§ 170.3(o)(20) of this chapter and as a color fixative for ripe olives, with no other limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

* * * * *

Dated: July 19, 1996.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–19305 Filed 8–1–96; 8:45 am]

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21 CFR Part 101

[Docket No. 93N–0153]

RIN 0910–AA19

Food Labeling; Nutrient Content Claims and Health Claims; Restaurant Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to remove the provisions that exempt restaurant menus from the requirements for how nutrient content claims and health claims are to be made and from the requirements for the provision of nutrition information with respect to the nutrients that are the basis for the claim, when claims are made. Because a significant number of meals are consumed outside of the home, the extension of these requirements to menus will help to increase the awareness of the American consumer to the relationships between diet and health. FDA is issuing this final rule at this time in response to a decision by the United States District Court for the District of Columbia.

DATES: This regulation is effective May 2, 1997. Written comments on the information collection requirements should be submitted by October 1, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Persons who believe it would be useful for the agency to hold a public meeting on what is required by this rule should also send their letters to the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Requirements for Nutrition Labeling and Nutrient Content Claims and Health Claims

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and the final regulations that implement the 1990 amendments (58 FR 2066, January 6, 1993, as modified at 58 FR 44020, August 18, 1993) provide for a number of fundamental changes in how food is labeled, including mandatory nutrition labeling on most foods, uniform definitions for terms that characterize the level of nutrients in a food, and the use of claims about the relationship between nutrients and diseases or health-related conditions. These changes apply to virtually all foods in the food supply, including foods sold in restaurants.

The provision on nutrition labeling that was added to the Federal Food, Drug, and Cosmetic Act (the act) by the 1990 amendments, section 403(q) (21 U.S.C. 343(q)), includes an exemption for foods that are served or sold in restaurants or other establishments in which food is served for immediate human consumption (section 403(q)(5)(A)(i)). This exemption, however, is contingent on there being no claims or other nutrition information on the label or labeling, or in the advertising, for the food. The use of nutrient content claims, health claims, or other nutrition information on the label or labeling of a food sold in a restaurant or other establishment in which food is served for immediate consumption will subject that food to the nutrition labeling provisions of the act (see sections 403 (q) and (r) of the act and § 101.9 (j)(2)(i) through (j)(2)(iii) (21 CFR 101.9 (j)(2)(i) through (j)(2)(iii))). Consistent with these provisions, in this discussion the term ''restaurant foods'' refers to foods served in restaurants and in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering) or sold only in such establishments. Firms selling such foods will be referred to as ''restaurants,'' and responsible individuals in these firms will be referred to as ''restaurateurs.''

In the January 6, 1993, final rules on nutrient content claims and health claims (entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'' (58 FR 2302); and ''Food Labeling; General Requirements for Health Claims for Food'' (58 FR 2478), respectively (hereinafter referred to as the ''nutrient content claims final rule'' and the ''health claims final rule,'' and collectively, as the ''claims final rules'')), the agency concluded that if claims on restaurant foods are to be useful to consumers, they must be valid. Thus, FDA stated that the same standards will apply to restaurant foods as to other foods with respect to basic definitions for nutrient content claims. FDA also stated that when a restaurant makes explicit or implied reference to a food or substance in food, and directly or indirectly links that substance to an effect on a disease or health-related condition (i.e., when both basic elements of a health claim are present), the restaurant must comply with the health claims regime (58 FR 2478 at 2516). At the same time, FDA acknowledged that how a restaurant demonstrates compliance with these requirements is a difficult matter. FDA pointed out, in the claims final rules (58 FR 2302 at 2386 and 58 FR 2478 at 2515), that it is not obligated under the act to regulate claims on restaurant foods in a manner identical to that in which it regulates claims on packaged foods. In the nutrient content claims final rule (58 FR 2302), the agency amended § 101.10 *Nutrition labeling of restaurant foods* (21 CFR 101.10) to provide flexibility for restaurants in determining compliance with FDA's requirements for the claims regime and in providing nutrition labeling for foods that bear a claim.

Consequently, although restaurant food must comply with the same standards as other foods to bear a claim, the way in which a restaurant determines the nutrient content of a food or meal, and the way in which nutrition information is communicated to consumers, may be different for restaurant foods than for foods from other sources. For example, § 101.10 provides that nutrient levels in restaurant foods may be determined through the use of nutrient data bases, cookbooks, or other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. For compliance purposes,

a restaurant is required to provide information on its reasonable basis for making a claim. Further, restaurants making a claim are required to provide consumers, upon request, with nutrition information on the nutrient that is the subject of the claim. However, § 101.10 provides that nutrition labeling may be presented in various forms, including those provided in § 101.45 (21 CFR 101.45) for raw fruit, vegetables, and fish, or by other reasonable means.

