April 9, 2007

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

**CITIZEN PETITION**
**REQUESTING THE FOOD AND DRUG ADMINISTRATION**
**TO DEVELOP REQUIREMENTS FOR THE USE OF THE TERM "NATURAL"**
**CONSISTENT WITH USDA'S FOOD SAFETY AND INSPECTION SERVICE**

## I. INTRODUCTION

Based in Downers Grove, Illinois, Sara Lee Corporation develops and markets many of the world's favorite high-quality baked goods, packaged meats and coffee. Leading brands and products include *Sara Lee* fresh breads, frozen desserts and deli meats, *Hillshire Farm* lunch meats, *Jimmy Dean* sausage and breakfast foods, *Ball Park* franks and the *Senseo* single-serve premium coffee system.

As a leading manufacture of premium bakery, meat and beverage items, Sara Lee Corporation conducts business under the regulatory oversight of both the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). In total, Sara Lee Corporation operates 56 manufacturing facilities and over 650 distribution centers regulated by FDA and operates 12 production facilities and five distribution centers under FSIS inspection.

Sara Lee Corporation is committed to providing safe and wholesome foods that are innovative and delight customers, while meeting their expectations for convenience and health. Sara Lee Corporation has long supported science-based regulation that is transparent to all stakeholders and a common approach by FDA and FSIS in their oversight of food products. As a result of this commitment, Sara Lee Corporation is petitioning both FDA and FSIS to take a uniform approach for defining the term "natural."

A single, uniform "natural" policy that captures the common elements of the current FDA and FSIS policies would provide consistency for consumers and food manufacturers over the large variety of foods that bear a "natural" claim. A uniform policy would meet each Agency's statutory obligation for ensuring that food labeling is neither false nor misleading and represent yet another instance in which the Agencies act in concert to advance the mutual goal of consumer protection. To provide optimal food safety options, a uniform

"natural" policy should recognize that natural preservatives are consistent with "natural" claims. Moreover, to adequately address the numerous contexts in which a "natural" claim can be used, the term should be defined in a flexible policy that provides for case-by-case consideration of the term instead of a static, fixed definition adopted through notice-and-comment rulemaking.

## II. ACTION REQUESTED: FDA AND FSIS SHOULD DEFINE "NATURAL" BY A SINGLE, UNIFORM POLICY

Sara Lee Corporation requests that FDA work jointly with FSIS to devise and adopt a unified policy governing use of the term "natural" as follows.

> Use of the term "natural" may be used to describe a food or food ingredient that does not contain any artificial flavor or flavoring, coloring ingredient (regardless of source), or any artificial or synthetic ingredient that is included within or not normally expected to be in the product. The degree of processing necessary to produce the food or food ingredient should be considered in determining consumer expectation.

This proposed statement of policy fairly captures the common elements of both Agencies' current policies and ensures the necessary flexibility to enable a context-specific determination that would bar use of the term when used in a false or misleading fashion.

We further respectfully request that the Agency adopt the foregoing as a statement of policy and that no notice-and-comment rulemaking be undertaken. While complete input of all stakeholders is important, the ability of the Agencies to protect consumers from false or misleading "natural" claims necessitates a degree of flexibility that cannot be achieved in a static regulation.

## III. STATEMENT OF GROUNDS

FDA and FSIS operate under common statutory mandates. Consumers benefit from a unified policy that is flexible, consistent and prohibits use of the term when used in a manner that is false or misleading. The Agencies cannot possibly adopt a one-size-fits all formal regulation that would take account of the numerous different contexts by which "natural" foods are accurately identified. This Petition recognizes that the diverse use of "natural" in an accurate, non-misleading fashion and the impracticability of attempting to codify a prescriptive definition that purports to take account of such diverse uses. The principles articulated by the proposed unified policy ensure the fundamental expectations for "natural" products are met.

