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July 28, 2003

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20857

RE: Docket No. 98N-0359; Program Priorities in

the Center for Food Safety and Applied

Nutrition

The Association for Dressings and Sauces (ADS) appreciates the opportunity to provide input regarding the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition's (CFSAN) program priorities for the year 2004, as requested in the June 5 *Federal Register* (*FR*) notice (68 *FR* 33727). ADS is an international association of manufacturers of dressings for salads, mayonnaise, mustard and specialty sauces and their suppliers. A list of our members is enclosed.

We applaud the Agency for continuing to provide interested parties the opportunity to participate in the CFSAN priority-setting process. ADS has offered the insight of the dressings and sauces industry on such priorities since the Agency began this initiative in 1998. (See ADS' most recent comments dated August 19, 2002). We continue to agree one of the Center's primary goals is ensuring the security of the nation's food supply. Earlier this year, FDA issued proposed regulations regarding facility registration and prior notice of imported foods as mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). Most recently, proposals regarding records establishment and maintenance and administrative detention were released also as required by the Bioterrorism Act. The dressings and sauces industry understands the need for such regulations and supports their intent. However, we urge the Agency to ensure the final regulations are reasonable, timely, and provide the necessary balance between FDA's authority in matters related to protecting the food supply and the rights of the food industry.

A priority of equal importance to food security is food safety. As part of the on-going efforts regarding food safety, the coordination on foodborne disease outbreaks should be a priority. Too often a food is wrongly implicated in a foodborne disease outbreak because of the lack of coordination among state and Federal agencies investigating the outbreak. Accurate and timely information regarding such outbreaks is in the best interest of all involved, and most importantly, the consumer.

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However, as our earlier comments have stated, there are other key functions in which the Agency should focus its efforts, specifically the continued maintenance and administration of the food standards program, national uniformity, promoting international harmonization, and preventing economic fraud. We still strongly believe these areas deserve CFSAN attention and a place on the "A" list of priorities.

It is evident from comments received on the Agency's Advance Notice of Proposed Rulemaking (ANPRM) on food standards (60 *FR* 67492; December 29, 1995) that a number of existing standards presently serve as barriers to the utilization of new technologies and required ingredients to improve existing products. As a result, petitions have been prepared and filed in several important product categories to affect needed amendments to recognize the advances in food technology and the need for flexibility.

On January 13, 1998, ADS submitted a Citizen Petition that reflected the consensus reached within the dressings industry on how FDA should proceed in implementing the ANPRM with respect to the standards of identity of interest to this industry. The Association requested that the Commissioner of Food and Drugs initiate rulemaking to (1) repeal the standard of identity for French dressing (21 CFR 169.15), and (2) revise, simplify and modernize the standards of identity for mayonnaise and salad dressing (21 CFR 169.140, 169.150). ADS' efforts to update or repeal obsolete standards should be supported by FDA, but almost six years later, no action has been taken by the Agency, despite the fact that the Association provided the necessary information to move forward. ADS continues to discuss with FDA personnel other means of expediting the petition, but no FDA action has been forthcoming. At a minimum, we believe the Agency should provide annual updates on standards petitions so that petitioners are aware of the status and can advise their constituents, accordingly.

Further, we should not lose sight of the original intent of the ANPRM, as its goal is important. Standards need to be updated and modernized in keeping with current technological innovations. We believe this remains a key goal and should be included in the 2004 priorities. As Americans continue to battle obesity, the changes recommended by ADS in its petition would allow companies to make mayonnaise and salad dressing that would contain less fat and fewer calories and offer consumers a greater choice of modified products to reduce or maintain weight. ADS strongly urges the Agency to revise the standards as outlined in our 1998 petition to allow companies to take advantage of the various technological and ingredient innovations available, and thereby providing more options to the consumer.

Similarly, national uniformity between Federal and state agencies should be an "A" list priority for CFSAN in FY 2004. There should be a single set of food safety regulations interpreted in the same way by both Federal and state regulators. A uniform set of regulations and interpretations will eliminate the confusion that currently exists as industry strives for compliance at the local and Federal levels. As an example, the Association is attempting to resolve conflicting state interpretations of the Federal acidified foods regulations. The paper, "Microbiological Safety of Mayonnaise, Salad Dressings and Sauces Produced in the United

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States: A Review," was developed by Dr. Richard Smittle to assist in this process. ADS staff has contacted FDA personnel to obtain direction on how to distribute the paper and related backgrounder to process authorities and state and Federal regulators to educate such persons on the safety of industry's products, and therefore, avoid conflicting interpretations. In discussions with FDA personnel regarding this issue, the Agency acknowledges the conflicts and reasons for the confusion, but ADS' offer to provide assistance in this area has not been utilized, and yet, no other FDA action is taken. ADS believes the Agency should establish a means for industry to communicate safety information to such FDA personnel as inspectors and process authorities to further their knowledge on the safety of industry-specific products.

The modernization and maintenance of United States (U.S.) food standards and national uniformity of regulations, including those pertaining to food safety, are also important as the U.S. participates in the Codex Alimentarius process. In order for the U.S. to be an effective player within Codex, U.S. standards must be science-based, reflective of current practices, and be national in scope, which will give the U.S. a strong basis for negotiation. It is, therefore, critical that the U.S. positions on several Codex standards be thoroughly reviewed by industry so current industry practices are reflected. We, therefore, encourage more timely communications between FDA and industry. In the increasingly global marketplace, the promotion of international harmonization is imperative, and the U.S. should take a leadership role in the Codex process. Thus, it is crucial that U.S. positions be shared with other countries in a timely manner so meaningful discussions can occur during Codex committee meetings.

Lastly, economic fraud should be a CFSAN priority because of its importance to both consumers and industry. FDA must continue to pursue and prosecute fraudulent activities. Individuals and companies engaged in such activities are just as likely to have little regard for the welfare and safety of the public and should not be allowed to operate. FDA's efforts in this regard should be to enforce the existing statutory provisions.

In conclusion, ADS appreciates the opportunity to provide comments on CFSAN's 2004 priorities. While we agree that the food security and food safety should continue to be CFSAN's top priorities, the Agency is also responsible for other important functions as outlined in these comments. Thus, we encourage the Agency to balance its resources accordingly.

Sincerely,

Pamela A. Chumley
Executive Director

Enclosures

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