Thus, although FDA encourages restaurants to provide full nutrition information according to § 101.9 whenever possible, the agency has determined that information on the nutrient amounts that are the bases for claims (e.g., if the claim is a ''low fat'' claim, the nutrition information must only state that ''this meal provides less than 10 grams of fat'') may, in a restaurant setting, serve as the functional equivalent of complete nutrition information as described in § 101.9. Further, this information may be provided by reasonable means, e.g., in a flier, brochure, poster, notebook, or orally. FDA concluded that these flexibilities (e.g., the ''reasonable basis'' criterion) would help to ensure that a restaurateur is provided with a readily achievable way to make claims for his or her food, while the consumer is provided with a reasonable assurance that the claim is valid (58 FR 2302 at 2387 and 58 FR 2478 at 2516).

The claims final rule contained two additional provisions. First, § 101.13(q)(5) (21 CFR 101.13(q)(5)) exempts nutrient content claims made on menus from the requirement that such claims comply with the requirements and definitions governing nutrient content claims. There is a similar provision with respect to health claims made on restaurant menus in §§ 101.10 and 101.14 with respect to nutrition labeling requirements for a restaurant food that makes a nutrient content claim or a health claim. The agency's decision to exempt restaurant menus from the requirements for nutrient content claims and health claims was based, in part, on the frequency with which menus change (sometimes daily) (58 FR 2302 at 2388 and 58 FR 2478 at 2517).

Second, because of concerns about the demands that the new labeling requirements would impose on small restaurants, FDA decided to use its enforcement discretion to delay for 1 year the effective date of its regulations governing the use of claims by these firms. The agency defined ''small restaurants'' as ''restaurant firms consisting of 10 or fewer establishments'' (58 FR 2302 at 2388 and 58 FR 2478 at 2517). Consequently, FDA provided that its requirements for health claims and nutrient content claims on restaurant labeling (except menus) would be effective on May 8, 1993, and May 8, 1994, respectively, for other than small restaurants (i.e., restaurant firms with more than 10 establishments), and on May 8, 1994, and May 8, 1995, for small restaurants.

FDA concluded that these additional measures of flexibility would help to ensure that restaurants, especially small restaurants, would not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. It is the latter two decisions that FDA decided to reconsider.

B. Decision to Reconsider

Among the final rules that FDA issued in the Federal Register of January 6, 1993, was one entitled ''Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments'' (58 FR 2066) (hereinafter referred to as the ''implementation final rule''). Among other things, the implementation final rule provided 30 days for the submission of comments on technical issues, such as inconsistencies or unintended consequences of specific provisions not raised in earlier comments. Two comments received during the technical comment period criticized the menu exemption and questioned its legality under both the 1990 amendments and the Administrative Procedure Act (the APA). One comment received during the technical comment period maintained that the effort required for small restaurants to comply with the new labeling requirements is no different from that required by medium and large restaurants. Another comment argued that delaying the effective dates for small restaurants is not consistent with the 1990 amendments.

After careful consideration of the comments and further study of the administrative record, the agency decided to reconsider these provisions. Based on its reconsideration, in the Federal Register of June 15, 1993 (58 FR 33055), FDA proposed to remove the exemption for menus from the coverage of the claims provisions. In this proposed rule (hereinafter referred to as the June 15, 1993, proposed rule), FDA tentatively concluded that the menu exemption is not consistent with the act or with the statutory charge provided by the 1990 amendments. FDA stated that it was concerned that health claims and nutrient content claims in menus will be of little utility if they fail to comply with the standards in the claims regulations, which are designed to ensure the validity of these claims. Further, FDA stated that the menu exemption could create a situation in which confusion about the valid information provided by authorized claims in non-menu labeling would result from the use of unauthorized claims in menus. FDA emphasized that (except for the deletion of the menu exemption) the proposed amendments do not alter the substance or status of the current regulations governing the use of nutrient content claims and health claims in restaurants (58 FR 33055 at 33057). Finally, the agency noted that it is virtually impossible to distinguish menus from other types of restaurant labeling, such as signs, placards, and other point of purchase information, that are covered by the claims final rules.

FDA also tentatively concluded that, in establishing dates of applicability for its requirements, it had no reasonable basis for differentiating among restaurants based on size. Consequently, the agency proposed to remove the provisions that delayed by 1 year the effective dates for compliance for small restaurants. However, because the agency was unable to publish a final rule before the May 8, 1994, and May 8, 1995, compliance dates for non-menu labeling, this aspect of the proposal, i.e., to shorten the delay in effective dates for small restaurant firms, is moot. Therefore, FDA is withdrawing that aspect of its June 15, 1993, proposed rule.