## A. A Uniform Approach to Regulation of "Natural" Claims is Consistent with the Agencies' Food Labeling Responsibilities

### 1. Common statutory authority

Congress has empowered FDA and FSIS to prohibit the sale of a food "if its labeling is false or misleading in any particular."1/ Notwithstanding the differences in regulatory approaches that arise in certain areas of food labeling, it is appropriate and valuable for the Agencies to guide their case-by-case assessment of "natural" claims based on a common set of principles set forth in a single policy. "Natural" is a term whose meaning varies greatly depending on the product category, the nature of the particular food, consumer experience and historical practices, as well as the context of the specific label bearing the claim. The diverse, non-misleading use of "natural" across all categories regulated by both Agencies underscores the value of a single, flexible policy.

The value of a unified policy is particularly evident from the significant number of "FDA-regulated" foods/ingredients that are used in "FSIS-regulated" products. FDA and FSIS-regulated products are intricately commingled in the marketplace. Very few consumers would be expected to differentiate between foods subject to the respective Agency's jurisdiction, and do not expect that "natural" would be regulated pursuant to different policies. Over the years, the Agencies have found that harmonized food regulation, when appropriate, advances their shared consumer protection goals. "Natural" is similar to many other areas of food labeling where consistency across all product categories yields tangible consumer benefits. Predictability, consistency and a level playing field arising from a unified "natural" policy are of great benefit to food marketers as well.

### 2. History of consistent labeling policies

FDA and FSIS have greatly advanced their common, respective consumer protection goals in numerous instances by adopting parallel policies and requirements. Virtually every aspect of nutrition labeling regulation by the Agencies is identical. While the Nutrition Labeling and Education Act of 1990 (NLEA) mandated new requirements for nutrition labeling and nutrient claims for FDA-regulated foods, FSIS on its own initiative adopted parallel regulations. FSIS stated: "[h]armonization will ensure consistency of format and content for consumers and thereby, will encourage use of the new labels, while minimizing the cost of compliance on the food industry." 2/

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1/ *See* 21 U.S.C. §§ 343(a), 453(h), and 601(n). FSIS ensures accurate labeling of meat and poultry products pursuant to the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), while FDA is authorized to regulate the labeling of most other food products under the Federal Food, Drug, and Cosmetic Act (FFDCA). 21 U.S.C. §§ 601(n)(1), 453(h)(1) and 343(a), respectively.

2/ 58 Fed. Reg. 632, 637 (Jan. 6, 1993). A decade later, FSIS made further refinements to its nutrition labeling rules (to provide for nutrient content claims on multiple-serve meal-type products and to adopt the FDA definition of "main dish" products) in the interest of maintaining consistency between FSIS and FDA. 69 Fed. Reg. 58799, 58801 (Oct. 1, 2004).

More recently, FSIS announced its intentions to require allergen labeling pursuant to the Food Allergens Labeling and Consumer Protection Act (FALCPA). This amendment to the Federal Food, Drug, and Cosmetic Act to require allergen labeling did not, of course, apply to FSIS-regulated foods. Nonetheless, we understand that FSIS is in the process of developing a proposed rule to provide for requirements parallel to FDA. 3/ FSIS also recently announced the Agency's plans to engage in rulemaking regarding trans fat declarations in the nutrition facts panel. Not only does the Agency plan to enact regulations that are consistent with those adopted by FDA, but, in the interim, the Agency announced it "will not object to the voluntary declaration of trans fatty acids in Nutrition Facts panels ...if the declaration is made in accordance with FDA regulations ...." 4/

Food standards reform is another area where the Agencies have worked together to foster consistency. FSIS noted that this consultation is necessary to "avoid inconsistency [and] possible impairment of the coordinated effective administration" of FSIS and FDA food labeling requirements. 5/ Over the past decade, FDA and FSIS have jointly solicited comments on the modernization of these standards and developed a common set of principles to guide their respective processes. 6/ In its advance notice of proposed rulemaking, FDA noted it:

> recognizes the need for consistency between FDA and FSIS in the development and implementation of food standards that set forth minimum compositional requirements. The agency believes that manufacturers will be better able to comply with the requirements of both agencies if similar approaches are used. Thus, to the extent possible, one of the agency's goals is to harmonize its regulations with those of FSIS. 7/

FDA and FSIS repeatedly have recognized that advancing their respective consumer protection responsibilities over food labeling are best achieved through the development of harmonized labeling policies when appropriate and consistent with their distinct statutory responsibilities. Common statutory authority, prior coordination and the realities of regulating the context-specific term "natural" dictate the need for a single, harmonized "natural" definition.

