



May 3, 2005

Ms. Loretta Carey
Food and Drug Administration
~~Center for Food Safety & Applied Nutrition~~
Office of Nutritional Products, Labeling
& Dietary Supplements (HFS-800)
5100 Paint Branch Parkway
College Park, Maryland 20740

Dear Ms Carey:

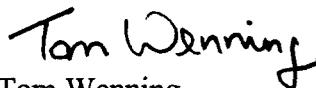
The purpose of this letter is to follow up on your recent conversation with Tim Hammonds, President and CEO of the Food Marketing Institute (FMI), regarding a joint citizens petition that was filed by FMI and the National Grocers Association (N.G.A.) in the mid-1990's regarding the application of the Food and Drug Administration's (FDA's) ingredient labeling regulations to in-store prepared take-out foods offered by retail grocers. (A copy of the petition is attached for your ready reference). To our knowledge the Food and Drug Administration (FDA) has never taken any action on our petition.

Nonetheless, in early March 2005, Dr. Hammonds received a telephone call from an FDA official asking if the petition could be withdrawn because the Agency had not acted on it. The purpose of this letter is to clarify that although the petition has been withdrawn for the Agency's administrative convenience, FMI and N.G.A. are hereby preserving all of the issues and concerns expressed in the petition and explicitly reserve our right to re-file the petition in the future should the need arise. In that case, we would expect the Agency to refer to the original filing date to give our petition top priority moving forward.

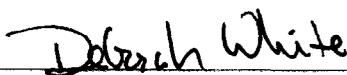
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We appreciate the opportunity to assist the Agency with its administrative priorities however we respectfully request that you reserve our rights on this issues.

Sincerely,



Tom Wenning
Sr. Vice President & General Counsel
National Grocers Association



Deborah White
Vice President
Associate General Counsel,
Regulatory Affairs
Food Marketing Institute

Enclosure

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**Petition to Modify the Ingredient)
Labeling Requirements Applicable to)
In-Store Prepared Take-Out Foods)
Offered by Retail Grocers)**

Docket No. _____

**Submitted by the
Food Marketing Institute
and the
National Grocers Association**

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

Citizens' Petition

The undersigned, Food Marketing Institute (FMI) and National Grocers Association (NGA), submit this petition to request that the Food and Drug Administration (FDA) amend its ingredient labeling requirements applicable to foods prepared and packaged at retail stores. This petition is submitted pursuant to section 403(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (codified at 21 U.S.C. § 343(i) (1982)).

The Food Marketing Institute (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 19,000 retail food stores with a combined annual sales volume of \$190 billion — more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 250 members from 60 countries.

The National Grocers Association (NGA) is the national trade association representing the retail and wholesale grocers who comprise the independent sector of the food distribution industry. Operating more than 50,000 stores, this industry segment accounts for nearly one-half of all food store sales in the United States.

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ACTION REQUESTED

Petitioners hereby respectfully request that FDA amend its ingredient labeling regulations by adding a new section under Part 101 of Title 21 of the Code of Federal Regulations. The new section would exempt foods prepared and packaged at retail stores from the complete ingredient labeling requirements specified in 21 C.F.R. §§ 130.3 and 101.4. Section 130.3(e) states:

Section 403(i) of the act requires the listing of all ingredients in standardized foods. All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

21 C.F.R. § 130.3(e). Section 101.4 states in part:

Ingredients required to be declared on the label or labeling of a food . . . shall be listed by common or usual name in descending order of predominance by weight . . .

21 C.F.R. § 101.4(a)(1). As a result, foods subject to these requirements require lengthy on-label ingredient statements.

Petitioners request that Section 101.4 be amended to provide as follows:

Foods prepared by supermarkets, grocers and other retailers sold in ready-to-eat form on-premise are not required to list all ingredients in a standardized food, and all ingredients need not be declared by their common or usual name, provided the ingredients are adequately described by the alternative nomenclature common for these foods, or the ingredient information is otherwise available to consumers at point-of-purchase.