In deciding whether to publish a final rule, several concerns were raised for the agency's consideration. These concerns involved evaluation of the extent to which the nutrient content claims and health claims that were being made on restaurant menus failed to meet FDA's definitions, and of whether consumers were experiencing confusion or were concerned about variations between the labeling of restaurant and packaged foods. Concerns were also raised about whether both nutrient content claims and health claims needed to be covered, about whether the regulations would cause restaurants to stop making claims and/or the associated foods, and about what the effect of the regulations would be on small restaurants.

Before the agency had fully resolved these issues, other events intervened. As noted in the June 15, 1993, proposed rule, FDA had been sued by two public interest groups and two individuals on the grounds that the menu exemption violates the 1990 amendments and the Administrative Procedure Act *(Public*

Citizen, Inc., et al. v. *Shalala,* Civil Action No. 93 0509 (D.D.C.)). On June 28, 1996, the court declared that the parts of the regulations that exempted restaurant menus from the nutrient content claim and health claim provisions of the 1990 amendments are contrary to the statute and ordered FDA to amend its regulations to include menus. Therefore, FDA is issuing this final rule. However, as explained below, in doing so, the agency remains committed to ensuring that the changes made by this final rule do not adversely affect either small restaurants or the flow of information from restaurant menus to consumers.

II. Comments

The agency received 37 letters, each containing 1 or more comments on its June 15, 1993, proposed rule, from consumers and consumer groups, restaurateurs, trade associations, registered dieticians, academia, and State officials. Some letters supported the proposal to delete the exemption for restaurant menus, stating, for example, that exempting restaurant menus that make claims from the new labeling requirements would undermine the ability of consumers to make improved dietary choices. Conversely, other letters opposed applying the new labeling requirements to restaurant menus, stating that the requirements are burdensome and not appropriate for a restaurant situation. Many of these comments, however, expressed confusion as to how the agency would implement its requirements with respect to restaurant foods.

In response to the latter comments, FDA prepared a guidance document on the labeling of restaurant foods. The agency announced in the Federal Register of September 19, 1995 (60 FR 48516), the availability of the guidance document. The agency also published, as an appendix to that notice of availability, answers to some of the most frequently asked questions. The guidance document, entitled ''Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments,'' explains how FDA will implement its requirements for restaurant labeling that bears a health claim or characterizes the level of a nutrient in a food.

Several comments addressed issues that are outside the scope of this rulemaking, such as modifying the criteria for nutrient content and health claims set out in the claims final rules. These comments are not responded to in this document. A summary of the comments that did address the proposal, and the agency's responses, follow.

A. Menu Exemption

1. A number of comments supported the proposal, stating that FDA is legally bound to include menus under the 1990 amendments. Comments stated that restaurant menus are labeling under the act and appropriate case law and, as such, are covered by the 1990 amendments. Comments further stated that Congress neither provided for nor intended an exemption for menus, and, therefore, FDA cannot grant one.

Other comments cited the importance of restaurant foods in the American diet, stating that applying the requirements of the 1990 amendments to menus would play a critical role in the ability of consumers to make healthy dietary choices. Comments maintained that menus are the primary means by which a consumer discovers information about the foods available in a restaurant. Thus, these comments argued, the new labeling requirements should apply to all types of restaurant labeling, including menus. As evidence of the need to apply the new requirements to restaurant menus, several comments submitted menus that, in their opinion, bear claims that do not comply with FDA's requirements.

Conversely, a number of comments maintained that many restaurateurs currently offer ''healthier'' menu items and promote the nutritional quality of these foods to consumers in a variety of ways that are truthful and not misleading. These comments maintained that applying the requirements of the 1990 amendments to restaurant menus is redundant and unnecessary because restaurant menus are already covered by section 403(a) of the act. Several comments stated that menus are also regulated by States and, because they are considered to be advertising, by the Federal Trade Commission (FTC).

FDA agrees that many restaurants currently provide consumers with useful information in a way that is not inconsistent with FDA's new requirements. Nonetheless, FDA concludes, based at least in part on the act, that it is necessary to make the proposed changes. Thus, the agency disagrees with the comments that state that applying the requirements of the 1990 amendments to restaurant menus is redundant and unnecessary.