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3/ "Questions and Answers Related to Ingredients of Public Health Concern," *available at* www.fsis.usda.gov/OPPDE/rdad/FSISNotices/FAQs_for_Notice_45-05.pdf (accessed Feb. 27, 2007). [Attachment A]

4/ "Trans Fat Declarations in the Nutrition Facts Panel on Product Labeling," *available at* http://www.fsis.usda.gov/Regulations_&_Policies/Trans_Fat_Declaration_on_Product_Labeling/index.asp. [Attachment B]

5/ 21 U.S.C. §§ 607(c), 457(b).

6/ 70 Fed. Reg. 29214 (May 20, 2005).

7/ 60 Fed. Reg. 67492, 67502 (Dec. 29, 1995).

### B. A Uniform Approach Would Benefit Food Manufacturers and Marketers

A uniform "natural" policy also would greatly benefit food manufacturers and marketers by providing consistency throughout the marketplace. An FDA-regulated food that could be used in a meat or poultry product (e.g., applesauce that could be sold independently or as part of a packaged meal that features Salisbury steak) could be developed to meet a singular definition of "natural." Likewise, FDA and FSIS-regulated foods could be co-marketed under a single "natural" claim if common criteria are applied by the Agencies.

A unified "natural" policy also would foster innovation. As consumer interest in how processed foods are formulated and prepared, companies will continue to strive to offer "natural" foods that meet consumer expectations for quality, safety and value. It is well-established that consistency in food labeling policy creates incentives to produce the types of foods consumers demand. In the context of nutrition information, the Federal Trade Commission (FTC) noted in comments to FDA "a consistent and coherent policy on food marketing is also important to protect consumers, to avoid conflicting legal standards, and to help stimulate competition to improve products so consumers can improve their diets." 8/ Finally, uniformity would reduce the cost of compliance by subjecting food manufacturers and marketers to a single regulatory scheme for all foods.

### C. Uniform "Natural" Policy Should Mirror Common Attributes of Existing Policies

The proposed uniform policy reflects the core elements of the respective Agency's longstanding policies. A uniform policy should permit "natural" claims on food components and products that do not contain artificial colors, flavors, and other synthetic ingredients. 9/ Although highly dependent on context (e.g., food category, product label) FDA and FSIS each have an add-on to their "natural" policy to protect consumer expectations – FDA/consumer expectations for type of product and FSIS/minimally processed. FDA, through marketplace surveillance, and FSIS, via prior label approval, have become quite adept at

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8/ Press Release, Federal Trade Commission, FTC Chairman Steiger Discusses Food Advertising; Announces Staff Comments to FDA on Proposed Food Label Regs, in Remarks Before Advertising Agencies (Feb. 25, 1992) (available at http://www.ftc.gov/opa/predawn/F93/steiger-ad.htm). [Attachment C]

9/ Under the terms of FDA's long-standing "natural" policy, "natural" means that "nothing artificial or synthetic (including all color additives regardless of source) is included in, or has been added to, a food that would not normally be expected to be in the food." 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). FSIS's current "natural" policy provides that the term may be used on meat and poultry products if (1) the product does "not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed." "Natural Claims" in Food Standards and Labeling Policy Book, FSIS (revised Nov./Dec. 2006). [Attachment D]

applying their informal policy on a case-by-case basis to prohibit deceptive use of "natural" claims. 10/

The compelling advantages of a unified policy outlined above underscore the limitations of the current approach. Sara Lee Corporation commends FDA and FSIS for their case-by-case contextual approach to the regulation of "natural." At the same time, the somewhat different emphasis of each approach has frustrated the ability of many companies to adopt a unified approach to the marketing of "natural" products.

The requested unified policy is intended to maintain the prohibition of artificial and synthetic ingredients yet allow for a flexible approach that encourages product innovation. The proposed unified policy largely mirrors FDA's current "natural" policy. With respect to FSIS, the proposed unified policy would simplify but not change its longstanding policy. The reference to "chemical preservative" is omitted to avoid confusion and debate over precisely what is a "chemical preservative." The proposed policy would enable the Agencies to readily exclude synthetic preservatives (e.g., those derived synthetically from petrochemicals) versus "natural" preservatives (e.g., salt, lactates from corn).