The requested action is necessary to correct certain unintended consequences resulting from new regulations implementing the Nutrition Labeling and Education Act of 1990 (NLEA) (P.L. 101-535) and certain noted features of the pre-existing requirements.

II. STATEMENT OF GROUNDS

Prior to enactment of the NLEA, Section 403(i) of the FD&C Act required that a food label bear the common or usual name of each ingredient for non-standardized foods and the common or usual name of optional ingredients for standardized foods. FD&C Act § 403(i). The NLEA requires, in part, that all standardized foods bear complete ingredient labeling of all mandatory and optional ingredients. Section 7 of the NLEA [21 U.S.C. § 343(i)]. FDA adopted corresponding, implementing regulations. See 21 C.F.R. 130.3(e). This requirement went into effect on May 8, 1993. As a result, the ingredient labeling requirements applicable to foods prepared and sold by supermarkets require a great deal more information on the in-store label. This substantially hinders the ability of supermarkets to provide these prepared items and results in labels that are cumbersome and do not serve the consumer's informational needs. Given the manner in which in-store prepared take-out foods are made and marketed, greater flexibility in how FDA regulates the ingredient labeling of those foods is necessary.

The FD&C Act provides for relief to parties that would be adversely affected by a particular labeling requirement. Section 343 of the FD&C Act provides that the Secretary may establish by regulation an exemption from a particular labeling requirement to the extent that compliance with the requirement

is "impracticable, or results in deception or unfair competition." 21 U.S.C. § 343(i). The application of complete ingredient labeling to in-store prepared take-out foods falls squarely within these grounds.

The necessity for Petitioners' requested regulatory relief is a result of the role supermarkets play in meeting the diverse needs of the typical American consumer. The food retailing industry plays a special role in the business community. Supermarkets see every family in America every week. They are the primary point where the consumer contacts the food industry. As a result, this industry is by necessity consumer driven, and grocers pride themselves on being the purchasing agents for their customers -- America's consumers.

As the purchasing agent for the nation's consumers, supermarket operators face a never-ending challenge of meeting consumer needs. Meeting these needs is fundamental to a successful food retailing operation. In recent years, changing consumer needs and demands have led to a tremendous growth in the take-out restaurant/deli/bakery food service segment of the industry. Supermarkets have responded to this challenge by offering customers a wide variety of ready-to-eat, prepared foods. The success of the industry's efforts in this new area underscores the tremendous consumer demand for prepared, convenient foods available at the supermarket.

Industry research reveals that take-out food offered by the retail grocer is important to consumers for several critical reasons: it gives them an entire meal all prepared and ready at once; is more relaxing than eating out in a restaurant; and provides them the opportunity to eat food they do not know how to make themselves or is too hard to make. Contemporary lifestyles with more career-oriented, busy people, means that this growth trend will continue for the foreseeable future.

In 1992, total supermarket deli sales reached \$16.5 billion, ^{1/} and bakery sales reached \$8.92 billion. ^{2/} Much of these sales represent customized products designed to meet individual consumer tastes. The success of supermarkets and others is dependent upon their ability to provide convenience, quality, variety and value consumers have come to readily associate with in-store prepared take-out foods now found at many supermarkets.

III. RELIEF WARRANTED

A. Complete Ingredient Labeling Impracticable

It is impracticable for the retail grocer to provide complete ingredient labeling. Ingredient labeling of in-store prepared take-out foods presents an operational nightmare. Retailers would be forced to abandon many foods and standardize those remaining items in order to provide complete ingredient labeling. If complete ingredient labeling is required, the in-store prepared foods marketed and sold by supermarkets would be significantly restricted.

1. Practicability of labeling rules a primary goal

Ensuring that the mandatory nutrition labeling and related labeling requirements are practical and achievable was an important consideration in the enactment and implementation of the NLEA. On July 30, 1990, Congressman

^{1/} *Supermarket Business*, (April 1993) page 37.

^{2/} *Supermarket Business*, (February 1994) page 83.