As stated in the nutrient content claims final rule (58 FR 2302 at 2388), before the 1990 amendments, when restaurants provided nutrition information they were subject to § 101.10, FDA's pre-1990 amendment nutrition labeling regulation. FDA enforcement of that regulation was virtually nonexistent, however. Further, while section 403(a) of the act prohibits labeling that is ''false or misleading in any particular,'' section 403(r) provides for requirements with respect to claims that are in addition to those established in section 403(a) of the act. FDA's statutory charge under the 1990 amendments is to ensure that nutrient content claims and health claims made for food accurately characterize the food and are scientifically valid. Finally, although FTC has jurisdiction over national advertising, restaurant menus are more akin to labeling than advertising in their use and function. Thus, they are appropriately included within the regulatory scheme designed for food labeling.

FDA notes that restaurant foods are an important part of the food supply. As stated in the nutrient content claims final rule (58 FR 2302 at 2387), as much as 30 percent of the American diet is composed of foods prepared in food service operations. The agency agrees with comments that menus are a primary source of information for consumers making purchase decisions in a restaurant or other establishment where food is sold for immediate consumption.

In the claims final rules, the agency justified the menu exemption on the grounds that it will help ensure that restaurants are not deterred by the requirements of the 1990 amendments from providing useful nutrition-related information. FDA also noted that fast food chains and other restaurants frequently use non-menu media, such as posters and placards, to convey nutrition information to consumers, and stated that it would focus its efforts on these media. However, FDA notes that menus are used to present information about the choices available in a restaurant or other establishment in which food is served for immediate consumption. Consequently, FDA concludes that menus that bear a nutrient content claim, health claim, or other nutrition information have a significant bearing on the ability of consumers to select foods that are useful in maintaining healthy dietary practices. Therefore, FDA finds that claims on restaurant menus should be subject to the same standards as claims on other food labels and in labeling.

FDA finds that, if it were to maintain the exemption for restaurant menus, it would have no specific criteria for determining whether a nutrient content claim made in a menu appropriately describes the food, or for determining whether a health claim is scientifically valid. Consequently, there would be no assurance that claims made in

restaurant menus are consistent with claims on other restaurant labeling or on the labeling of other foods, or that such claims would help consumers select foods that are useful in maintaining healthy dietary practices.

On further review of the legislative history, FDA noted that section 405 of the act (21 U.S.C. 345), which authorizes exemptions to the act, was amended by the 1990 amendments to state: ''This section does not apply to the labeling requirements of section 403(q) and 403(r).'' Because the menu exemption is an exemption from section 403(r) of the act, FDA tentatively concluded that it is barred by section 405 of the act.

FDA also noted that section 403(r)(5)(B) of the act limits the extent to which the nutrient content claims and health claims provisions of the act apply to restaurants by, e.g., exempting restaurant foods from certain disclosure statements that apply to claims on packaged food labels. In its discussion of whether Congress intended to apply the 1990 amendments to restaurant menus (58 FR 33055 at 33056), the agency cited a sponsors' report explaining this section. That report stated that restaurants that use nutrient content claims in connection with the sale of a food must comply with regulations issued by the Secretary of Health and Human Services under section 403(r)(2)(A)(I). In that report, the sponsors specifically gave the example of the use of the word ''light'' or ''low'' on a menu as the type of labeling that must comply with FDA's requirements (136 Congressional Record H5841 (July 30, 1990)). This part of the bill was passed by the Senate unchanged. Thus, FDA concludes that the menu exemption is not consistent with the congressional intent in adopting the 1990 amendments, and that there is no basis for exempting menus from the coverage of section 403(r) of the act. (See also *Public Citizen* v. *Shalala, supra*.)

2. A number of comments stated that consumers' need for useful nutrition information outweighs any burden that the requirements might place on restaurants making claims on their menus. One comment stated that it did not believe that the new requirements would be burdensome for restaurants because, according to the comment, a ''good'' restaurant ordinarily keeps track of ingredient quantities to evaluate food preparation costs. Several comments stated that ample resources exist to aid restaurants in developing menu items that comply with FDA's requirements. They noted that applying the new requirements to menus would not interfere with a restaurant's ability to provide dietary guidance on a menu, e.g., to identify those foods with a nutrient content such that the food could be helpful to consumers in achieving a diet consistent with the dietary guidelines of a professional health organization.

A number of comments stated that it is important that claims be used in a consistent manner across the food industry. One comment argued that exempting menus from the nutrient content claims and health claims provisions would create an uneven playing field between restaurateurs and food processors. Another comment maintained that the need for a single rule for the use of claims is further evidenced by FTC's decision to adopt FDA's definitions for nutrient content claims.