The proposed unified policy would also identify "minimal processing" as an important consideration but not force FSIS in each instance to rationalize or set forth confounding distinctions among different types of processing. As FSIS concluded several years ago with respect to sucrose (table sugar), the ingredient is not more than minimally processed because the myriad of steps undertaken to refine sugar from its plant sources is the minimum necessary to create table sugar. The proposed policy would continue FSIS's policy to bar "natural" claims for foods or ingredients that are highly processed to a point beyond consumer expectations.

The proposed policy maintains the Agencies' respective approaches to "natural" while allowing a simplified regulatory approach that realizes the benefits of a unified labeling policy. The consumer and industry benefits identified are realized through the adoption and enforcement of a unified policy that directly advances the Agencies' shared consumer protection mission.

### D. Use of "Natural" Pervasive and Growing: Regulatory Approach Should Mirror Marketplace Developments

Customer demands and expectations related to the availability of "natural" products are substantial and continue to increase. In 1997, sales of natural and organic foods

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10/ For instance, an ingredient that is more than minimally processed, such as modified food starch, can be used in a "natural" product if it can be demonstrated that the ingredient would not significantly change the "natural" character of the product and the "natural" claim is appropriately qualified to reflect the ingredient's presence (e.g., "all natural except modified food starch"). Moreover, FSIS has determined that other ingredients that are more than minimally processed, such as refined oils, can be used in meat and poultry products bearing a "natural" claim without qualification, provided they do not significantly change the "natural" character of the product.

were less than $9 billion, with natural products representing less than half these sales. A total of 476 new food products bearing primary "natural" claims were released worldwide in 2003, 11/ and by the middle of 2006, annualized sales of "natural" products alone had expanded to $17.7 billion. 12/ As of 2004, approximately 63 percent of all households had purchased "natural" food, 13/ while as of 2005, six to 15 percent of U.S. consumers said they purchased natural and organic products on a regular basis, and these numbers are increasing. 14/ Sales of natural and organic food products are predicted to exceed $46 billion by 2010. 15/

FDA-regulated products primarily occupy the "natural" market. In 2005-2006, FDA-regulated product represented over 96 percent of all products available with a "natural" label, while packaged meats and other FSIS-regulated products accounted for the remaining four percent of the total market. 16/ While sales of FSIS regulated products comprise a relatively low percentage of the total "natural" market, they are growing dramatically. Total "natural" packaged meat sales showed 13 percent growth from 2005 to 2006, 17/ and sales of "natural" and/or organic meats are predicted to increase at a compounded annual growth rate of 19 percent from 2004 to 2009. 18/

The overarching motivations for purchasing natural products are health and wellness. American consumers are seeking more "natural" options, consistent with the faster growth of the natural products category. Consumers are also expecting that "natural" products – regardless of the Agency that has regulatory oversight on that product – meet the same expectations and, hence, the same regulatory definitions. Consumer also expect that "natural" products have the same inherent food safety as products not labeled as natural. Because a common approach to the term "natural" is desired by consumers and industry alike, the market for such products is growing rapidly, and the large majority of "natural" products are regulated by FDA, we are requesting that FDA and FSIS adopt a uniform "natural" policy that largely mirrors FDA's long-standing regulatory approach.