Henry Waxman (D-Ca) stated: "Where full labeling would be impractical, the bill provides for an exemption or requires that the information be provided in modified form." 136 Cong. Rec. H5836 (daily ed. July 30, 1990) (Statement of Rep. Henry Waxman). In the preamble to the NLEA implementing regulations, FDA explains that the agency "believes that where these problems are present, food service facilities may not reasonably be expected to provide information concerning nutrient profiles, and that exemptive provisions should be established. Such provisions are included in this proposal . . ." 58 Fed. Reg. 29505.

In those instances where Congress anticipated that the NLEA requirements would prove unworkable or unduly burdensome, special allowances were provided for by statute. Several of these instances involve foods that are prepared and sold to consumers in a manner similar to the in-store, prepared take-out foods offered by grocers. For example, restaurant and other foods offered for sale for immediate consumption (on or off-premises) are expressly exempt from the law's mandatory nutrition labeling requirements.

Section 403 (5) (A) Subparagraphs (1), (2), (3) and (4) shall not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. . .

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

FDA's implementing rules specifically exempt the in-store deli, bakery and similar establishments.

See 21 CFR § 101.9(j)(2).

Thus, Congress and FDA have wisely acknowledged the necessity for an exemption from mandatory nutrition labeling due to the unique circumstances presented by prepared foods offered for sale by restaurants and other food service operators. Complete ingredient labeling of in-store prepared take-out foods poses similar difficulties. Therefore, the agency should adopt a comparable regulatory policy with respect to the ingredient labeling of prepared foods sold by in-store, supermarket operators.

2. Complete ingredient labeling of in-store prepared take-out foods will result in reduced consumer choice

Retail grocers provide consumers with a wide range of prepared foods to satisfy demand for variety, innovation, and quality. These items typically include: sandwiches, salads and side dishes, hot entrees, cakes, cookies and similar items. The ingredients of these various foods change frequently, typically in response to a consumer's individual preference (e.g., in preparing a sandwich) or in order to offer variety (e.g., soup or quiche of the day). Variations and substitutions of ingredients to meet individual consumer requests are common, inevitable and critical to the success of an in-store prepared take-out food operation.

Imposing the impracticable requirements of complete ingredient labeling of in-store prepared take-out foods would severely hinder a retail grocer's ability to meet the consumer demand for these foods, to the detriment of consumers and supermarket operators alike. A primary consequence of complete ingredient labeling is a reduction in consumer choice. Retailers have already indicated that they will be forced to reduce the number of products they prepare in-store in order to better comply with the applicable regulations. For the remaining items that are

available, retailers would be required to standardize prepared options available to consumers. Day-to-day variations in the food items, critical to the supermarket's ability to attract and maintain loyal customers, would all but disappear.

Complete labeling of standardized and other ingredients would be a tremendous problem for the industry in terms of operation and cost. It is operationally impracticable for retailers to create and maintain a separate label for each of the myriad combinations of ingredients used on any given day in the preparation of the vast variety of foods offered by retailers. Moreover, it would be difficult for the store associate to place the correct label on each and every one of these individually prepared items.

It would be cost prohibitive and, therefore, impractical, to provide complete ingredient labeling of in-store prepared take-out foods. Different labels for the variety of ingredient combinations used in different foods would have to be manufactured. There is no way to estimate the actual cost of printing these new labels for the several hundred thousand stores. The costs would be enormous, and would force many retailers to eliminate or sharply curtail the preparation of in-store prepared take-out foods.

B. Complete Ingredient Labeling Will Create Consumer Confusion and Produce Labels That Deceive, Not Inform Consumers

According to Trends -- Consumer Attitudes and the Supermarket, many factors continue to influence consumers' food shopping and selection habits today. Consumers like the idea that take-out food requires no cooking, saves time, and requires very little clean-up. Buyers use take-out food when they are too tired to cook, when they come home late, when they are too busy to cook, and when they are in a hurry.