Conversely, a number of comments stated that the menu exemption provides critical flexibility to the restaurant industry. Comments cited numerous differences between restaurant foods and standardized, processed foods, including: Ingredient supply sources, methods of preparation, and marketing. One comment stated that many food service operations find the new regulations to be burdensome and poorly suited to the food service industry. Another comment argued that the nutrition labeling regulations would impose a greater burden on restaurants than on food manufacturers because restaurants may change their menus more than once a day, for example, between lunch and dinner. Several comments stated that revoking the menu exemption would create a barrier to the dissemination of beneficial information to the consumer, would increase the cost of creating and promoting nutritionally improved foods, and would ultimately limit the number of nutritionally improved foods in restaurants.

In response to comments that compliance with the requirements of the 1990 amendments will be burdensome, FDA notes that these rules place no affirmative requirements on restaurants that do not make claims. In other words, a restaurant would be in complete compliance with the new regulations if it simply refrained from making a nutrient content claim or a health claim. However, FDA does not believe such a situation would be the most desirable outcome.

As stated in the nutrient content claims final rule (58 FR 2302), two of the goals of the 1990 amendments are to provide for information that can assist consumers in maintaining healthy dietary practices and to encourage product innovation through the development and marketing of improved foods. FDA has concluded that, for information to be useful to consumers, nutrient content and health claims must be valid. At the same time, the agency has recognized that there are sources of variation unique to restaurant foods (e.g., methods of preparation). Consequently, to ensure that the new requirements do not place an unreasonable burden on restaurants, FDA has included a number of provisions to provide flexibility in how these requirements can be met in a restaurant situation. For example, as stated above, §§ 101.13(q)(5)(ii) and 101.14(d)(2)(vii)(B) provide that a restaurant may make a nutrient content claim or a health claim for a food as long as it has a ''reasonable basis'' for believing that the food contains the requisite level of the nutrient in question (58 FR 2302 at 2387 and 58 FR 2478 at 2516). The ''reasonable basis'' criterion provides that nutrient content levels may be determined by use of nutrient data bases, cookbooks, analyses, or other sources that provide reasonable assurance that the food meets the criteria for a claim.

FDA also notes that restaurants may develop and market menu items that help consumers to achieve certain dietary goals without subjecting the food to the requirements of the 1990 amendments. For example, restaurants may offer alternative selections whose value in a diet that conforms to dietary guidelines may be recognized by consumers without elaboration, e.g., raw vegetables, steamed vegetables, pasta with a tomato based sauce instead of a cream sauce, a grain dish, or a fresh fruit plate. Optional preparation or serving methods may be highlighted on menus by statements such as ''may be prepared with half the oil on request,'' ''smaller portions,'' or ''dressings and sauces available on the side.''

Further, foods that meet the dietary guidelines of a recognized dietary authority or health professional organization may be highlighted without subjecting the food to the nutrient content claims regime, provided the statement that a food meets dietary guidelines does not go on to characterize the level of a nutrient in the food (§ 101.13(q)(5)(iii)). For example, a restaurateur may signal to consumers by the use of a term or symbol that a meal is formulated in complete accordance with the Dietary Guidelines for Americans (e.g., moderate calories, less than 30 percent of calories from fat, less than 10 percent of calories from saturated fat, emphasis on vegetables, fruits, and grain products,

and moderate use of sugars and sodium). Likewise, dietary guidance that, within the context of the labeling, does not meet the definition of a health claim, i.e., does not include both the food or substance element and the disease-related element (e.g., ''eating five fruits and vegetables a day is an important part of a healthy diet''), would be considered dietary guidance and not a health claim subject to section 403(r) of the act (§ 101.14(a)(1)). FDA advises that foods bearing statements outside the coverage of section 403(r) of the act are still subject to section 403(a) of the act, which requires that the label be truthful and not misleading, and to section 201(n) of the act which describes the circumstances in which labeling is misleading.

The agency acknowledges that a significant effort will be required on the part of some restaurants to examine their meals and menus to ensure that they are in compliance with the new regulations. However, many of the comments that argued that the requirements for nutrient content claims and health claims would be burdensome for restaurants consistently evidenced a significant misunderstanding of the relevant provisions, such as the application of ''reference amounts customarily consumed'' and the need for a ''reference food'' when making some types of claims. For example, several comments seemed to believe that restaurants would be forced to alter their portion sizes to be identical to the established reference amounts. Another comment expressed the belief that restaurants would be required to declare the serving size of its food as the same as the reference amount, even if the amount served differed from the reference amount. A number of comments expressed concern that restaurateurs would be required to develop recipes for, analyze, and market, a reference food for every food that bears a claim. Several comments maintained that there is not enough room on menus to provide the nutrition information that they assumed FDA would require.