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11/ "Natural products set to gain ground," *Food Week* (Jan. 27, 2006). [Attachment E]
12/ ACNielsen, Total U.S. – F/D/MM excl. Wal-Mart, 52 weeks ending June 17, 06.
13/ Christina Veiders, "Taking the advantage; new SN consumer research reveals supermarkets have not capitalized on the opportunity to capture more market share from natural/organic shoppers," *Supermarket News* 10 (Mar. 1, 2004). [Attachment F]
14/ "The next big thing: filling the void left by low-carb items, the natural and organic segment has been coined the newest universal consumption trend, but is everyone really onboard?" *Private Label Buyer* 20: 38 (Jan. 2006), citing ACNielsen data. [Attachment G]
15/ Barry Shlachter, "What's in a label? Debate simmers over what is a 'natural' food," *Ft. Worth Star-Telegram*, July 9, 2006, citing predictions from Packaged Facts. [Attachment H]
16/ ACNielsen, Total U.S. – F/D/MM excl. Wal-Mart, 52 weeks ending June 17, 06. Additionally, 56 percent of all consumers have purchased "natural" products, but only eight percent purchased natural and/or organic meat. Mintel/SPINS, Nov. 2004.
17/ ACNielsen, Total U.S. – F/D/MM excl. Wal-Mart, 52 weeks ending June 17, 06.
18/ Doug Perkins, "Serving the underserved?" *Beef* 43: (Oct. 1, 2006). [Attachment I]

## E. "Natural" Preservatives Such as Sodium Lactate are Essential to Ensuring Safe "Natural" Products

### 1. Recent FSIS actions have created uncertainty as to the compatibility of "natural" foods that contain preservatives

FDA's long-standing policy on "natural" claims prohibits artificial or synthetic ingredients generally, and the Agency has made it clear that products bearing "natural" claims may not contain chemical preservatives. 19/ FSIS's policy is similar yet it specifically prohibits the use of "chemical preservatives" – synthetic ingredients commonly derived from petrochemicals. Nevertheless, several actions taken by FSIS in late 2006 have changed the Agency's "natural" policy to suggest that the use of natural preservatives is no longer compatible with the term. The abrupt shift in policy, apparently intended to stay in place for the next several years while rulemaking is attempted, is of great concern.

In October 2006, Hormel Foods Corporation submitted a petition to FSIS requesting the Agency to initiate rulemaking to define the term "natural" by regulation. 20/ In conjunction with initiating this rulemaking process, in late 2006, FSIS revised its "natural" policy to redefine the term "chemical preservative" in a manner that prohibits the use in "natural" products of any ingredients that exhibit antimicrobial (i.e., preservative) effects. 21/ Specifically, the use of sodium lactate, an ingredient derived from corn that is used for both flavoring and antimicrobial purposes, was at the center of this change. FSIS also sent letters to food manufacturers currently utilizing sodium lactate and other natural antimicrobials in "natural" products requesting them to demonstrate that these ingredients do not have preservative effects in these foods. These actions are a direct departure from the long-standing FSIS "natural" policy that allowed the use of sodium lactate and other natural preservatives in "natural" meat and poultry products.

The recent actions by FSIS to restrict the use of preservatives in "natural" products also creates substantive differences between FSIS and FDA's "natural" policies. We firmly believe "natural" claims should be regulated in a manner that allows for the consistent commercial processing and distribution of all food products, regardless of the Agency jurisdiction under which they are regulated. As such, differences between the two Agencies' policies as to the definition of "chemical preservative" should be eliminated.

Moreover, we are unaware of any basis for concluding that a naturally-derived preservative is incompatible with consumer expectations. The Hormel petition makes reference to consumer research, but the references do not support many of the assertions presented. In fact,

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19/ *See, e.g.,* Letter from Thomas Hooker, FDA, to Ronald Quibell, Quibell Corporation (Jul. 20, 1992).

20/ *See* Hormel Foods Corp., "Petition for the Issuance of a Rule Regarding Natural Label Claims" (Oct. 9, 2006, revised Oct. 25, 2006) ("Hormel Petition") available at: http://www.fsis.usda.gov/Regulations_&_Policies/Petition_Natural_Label_Claims/index.asp. [Attachment J]

21/ U.S. Department of Agriculture, Food Safety and Inspection Service, "Natural Claims" in *Food Standards and Labeling Policy Book* (revised Nov./Dec. 2006).

there is only one direct reference to consumer research regarding the presence of preservatives in "natural" products: "The term [natural] indicates the absence of artificial colors, artificial fragrances, preservatives, and synthetic functional ingredients." 22/ Not only does the cited study used to substantiate this statement focus on "natural" claims on personal care products, which are not necessarily relevant to foods, but the study was misquoted by deleting the word "synthetic" from qualifying "preservatives," which materially impacts the conclusion drawn from the study. 23/

