Leading the Foodservice/Hospitality Industry

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NATIONAL RESTAURANT ASSOCIATION

April 23, 1997

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Dockets Management Branch
Food and Drug Administration
HFA-305
12420 Parklawn Drive
Room 1-23
Rockville, Maryland 20857

Ladies and Gentlemen:

The National Restaurant Association, with more than 32,000 member companies representing more than 170,000 individual restaurant operations, wishes to enter comments for the record on Current Good Manufacturing Practice in Manufacturing, Packing, or Holding of Dietary Supplements, 21 CFR Ch. I, Docket No. 96N-0417, dated February 6, 1997.

We would first like to congratulate the Agency for including irradiation as one of several measures to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance. The Association believes that availability and education of new and approved technologies is important for the food industry to increase food safety efforts and provide additional cost/benefit options.

However, we are concerned with the overall framework of the proposed rule. Section II. B., Statement of Purpose states that "dietary supplements are classified as foods, and the Good Manufacturing Practices applicable to them are similar to those generally applicable to other foods." Nonetheless, in many instances, the proposal does not reflect provisions of the FDA Federal Food, Drug and Cosmetic Act {21 USC 301} or the recommendations/ principles of the FDA Model Food Code.

Examples of such inconsistencies are demonstrated below:

> In the definition section on page 5, Section II. B. (t) "Sanitize", which is defined in the proposal "to adequately treat equipment, containers, or utensils by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer." In contrast, the 1995 FDA Food Code, 1-201.10 (B)(71) defines "sanitization" as "to apply cumulative heat or chemicals on cleaned food contact surfaces that when evaluated for efficacy, yield a reduction of 5 logs, which is equal to 99.999% reduction, of representative disease microorganisms of public health significance."

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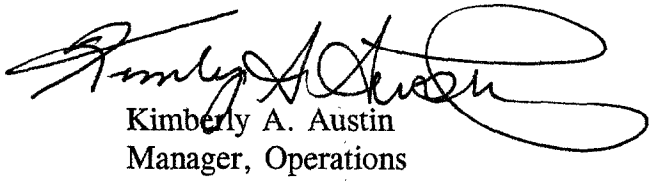
Page 18, IV. (3) and (4), Summary and Request for Comments, the FDA requests comments on standards that should be met in certifying that a dietary ingredient or supplement is not contaminated, and whether a certification will provide assurance the product is safe and wholesome; and requests comments on whether there is a need for CGMP to include requirements for manufacturers to establish adequate standard operating procedures for quality control on a day-to-day basis. Such standards or protocols can and should be adequately addressed by the use of Hazard Analysis Critical Control Point (HACCP) principles, yet HACCP is not mentioned throughout the proposal.

The National Restaurant Association has long been a proponent of regulatory uniformity and we believe that this proposal could easily observe existing FDA regulations and recommendations which protect food. FDA should not "reinvent the wheel." We also suggest that FDA may need to consider the economic impact this proposal may have on the various industries covered by the proposal, and whether a regulatory impact statement should be made.

Thank you for the opportunity to comment. If you have any questions or would like to discuss this further, please do not hesitate to call me at 202-331-5987.

Sincerely,



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