The agency advises that there is no basis for the concerns expressed by these comments. In a January 6, 1993, final rule, entitled ''Food Labeling; Serving Sizes'' (58 FR 2229) (hereinafter referred to as the ''serving size final rule''), FDA defined reference amounts, and the serving sizes derived from them, on the basis of the amount of food customarily consumed per eating occasion (reference amount customarily consumed or ''reference amount'') in order to facilitate comparison of the nutrient content of similar foods. FDA established reference amounts for 139 food product categories (§ 101.12 (21 CFR 101.12)). The agency provided that, in order to make certain nutrient content claims or health claims, a food must meet the criteria for the claim based on the amount of the particular nutrient present in the reference amount of the food. For example, the reference amount for all soups is 245 grams (g) based on a serving size of 1 cup. However, restaurants may offer soup in more than one portion size, e.g., by the cup and by the bowl. In order to bear a ''low fat'' claim a cup of soup may contain up to 3 g of fat per reference amount (245 g). If this same soup is served to customers in a bowl that contains 367 g of soup (367 g serving/ 245 g per reference amount for all soups = 1.5), it may contain up to 4.5 g of fat (3 g of fat per reference amount x 1.5 = 4.5 g of fat) and still be labeled ''low fat.''

Criteria for claims on meals and main dishes (as defined in § 101.13(l) and (m)) are generally based on the level of a nutrient in 100 g of the food. For example, a ''low fat'' meal weighing 333 g can contain up to 10 g of fat (333 g serving /100 g = 3.3; 3 g of fat per 100 g of food x 3.3 = 10 g of fat). Again, a restaurant serving a larger portion of a meal or main dish item is not at a disadvantage compared to other food sources when making a ''low fat'' claim. FDA advises, however, that some claims, e.g., ''free'' claims and cholesterol claims, have additional criteria based on the labeled or actual serving size. The criteria for specific nutrient content and health claims are set out in part 101 (21 CFR part 101).

FDA advises that it is not necessary for restaurants to produce and market a reference food in order to sell a food that bears a claim. Reference foods are necessary only for comparative nutrient content claims, i.e., claims about the level of a nutrient in one food compared to another, such as ''reduced sodium'' or ''less fat.'' Provisions for the use of data bases and other means to determine nutrient values for an appropriate reference food are set out in § 101.13(j)(1)(ii). FDA also advises that, while restaurants are required to provide nutrition information on request for foods that make a claim, FDA is providing considerable flexibility in § 101.10 as to the type of nutrition information that must be provided and on how this information can be provided. For example, in a restaurant situation, nutrition information may be presented in various forms, including those provided in § 101.45 and by other reasonable means (e.g., using posters, fliers, brochures, notebooks, or communicated orally by restaurant staff). In sum, FDA notes that the types of misconceptions presented by these comments have resulted in a perception of burdens that do not in fact exist.

Given the flexible provisions, such as the ''reasonable basis'' criterion that the agency set out in the claims final rules, FDA concludes that most restaurants that wish to make claims will be able to do so. Further, as stated in several comments, many resources, including Federal, State, and local governments; professional health organizations; and dietary professionals, are available to aid restaurants in their efforts to comply with FDA's requirements. Moreover, as stated above, FDA has made available the labeling guidance document to assist restaurants and other retail establishments in developing or revising their labeling to comply with the new requirements.

Although these resources will likely be sufficient to meet the needs of restaurateurs for information, FDA is willing, if necessary, to take other steps to help restaurants, particularly small restaurants, to understand and respond to the requirements established in this final rule. The agency requests that restaurateurs contact the agency (see address above) if they believe that it would be useful to have a national meeting or regional meetings to discuss what is required for health or nutrient content claims made on menus to comply with FDA's regulations. If the agency receives a sufficient expression of interest, it will hold such a meeting or meetings. If it decides to hold a meeting, FDA will provide ample notice of the time and place in the Federal Register.

While FDA acknowledges that some restaurants may discontinue offering improved food selections because menus have to comply with the requirements for claims, the agency concludes that most restaurants will continue to work to develop improved foods about which they can make claims. Consumer interest in improved food choices provides a continuing incentive for such efforts. The number of menus that currently bear claims and other nutrition information evidences the impact of consumer demand. FDA intends to work, as described above, to help restaurants to minimize the number of claims that are removed and to monitor the extent of this effect.

3. One comment argued that the First Amendment to the Constitution protects menus through its guarantee of freedom of the press. Another comment stated that FDA is not authorized to regulate restaurant foods under the Tenth

Amendment, as this power is not one provided for in Article I, Section 8, of the Constitution.