The FSIS Notice and the Hormel petition's references are of concern because the issues are generally framed in the context of sodium lactate and the National Organic Program's National List. While important, a policy review must account for the myriad of contexts in which "natural" is used for FDA and FSIS-regulated foods. 24/

**2. Sodium lactate and other natural preservatives are appropriate for use in "natural" products**

In creating a uniform "natural" policy, FDA and FSIS should recognize that natural preservatives and other traditional preservative ingredients are consistent with "natural" claims. Natural preservatives, such as sodium lactate sourced from corn, are derived from plants, animals, and/or microflora and, thus, are "natural" ingredients. That some of these ingredients may also provide antimicrobial or other preservative effects should be viewed as a food safety benefit and not a means to classify them as "chemical preservatives."

Certainly, the traditional preservative ingredients – such as salt, vinegars, vegetable extracts, spices, wood smoke – serve a preservative function and yet should not be prohibited from inclusion in a "natural" product. Likewise, other "natural" ingredients that have antimicrobial or other preservative properties are consistent with "natural" claims. 25/

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22/ Hormel Petition, *supra* note 21 at 8.

23/ *See* Lambros Kromidas, "Making natural claims for personal care products: there are no regulatory guidelines, but the industry should put aside their varying interests and consider what consumers expect from products that make various 'natural' claims and formulate their products accordingly," *Household & Pers. Products Industry* 41: 55 (Dec. 1, 2004). [Attachment K]

24/ "Natural cheese" offers a compelling example. USDA has authored guidelines for making natural cheeses. At the same time, the new FSIS policy would likely prohibit "natural cheese" notwithstanding distinct USDA guidance to the contrary.

25/ In contrast, many other preservative ingredients do not comport with a "natural" claim. For example, butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) are known "chemical preservatives" that are derived from petrochemicals such as 4-methoxyphenol, isobutylene, and p-cresol. BHA and BHT are safe and suitable for use in foods, but their synthetic nature rightfully prohibits their inclusion in "natural" products. In addition, BHA and BHT would not normally be expected in a "natural" food.

## F. FDA and FSIS Must Adopt a Policy that Maximizes the Safety of "Natural" Products

The food industry and the governing agencies have made tremendous strides in improving the food supply and reducing contamination from bacteria like *E. coli* O157:H7, *Salmonella enteritidis*, and *Listeria monocytogenes*. Nevertheless, we are concerned that the recent actions taken by FSIS could undermine the success achieved to date in managing the food safety risks of these foods.

Not only are the agencies mandated by their governing statutes to ensure a safe and wholesome food supply, but consumers expect "natural" products to be as safe and wholesome as any other food product. As provided in the FMIA and in the PPIA, "[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products [and poultry products] distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 26/ A viable "natural" policy must reflect this statutory mandate and consumer expectation. We view the recent FSIS change in its "natural" policy as unwittingly compromising this vital, primary safety mandate.

"Natural" should be defined in a manner that encourages and allows for the use of traditional and new approaches to enhancing food safety, provided these approaches are consistent with the proposed uniform policy. The proposed uniform definition would advance food safety by allowing food manufacturers to use natural preservatives, which are appropriate food safety tools that have been utilized in "natural" foods for years. New technologies such as high pressure processing (HPP) might be appropriate for "natural" products, but FSIS should not at the same time foreclose valuable food safety tools that are both affordable and effectively employed by numerous food companies of all sizes.

## G. "Natural" Should be Defined by Policy Rather Than Regulation

A flexible "natural" policy cannot be accomplished through rulemaking due to the unique nature of the term. The need for flexibility is driven by the numerous contextual meanings "natural" has across the diverse types of food products regulated by FDA and FSIS. The very nature of "natural" (whereby its meaning is drawn from the context in which it is used) forecloses a static, fixed definition adopted through notice-and-comment rulemaking. 27/ Thus, we respectfully oppose the several requests for rulemaking contained in petitions submitted to FDA and FSIS over the past year and the tentative decision to initiate rulemaking on "natural" claims by FSIS.