Based on extensive experience with the American consumer who purchases in-store prepared take-out food items, FMI and NGA can demonstrate that it is likely that complete ingredient labeling will prove confusing to consumers. Examine a label for a typical submarine sandwich, for example:

Prior to May 8, 1993:

Ingredients: sub bun, turkey bologna, turkey salami, Iowa brand loaf, pasteurized processed cheese, mayonnaise, Dijon mustard, lettuce.

Now:

Ingredients: White sub bun [enriched flour (unbleached wheat flour, malted barley flour, iron, niacin thiamin mononitrate, and Riboflavin), water, glucose, vegetable shortening (partially hydrogenated soy bean and/or cottonseed oil), yeast, milk, salt, wheat gluten, dough (flour, monocalcium phosphate, calcium carbonate, vegetable mono and diglycerides, ascorbic acid, fungal protegie, potassium bromate, potassium iodate)], turkey bologna [turkey, water, salt, dextrose, corn syrup solids, mustard, sodium phosphate, flavorings, sodium erythorbate, spices, smoke flavoring, paprika, sodium nitrate], turkey salami [turkey, turkey hearts, water, salt, dextrose, mustard, sodium phosphate, spices, hydrolyzed soy protein, dehydrated garlic, natural smoke flavoring, sodium erythorbate, and sodium nitrite], Iowa brand loaf [pork, water, salt, sugar, sodium erythorbate, and sodium nitrate], pasteurized processed American cheese [American cheese (milk, salt, cheese cultures, enzymes), water, cream, sodium citrate, salt, sodium phosphate, and sorbic acid added as a preservative], sub sauce [mayonnaise (soybean oil, egg yolks, water vinegar, sugar, salt, mustard, flour, cider flavor, lemon juice and calcium disodium EDTA (added to protect flavor), Dijon mustard (water, mustard seed, distilled vinegar, salt, white wine, citric acid, tartaric acid and spices)], lettuce.

The first label is user friendly and meets FDA's regulatory goal of informing the consumer. The second label is information overload. Over the years, the supermarket industry has learned that consumers respond to clear, concise, positive messages. When reading the second label, consumers' eyes simply glaze over. In fact, this information is likely to confuse even the most educated consumer. The second label also covers up much of the product, interfering with the consumer's ability to look at the product they are purchasing, another important factor in consumers' purchasing decisions.

The nomenclature presently used conveys the ingredients of in-store prepared foods to consumers. Petitioners carefully track consumers' concerns and complaints. The ingredient labeling currently provided for in-store prepared food has not elicited complaints from consumers. Moreover, alternatives to a complete, on-label ingredient statement exist that would enable consumers to obtain ingredient information. Information about a food's ingredients that is not ascertainable by a particular consumer from the label could be easily obtained from store personnel or other means. Thus, the manner in which in-store prepared take-out foods are offered for sale to consumers enables -- indeed demands that -- FDA to adopt a flexible approach to the ingredient labeling regulation of these foods.

Petitioners believe that consumers should have access to adequate label information in a manner consistent with consumer expectations. The requested amendment to FDA's ingredient labeling requirements would best achieve this goal while providing critical flexibility not permitted by the regulations.

FDA Should Regulate Prepared Foods in a Consistent Manner to Ensure That Federal Regulation Does Not Unfairly Impede a Segment of the Take-Out Prepared Foods Market

1. Ingredient labeling not required for virtually all prepared take-out foods

FDA has consistently and wisely determined that it would be impracticable and inappropriate to require ingredient labeling of prepared foods offered for sale by restaurants and comparable food service operators. For example, in 1986, FDA denied a petition submitted by the Center for Science in the Public Interest that would have required restaurants to comply with the agency's ingredient labeling provisions. See letter from John M. Taylor, Acting Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to Michael F. Jacobson, Center for Science in the Public Interest (September 5, 1986).