The agency disagrees. FDA's authority to regulate the content of the labels and labeling of food in interstate commerce has been broadly upheld against First Amendment and other constitutional challenges. The agency's authority to regulate food labeling, including the labeling of restaurant foods, is discussed at length in the claims final rules (58 FR 2302 at 2392 and 58 FR 2478 at 2524), which are incorporated herein by reference. The comments did not provide any information, or make any arguments, that the agency has not previously considered and found to be without merit.

4. Several comments maintained that FDA cannot legally justify reversing its policy with respect to restaurant menus. These comments maintained that FDA has received no new information or facts since the claims final rules on which to base its reconsideration. They further maintained that the proposal to delete the menu exemption without, in the comments' opinion, adequately explaining the departure from the past norm constitutes arbitrary and capricious rulemaking and is a violation of the APA.

FDA disagrees with these comments. An agency may always change its mind and alter its policies. *Conference of State Bank Examiners* v. *Office of Thrift Supervision*, 792 F. Supp. 837, 845 (D.D.C. 1992). While the burden is on the agency to justify the change from the status quo, that justification need not consist of an affirmative demonstration that the status quo is wrong. It may also consist of a demonstration that there is no cause to believe that the status quo is right, so that the existing rule has no rational basis to support it. *Center for Auto Safety* v. *Peck*, 751 F.2d 1336, 1349 (D.C. Cir. 1985).

Concern about whether a rational basis existed for the agency's rule is exactly what motivated FDA. In its June 15, 1993, proposed rule, the agency pointed out that, in confronting the issue of what defines a menu in the wake of the publication of the January 6, 1993, final rules, it found that it was virtually impossible to distinguish menus from other types of restaurant labeling, such as signs, placards, and other types of point of purchase information that are covered under the agency's rules (58 FR 33055 at 33056). Thus, the agency had ample basis to be concerned about the distinction that it had drawn in the final rules. This concern was underscored by technical comments that the agency received on the menu exemption (*id*). The conclusion that the agency has reached based on its consideration of the comments that it received on the June 15, 1993, proposed rule is that there is, in fact, no rational basis for distinguishing menus from other types of restaurant labeling, and, therefore, FDA is revoking the provisions that established that distinction.

5. One comment objected to what it perceived as the agency's inability to define menus in the June 15, 1993, proposed rule. The comment maintained that this problem was not a reasonable basis for deleting the menu exemption. The comment argued that, at the least, FDA should issue an advanced notice of proposed rulemaking on this issue.

FDA believes that the comment misinterpreted the agency's statement in the June 15, 1993, proposed rule (58 FR 33055 at 33056), about distinguishing between menus and other restaurant labeling. FDA did not say that it could not define menus, but rather, that the agency found that it is virtually impossible to distinguish menus from other types of restaurant labeling, such as signs, placards, and other point of purchase information, that the agency said in the claims final rules would be covered.

The agency notes that if its problem were one of defining ''menu,'' it has numerous sources to which it could turn. Webster's II New Riverside University Dictionary defines ''menu'' as ''A list of the food and drink available or to be served for a meal.'' Comments received during the 30-day technical comment period to the claims final rules provided additional guidance, stating that a menu ''includes any medium available to consumers in a restaurant that can be consulted in making a purchasing decision in terms of food selection or price.'' One comment stated that ''A broad range of formats are used to convey selection and price information on which consumers rely. These formats are all properly ''menus'.''

However, the problem that the agency stated that it was having in June of 1993 was one of drawing a rational distinction that would justify its treatment of menus on the one hand and of other types of restaurant labeling on the other. Such a distinction is particularly difficult to draw given that some of the same types of restaurant media that FDA said were covered in the claims final rules, e.g., signs, posters, and placards, are used, like menus, to convey purchase information to consumers. Both menus and non-menu media may be used to provide restaurant patrons with information about the foods available in a restaurant.

Accordingly, for the foregoing reasons, FDA is amending its food labeling regulations by removing the provisions of the regulations that exempt nutrient content claims and health claims made on restaurant menus from the coverage of these regulations. Specifically, FDA is amending the regulations by removing: (1) From § 101.10, pertaining to nutrition labeling of restaurant foods, the language that reads ''* * * (except on menus)''; (2) from § 101.13(q)(5), pertaining to nutrient content claims on restaurant foods, the language that reads ''* * * (except on menus)''; and (3) from § 101.14(d)(2)(vii)(B), pertaining to health claims on restaurant foods, the language that reads ''* * * (except if the claim is made on a menu).'' Thus, the requirements of FDA's food labeling regulations will be applied to all forms of restaurant labeling, including menus, signs, posters, or placards, that bear a nutrient content claim, health claim, or otherwise characterize the level of a nutrient in a food.

