



THE ASSOCIATION FOR  
*DRESSINGS  
& SAUCES*

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June 29, 2000

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

RE: Docket No. 99N-2497; Citizen Petitions; Actions That Can Be Requested by  
Petition; Denials; Withdrawals, and Referrals for Other Administrative Action

The Association for Dressings and Sauces (ADS) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) notice, "Citizen Petitions; Actions That Can Be Requested by Petition; Denials; Withdrawals and Referrals for Other Administrative Action" (64 *Federal Register (FR)* 66822; November 30, 1999). 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.

ADS can appreciate FDA's desire to streamline the Citizen Petition process in light of current resources to review such petitions. However, any changes must be consistent with the Federal Food, Drug and Cosmetic Act (FFDCA), and be equitable to both consumers and the food industry. To that end, the National Food Processors Association (NFPA) expressed valid concerns in their February 28 comments regarding proposed changes to the Citizen Petition process, noting the proposed action would "frustrate the purposes and objectives of the [FFDCA] by limiting the ability of regulated companies and consumers to seek amendment of the Agency's regulations, regardless of their substance, and other appropriate administrative action in a meaningful and legally binding way." ADS shares NFPA's concerns.

In particular, there is concern that through this proposal, FDA would be able to dismiss requests to amend or establish standards of identity, or take action in other areas of economic regulation. Proposed Section 10.30(e)(4)(i)(D) would allow FDA to refer a Citizen Petition "for other administrative action instead of issuing a response" if the Petition "[d]oes not involve a significant public health or consumer protection issue." Similarly, proposed Section 10.30(e)(2)(ii) would provide that FDA's denial of a citizen petition may be "brief, as appropriate," with the following example at 64 *FR* 66824:

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"3. A citizen petition where the agency has determined that the petition does not implicate a significant public health issue, and the agency lacks the resources to provide a more detailed response or to take the action requested by the petitioner. This may occur, for example, where the petitioner requests a change in FDA's regulations that has no significant public health implications, such as amending or establishing common or usual names regulations or standards of identity, quantity, and fill of container regulations for foods.... In the absence of a significant public health issue, and considering the intense demand on FDA's resources, the agency must allocate its resources carefully and wisely, so brief denial of these types of citizen petitions would be appropriate."

ADS opposes the Agency's position that the decision to amend standards of identity regulations be based solely on resources not previously committed to "significant public health issues." Further, limiting the use of the Agency's resources to focus on Citizen Petitions dealing solely with food safety is unacceptable. In their comments regarding the proposed changes to the Petition process, NFPA accurately states: "...creating obstacles to amending food standards of identity so as to render any such changes impracticable, a likely consequence of a rule resulting from the Citizen Petition initiative as proposed, would not remove the Agency's statutory authorities and obligations, or industry's rights, with respect to food standards of identity. Section 401 of the FFDCFA provides for the establishment of these standards..." NFPA goes on to state that they are unaware "of any lawful means by which a procedural regulation can void authority under the statute."

It is evident from comments received on the Agency's previously published 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.

ADS submitted a Citizen Petition which 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). The petition was submitted on January 13, 1998, and to date, no action has been taken by the Agency, despite the fact that the Association provided the necessary information to move forward.

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Recently, ADS staff engaged FDA officials in discussions regarding a specific portion of ADS' petition. Specifically, ADS' 1998 petition stated: "...because we do not believe that condiment products are key nutritional sources, we also propose that Vitamin K not be considered in assuring nutritional comparability under section 130.10(b)." Section 130.10(b) requires nutrient addition for foods that "substitute for a standardized food" if necessary to assure the nutritional comparability for all nutrients for which RDIs have been established. That list was expanded in 1995 to include Vitamin K. In keeping with the spirit of the proposed changes to the Citizen Petition process, ADS asked for guidance from FDA on next steps to affect such a change, e.g., request for an advisory opinion. However, FDA officials stated the only way to resolve this issue was to amend Section 130.10.