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26/ 21 U.S.C. § 602; 21 U.S.C. § 451. As such, FSIS has the authority to inspect meat products and poultry products and to issue regulations governing the production, storage, and handling thereof. 21 U.S.C. §§ 603 -606, 608; 21 U.S.C. §§ 455-456.

27/ Sara Lee Corporation has supported many rulemaking initiatives of FDA and FSIS. Generally, we view rulemaking as an optimal way to establish regulatory policy. We oppose rulemaking for "natural" simply because it does not allow the Agencies the flexibility needed to interpret the context in which the term is used.

Prior attempts to establish a definitive regulation have proven unsuccessful over the past 30 years. The FTC first addressed this issue in 1974 and ultimately ceased its efforts in 1983. In noting the difficulties with defining the term, the Agency stated "the context in which 'natural' is used determines its meaning" and "it is unlikely that consumers expect the same thing from a natural apple as they do from a natural ice cream." 28/ Moreover, FDA and FSIS joined the FTC in 1978 to hold public hearings on a variety issues, including the definition of natural. These proceedings resulted in no formal regulation but served to instigate FDA and FSIS's adoption of policy approaches. 29/ Finally, FDA solicited comments on several issues related to "natural" when conducting rulemaking to implement the NLEA in the early 1990s, but "none of the comments provided FDA with a specific direction to follow for developing a definition" to regulate use of the word "natural." 30/ As recently as 2005, the Agency stated that it has not seen fit to "move away from [its] current policy." 31/

Prohibiting false and misleading "natural" claims has worked without the existence of a formal, codified regulation. FDA's policy approach for "natural" claims has proven successful, with the Agency enforcing its natural policy through the issuance of warning letters. Throughout the past two decades, FSIS has "modified its guidance on occasion to make it consistent with prevailing policies, to reflect case-by-case decisions made by the Agency, and to update references to regulations." 32/ FSIS has effectively enforced the Agency's policy over the years by reviewing "natural" claims on a label-by-label basis during the prior label approval process. The Agencies have adopted by necessity the only viable approach: flexible policies. The myriad of appropriate uses of "natural" simply cannot be captured in a single, static regulation.

We have noted to FSIS that it certainly should not to be faulted for considering rulemaking as a response to the Hormel petition requesting it. The transparent, orderly process of rulemaking typically benefits all stakeholders. However, the very nature of the term "natural" presents a circumstance where rulemaking simply will not work. Based on the Agencies' experience over the past 30 years, and the pressing need to devote resources to rulemaking that are necessary, we have recommended that FSIS withdraw this proposal.

## IV. ENVIRONMENTAL IMPACT

The action requested by the petition is not expected to have a significant effect on the quality of the human environment and is subject to categorical exclusion under 21 C.F.R. § 25.32(a).

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28/ "Termination of Proposed Trade Regulation: Rule on Food Advertising," 48 Fed. Reg. 23270 (May 24, 1983).

29/ "Food Labeling; Tentative Positions of Agencies," 44 Fed. Reg. 75990, 76012 (Dec. 21, 1979).

30/ 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

31/ Letter from Margaret O'K. Glavin, Assoc. Comm'r for Regulatory Affairs, FDA, to Antonio Zamora (Dec. 12, 2005).

32/ 71 Fed. Reg. 70503, 70504 (Dec. 5, 2006).

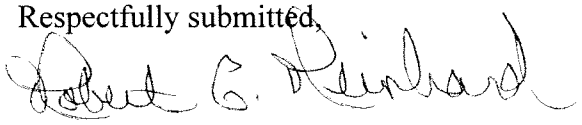
## V. CONCLUSION

For the reasons described above, Sara Lee Corporation requests FDA to work with FSIS to devise and adopt a uniform policy governing the use of the term "natural." A common approach would simplify the marketplace for consumers and food manufacturers alike and would foster the Agencies' statutory mandates to avoid food labeling that is false and misleading. A uniform, flexible "natural" policy will allow the term to be assessed in a context-specific nature that cannot be considered by a static definition established through notice-and-comment rulemaking.

## VI. CERTIFICATION

The undersigned certifies 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 that are unfavorable to the Petition.

Respectfully submitted,



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