In comments submitted to FDA in response to its November, 1993 ingredient labeling proposals, commenters stated that it would be impossible for restaurants to provide ingredient labeling because it would: (1) hinder work on new formulations; (2) require a standardized menu; (3) limit menu items; and (4) escalate prices. FDA agreed, noting in the preamble to the new ingredient labeling rules: "The agency cannot reasonably expect restaurants that frequently change their menu items to provide information on ingredients." 58 Fed. Reg. 2872. Each time FDA has considered the feasibility and wisdom of complete ingredient labeling of prepared food items, it has concluded that such requirements would be impossible.

2. Supermarkets will be forced to abandon or curtail successful marketing of in-store prepared foods due to ingredient labeling rules not applied to comparable foods

The unfair competitive consequences that will result from requiring complete ingredient labeling of in-store prepared foods by supermarkets is an additional reason for FDA to modify its current ingredient labeling regulation. The

ability of a supermarket or similar operator to compete in the growing take-home prepared foods market would be severely undermined absent regulatory relief. Such requirements would force the standardization of such foods thereby severely undermining the supermarkets' ability to attract consumers. The economic consequences of such a result would also be enormous.

Take-out prepared foods attract consumer dollars by offering convenience, value, quality and variety. Increasingly, in-store prepared foods have met this challenge, in addition to take-out foods offered by traditional restaurants and similar operations. Burdening one segment of this growing market with complete ingredient labeling requirements not suited or necessary for these prepared foods renders application of the ingredient rules improper and unfair.

Food retailers have committed substantial resources to developing food service departments, including in-store delis, bakeries, and food courts. The recent growth in the sale of in-store prepared take-out foods is directly attributable to consumer demand and to a competitive marketplace. This trend is likely to continue. Presently, about 15 percent of the dollars that Americans spend on food is for take-out. Food retailers are attempting to satisfy the needs of their customers for convenience, fast service, and variety. Two-thirds of the dollars that consumers spend on take-out food is spent in restaurants. About one-third (36%) of the dollars is spent at retail food stores. ^{3/} In many cases today, it is impossible to distinguish between a restaurant and a grocery store in this respect.

^{3/} *Shopping a Cart*, page 25.

Although a majority of take-out meals are eaten at home, 18 percent of all take-out meals are consumed at the place of employment. Prepared foods that consumers can eat at home or at work with minimal cooking are an important tool in the retail grocer's constant battle to attract and retain customers.

Supermarkets compete on many levels and have to offer a variety of in-store prepared take-out products that are appealing and profitable.

Differentiation within the take-home segment of the industry, whether a restaurant or grocery retailer, poses a difficult challenge. For example, the development of signature items, if executed well, can make a substantial image impact with consumers. Retailers have learned that the factors that distinguish their departments from others contributes to customer satisfaction and lasting customer relationships. Limiting and standardizing product lines would cause a retail operation to lose its basic character and appeal. It is unfair and unreasonable to impose a regulatory burden on food retailers who prepare and market foods in a manner identical to foods prepared and sold by other food service operators that are exempt from complete ingredient labeling requirements.

D. Environmental Impact

This action will not require the preparation of an environmental assessment because it does not have a significant impact on the environment. 21 C.F.R. 25.21(a)(11).

E. Economic Impact

An economic impact statement under 21 C.F.R. § 10.30(b) is not required at this time.

Conclusion

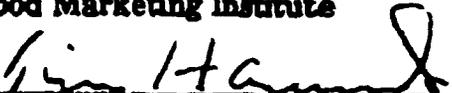
In-store prepared take-out food is a significant and growing market for supermarkets. Demographics and changing consumer lifestyles point to the continued growth of these operations for supermarkets. It is, therefore, important that retailers not be subject to ingredient labeling requirements that are impracticable, result in unfair competition, and will not be of any benefit to consumers.

Congress and FDA clearly have acknowledged the unique characteristics of in-store prepared take-out foods. Petitioners, therefore, seek publication and adoption of regulations providing for modified ingredient labeling of foods processed and packaged at retail stores.

The undersigned certify that, to the best of their knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Food Marketing Institute



Tim Hammonds, President & CEO

National Grocers Association



Thomas Zaucha, President & CEO