GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition, Fiscal Year 2002; Request for Comments

The Grocery Manufacturers of America (GMA) is pleased to offer comments concerning program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2002 (October 1, 2001 through September 30, 2002). GMA supports CFSAN's ongoing efforts to prioritize its workload to focus resources on core activities, and appreciates this opportunity to participate in the priority-setting process.

GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than $450 billion, GMA members employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues.

The following comments relate to CFSAN's program priorities in the regulation of food and beverage products. For ease of reference, topics are addressed in the order in which they appear in the FY 2001 work plan.

FOOD SAFETY INITIATIVE

GMA urges CFSAN's continued emphasis on food safety as the Center's top priority. While CFSAN has undertaken many worthwhile projects as part of the Food Safety Initiative (FSI), a number of projects in particular merit special attention, resources, and continued placement on the "A" list in FY 2002. Among these are completion of the planned egg safety proposal, initiation of a salmonella enteritidis (SE) research plan, continued risk assessment and risk communication efforts as identified in the FY 2001 work plan, and adequate inspection coverage of

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both domestic and imported foods, with priority placed on facilities representing the highest food safety risks.

Activities related to *Listeria monocytogenes* (LM) also warrant continued "A" list attention, particularly with regard to risk assessment and risk communication. Publication of the draft LM risk assessment represented an important milestone, but additional data are needed to generate product/pathway-specific risk assessments that would better serve as a guide to future agency action. Only by fully exploring the nature and extent of risks imposed by specific food categories, and the handling and holding practices that characterize them, can effective, scientifically sound control strategies be identified and applied. Along these lines, to the extent that adequate data are available for particular food categories, CFSAN should explore the possibility of establishing tolerances for those categories so that resources may be concentrated on the foods that present the greatest risk of listeriosis.

Risk communication is important to all FSI areas of concern but is particularly vital to the control and prevention of LM, which can be harmful to susceptible populations. GMA encourages CFSAN to maintain as an "A" list priority consumer and health care professional information and education efforts regarding LM, targeting at-risk populations. GMA also supports continued emphasis on related education programs such as the secondary schools food safety curriculum.

To accomplish these and other FSI projects in the most effective manner possible, coordination of federal, state, and local efforts is critical. While some progress has been made in eliminating the existing patchwork of food safety requirements, additional efforts are needed to avoid inconsistent standards, and to ensure coordinated regulatory responses when safety-related incidents occur.

NUTRITION, HEALTH CLAIMS, AND LABELING

GMA supports promotion to the "A" list items of a proposed rule on food irradiation labeling approaches. The current labeling scheme has the tendency to alarm consumers unnecessarily about use of a technology that is considered by CFSAN and other major governmental and nongovernmental public health organizations to be safe and beneficial under its intended conditions of use. Action is needed to provide more accurate and nonmisleading labeling alternatives to ensure that consumers are fully informed and are not misled regarding the nature of foods that have been treated with irradiation to ensure food safety.

DIETARY SUPPLEMENTS

GMA supports continued emphasis on dietary supplement issues identified in the FY 2001 work plan, including publication of the dietary supplement GMP proposal, rapid identification of high priority safety issues, initiation of enforcement actions against unsafe products and unsubstantiated claims, and development of an effective adverse event reporting (AER) system. GMA also urges CFSAN to ensure consistent regulatory treatment of dietary supplements and conventional foods, particularly with regard to the clear First Amendment guidelines provided by the court in *Pearson v. Shalala.*

SCIENCE BASE

Sound science is the underpinning to CFSAN's food safety efforts, among other regulatory initiatives. Accordingly, attention to CFSAN's research agenda and risk analysis efforts is critical, as discussed elsewhere in these comments. GMA also supports continued "A" list attention to such matters as implementation of a new Food Advisory Committee structure, which would enhance the Committee's ability to provide expert scientific advice in the critical areas of dietary supplements, food additives and ingredients, contaminants and natural toxicants, and food biotechnology.

