impact on all sectors of the food industry, and NFPA will continue to advocate that the playing field stays level.

Thank you.