It appears that FDA still acknowledges the importance of updating standards to reflect new technologies. In other Agency action, ADS was pleased to note that FDA has included an item related to food standards of identity on the priority list for the Center for Food Safety and Applied Nutrition's priorities for the fiscal year 2000. Item 2 on the "B" list for Strategy 2.2 – Nutrition, Health Claims and Labeling is to "develop a coordinated plan between FDA and USDA to correlate existing food standards with current technological innovations." ADS agrees with this goal and urges prompt attention to unresolved Citizen Petitions. ADS' petition would aid the Agency in achieving this goal from the standpoint of streamlining the standards for mayonnaise and salad dressing and allowing manufacturers of these products to take advantage of current technological innovations.

In conclusion, ADS supports NFPA's opposition to any FDA action to reject a Citizen Petition based on insufficient Agency resources or to refer Citizen Petitions that do not involve significant public health or consumer protection issues for other administrative action, rather than responding. ADS also supports NFPA's recommendation that the Agency use its limited resources to refine and implement the existing Citizen Petition process more efficiently. We encourage action in this area and in the area of response to existing Citizen Petitions, such as ADS' January 1998 petition.

We appreciate the opportunity to provide comments on this notice.

Sincerely,



Pamela A. Chumley  
Executive Director

PAC/jcm



*The Association for Dressings & Sauces*  
*Manufacturer Member List*



Bestfoods	T. Marzetti Company
Cains Foods, Inc.	McIlhenny Company/TABASCO® Brands
Chelton House Products, Inc.	Mega Alimentos, S.A. de C.V.
Clements Foods Company	Morehouse Foods, Inc.
The Clorox Company	Mount Vernon Enterprises
Dean Dip & Dressing Company	Mrs. Clark's Foods, Inc.
Food Specialties Company, Inc.	North Coast Processing, Inc.
Furst-McNess Company	Olds Products Company
G&L Food Products, LLC	Ott Food Products Company
M.A. Gedney Company	Piknik Products Company
Martin Gillet & Company, Inc.	Pillsbury (Skollsberg's)
Gold Pure Food Products Company, Inc.	Plochman Inc.
Golden State Foods	Purity Products, Inc.
Green Garden Food Products, Inc.	Q & B Foods, Inc.
Griffin Foods Company	The Red Wing Company, Inc.
Halben Food Mfg. Company, Inc.	Reily Foods Company
Hartville Kitchen, Inc.	Richelieu Foods, Inc.
The Hudson Companies, Inc.	Safeway, Inc.
Intercorp Excelle Foods, Inc.	The C.F. Sauer Company
Ken's Foods, Inc.	Silver Spring Gardens, Inc.
Kimlan Foods Company, Inc.	Sunlight Foods, Inc.
Kraft Foods, Inc.	Superior Coffee & Foods
The Kroger Company	Supreme Oil Company
Land O'Lakes, Inc.	Thor-Shackel Horseradish Company
Leo's Italian, Inc.	Tulkoff Products, Inc.
Lipton	Unifine Richardson B.V.
Litehouse, Inc.	Van Law Food Products, Inc.
Louis Albert & Son Foods Company	Ventura Foods, LLC
Marie's Quality Foods, Inc.	Walden Farms, Inc.