INTERNATIONAL

GMA is committed to meaningful liberalization of international trade in food and beverages. Such liberalization is critically dependent upon scientifically sound applications of sanitary and phytosanitary (SPS) measures and elimination of technical barriers to trade. To ensure the development of appropriate scientific measures on a global basis, GMA supports a continued "A" list designation for CFSAN's work in Codex, JECFA, WHO food safety planning programs, and NAFTA technical working groups. Participation in Codex is particularly important in an era in which the so-called "precautionary principle" is being increasingly cited as a justification for disguised trade barriers.

EMERGING AREAS—FOOD ALLERGENS

GMA member companies are committed to meeting the needs of the food allergic community. GMA, along with numerous other food trade associations and the Food Allergy and Anaphylaxis Network, formed the Allergy Issues Alliance several years ago because the food

industry wished to proactively address the allergen issue. The Alliance has published an Allergen Labeling Program that provides labeling guidelines for foods that contain allergenic proteins from the "Big 8" major allergens.

GMA encourages CFSAN to develop and maintain a strong enforcement presence with regard to food allergens. GMA also urges CFSAN to recognize the progress the industry has made in reaching consensus as to effective GMP and labeling measures that address allergen concerns, and to refrain from considering additional regulations as industry guidelines are implemented. Additional regulations are unnecessary as CFSAN's existing statutory framework and regulatory tools provide ample authority to take all necessary and appropriate actions to protect public health.

EMERGING AREAS—BIOTECHNOLOGY

To ensure that consumers are not misled regarding the use of modern biotechnology in the production of food, GMA urges CFSAN to designate as an "A" list priority issuance of final labeling guidance on voluntary label statements indicating whether a food has or has not been developed using modern biotechnology. The final guidance must make clear, consistent with CFSAN's proposal, that misleading claims (e.g., "GMO free") are not permitted. GMA also recommends that CFSAN finalize its biotechnology mandatory premarket notification proposal.

EMERGING AREAS—BOVINE SPONGIFORM ENCEPHALOPATHY

The recently published BSE/TSE Action Plan of the Department of Health and Human Services, 66 Fed. Reg. 44146 (Aug. 22, 2001) identifies several action items that FDA has undertaken to enhance, sustain, and communicate safeguards against BSE and TSE. GMA urges FDA to focus in particular, and to designate as an "A" list item, expansion of its regulatory research agenda regarding TSEs. While existing border controls must continue to provide the first line of defense, progress must be made in advancing understanding of BSE/TSE infectious agents. Critical research needs include studies to evaluate the safety and effectiveness of sterilization, decontamination, and inactivation procedures for BSE/TSE agents.

ADDITIONAL RECOMMENDATION FOR PRIORITY STATUS

GMA requests that CFSAN add to its list of priorities incorporation of the most recent edition of the Food Chemicals Codex

(FCC) standards into appropriate parts of 21 C.F.R. This action is needed to update those regulations that reference the FCC.

Many of the specifications and test methods referenced in 21 CFR are to earlier versions of the FCC that have since been revised. By way of example, many of the more recent monographs have stricter specifications for heavy metals than those referenced in the regulations. By using the current FCC specifications CFSAN will ensure that the most recent information about food additives and GRAS substances is incorporated in its regulations. Such actions also will eliminate the confusion of whether manufacturers should adopt the specifications in the existing FCC monographs or the specifications cross-referenced in the food additive and GRAS regulations.

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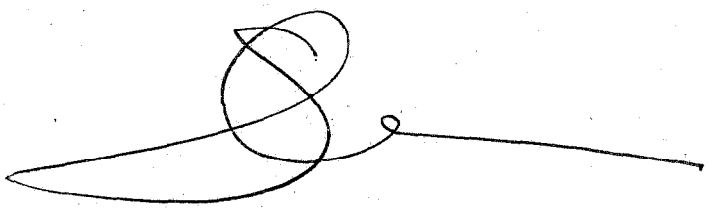
GMA is committed to enhancing the safety and quality of America's food supply through cooperative, science-based efforts of industry and government. GMA looks forward to working with the Agency in FY 2002 and beyond and would be pleased to discuss with CFSAN any of the points made in these comments.

Sincerely,



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