# *The Association for Dressings & Sauces*

## *Supplier Member List*

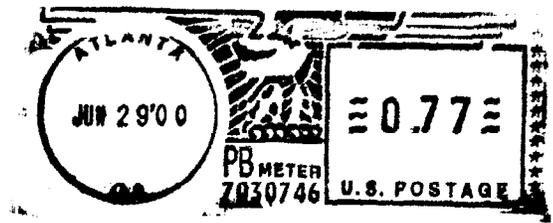


Accurate Ingredients, Inc.  
Admix, Inc.  
AG Processing, Inc.  
Ajinomoto USA, Inc.  
Anchor Glass Container Corporation  
Archer Daniels Midland Company  
AVEBE America, Inc.  
Ball-Foster Glass Container, LLC  
Baltimore Spice, Inc.  
Basic Vegetable Products  
Bender-Goodman Company, Inc.  
Bran + Luebbe, Inc.  
Brown Produce Company  
Bunge Foods  
Burns Philp Food Ingredients  
Butter Buds Food Ingredients  
Cancom Grain Company, Inc.  
Cargill Foods  
Cerestar USA, Inc.  
Chemicolloid Laboratories, Inc.  
Chianti Cheese Company  
Commercial Creamery Company  
Continental Colloids, Inc.  
Corn Products International, Inc.  
Cryovac, Sealed Air Corporation  
Curwood, Inc.  
Cutler Egg Products, Inc.  
Danisco Cultor, Inc.  
Demeter (1993), Inc.  
DiverseyLever U.S. Food Group  
Dow Chemical Company  
G.S. Dunn & Company, Ltd.  
E.E. & Brian Smith (1928) Ltd.  
Edlong Flavors  
Elite Spice, Inc.  
Enercon Industries Corporation  
FMC Biopolymers  
Fabri-Kal Corporation  
FIS - North America, Inc.  
Fort Dearborn Company  
Francis-Mustoe & Company  
Frencharoma Imports Company, Inc.  
French's Ingredients  
Ful-Flav-R Food Products Co., Inc.  
Genpak-Processor Division  
Gilroy Foods  
Givaudan Roure Flavors  
GRAFCO PET Packaging Technologies  
Grain Processing Corporation  
Gum Technology Corporation  
Haliburton International Corporation  
Chr. Hansen, Inc.  
Harvest States Oilseed Refining  
T. Hasegawa U.S.A., Inc.  
Hassia USA, Inc.  
Heller Seasonings & Ingredients, Inc.  
Hickory Specialties, Inc.  
Hueck Foils, LLC  
Hunter, Walton & Company, Inc.  
ISP Alginates, Inc.  
Imperial Sensus  
Inova Food Ingredients  
International Flavors & Fragrances  
JPS Packaging  
Jungbunzlauer, Inc.  
Kalsec, Inc.  
Kelco Biopolymers  
Kerr/Suncoast Closures  
Letica Corporation  
Liquid Container/Plaxicon  
MD Foods Ingred., Inc. - North America  
J. Manheimer, Inc.  
McIlhenny Company/TABASCO® Brands  
Meta Systems from Containerboard  
Michael Foods, Inc/Papetti's  
Morton Salt (Div. Morton Intl., Inc.)  
Nakano Foods  
National Starch & Chemical Company  
Nutrients, Inc.  
Nutrinova, Inc.  
Omega Protein, Inc.  
Opta® Food Ingredients  
Pechiney Plastic Packaging, Inc.  
Phoenix Closures, Inc.  
Pretium Packaging  
Printpack, Inc.  
Purac America  
Quest International  
RXI Plastics, Inc.  
Rhodia, Inc.  
Ripon Pickle Company, Inc.  
Roquefort Association, Inc.  
SKW Biosystems, Inc.  
Sakai Spice (Canada) Corporation  
Saputo Cheese USA, Inc.  
Sartori Food Corporation  
Schröder North America Corporation  
Scott Turbon® Mixer, Inc.  
Sealright Company, Inc.  
SHURflo  
Silgan Containers Corporation  
Silliker Laboratories Group  
Sokol and Company  
Sonstegard Foods Company  
A.E. Staley Manufacturing Co.  
SupHerb Farms  
Takeda Vitamin & Food USA, Inc.  
TIC Gums, Inc.  
Todhunter Foods  
Tomen America, Inc.  
Tower Intercontinental Group  
TricorBraun (Div. of Kranson Ind.)  
UFL Foods Corporation  
United Specialty Flavors  
Universal Flavors  
Vanguard Container Corporation  
Vegetable Juices, Inc.  
Walle Corporation  
Winpak Lane, Inc.  
Wisconsin Spice, Inc.



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