6. One comment suggested that FDA specify that the term ''menu'' applies to all types of menus, including wallboards, take- out menus, and menus delivered to the table.

FDA advises that, in the claims final rules, it differentiated between menus and non-menu media by describing those media that it did not consider to be menus, e.g., posters, signs, and placards. However, as discussed in response to the preceding comment, the agency has determined that it is virtually impossible to distinguish between menus and other media that are used to convey purchase information to consumers. Therefore, FDA is amending its food labeling regulations by removing the provisions that exempt menus from the coverage of these regulations. Because the requirements will be applied to all forms of restaurant labeling that bear a claim, the issue of distinguishing between menus and non-menu labeling is rendered moot.

B. Modification of Effective Date

The claims final rules provided that regulations governing the use of health claims in restaurant labeling (other than menus) would become effective on May 8, 1993, except for small restaurant firms consisting of 10 or fewer establishments for which these provisions were to become effective 1 year later, i.e., May 8, 1994. With respect to the use of nutrient content claims and other nutrition information in restaurant labeling (except for menus), FDA's requirements were to

become effective on May 8, 1994, for medium and large restaurant firms and on May 8, 1995, for small firms.

In the claims final rules, FDA stated that it recognized that a significant effort would be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with FDA's regulations for the use of nutrient content claims and health claims. At that time, the agency believed that it would be especially difficult for small restaurants to become familiar with Federal requirements and to determine how to apply these requirements to their individual food selection and preparation methods in a short time. Consequently, FDA had decided that small restaurants should be given the additional time (i.e., 1 year) to come into compliance.

During the technical comment period, FDA received information that convinced the agency that it was appropriate to reconsider its decision to delay the effective date of the claims requirements for small restaurants. Thus, in its June 15, 1993, proposed rule (58 FR 33055 at 33057), FDA proposed to modify the delay in the effective dates for small restaurant firms. However, based in part on numerous demands associated with implementing the 1990 amendments and the agency's limited resources, this speed-up did not happen. FDA's efforts to move up those dates have effectively been rendered moot by the agency's inability to issue a final rule. Consequently, the following comments are now only relevant as they apply to restaurant menus.

1. Delay for Small Restaurants

7. One comment argued that compliance would be more difficult for small firms compared to large restaurant chains because of limited resources. The comment did not, however, provide any information that the agency had not previously considered. Another comment maintained that an extension for small restaurants is justified by the ''lack of real harm'' to the public from such a delay.

Conversely, the majority of letters that addressed the proposed modification in effective dates supported the agency's proposal to establish uniform effective dates for all restaurants. These comments maintained that there is no appropriate basis for differentiating among restaurants based on size when establishing a date by which each must comply with FDA's requirements. Thus, the comments stated, the agency should enforce its labeling requirements for large and small restaurants, at the same time. However, the comments contained numerous and varied suggestions as to when the new effective dates should be.

Having considered the comments, FDA concludes that, although there are some areas where small restaurants may be at a disadvantage compared to large restaurants, e.g., the cost of a one-time menu change relative to more limited resources, in most respects, the distinction between small restaurants and larger restaurants is not as great as the agency had believed when it issued the January 6, 1993, final rules. For example, not all restaurant firms with greater than 10 establishments are familiar with the new requirements or have established nutrition support personnel. Further, in establishing the requirements for restaurant labeling in the claims final rules, the agency worked with restaurant industry representatives to make its requirements feasible for both large and small restaurants. FDA advises that the flexibility built into these requirements, e.g., the ''reasonable basis'' criterion, provides a wide range of options for how a restaurant may determine the nutrient content of its food, and how it communicates this information to consumers. FDA finds that this flexible approach will allow most restaurants, including small restaurants, to choose options that fit their own needs and resources. Thus, FDA finds nothing in the comments that would provide a basis for differentiating among restaurants based on size when establishing a date by which restaurants must comply with these requirements.

2. Establishment of Effective Date for Menus

FDA is removing the exemption for menus that it adopted inappropriately. While, in light of overwhelming support from comments and in the absence of any new information to the contrary, FDA has concluded that the same date of applicability should apply to menus in all restaurants, regardless of size, the agency wants to be sure that the effect of its decision is not punitive for restaurants. FDA finds that it has flexibility in setting the date by which menus must comply with its requirements for claims. Thus, the agency is using that discretion in setting the date by which menus must comply with the rules on the use of claims. The issue that FDA has considered is what effective date will provide all restaurants with a reasonable amount of time to make any necessary changes in their menus while providing consumers with useful information as quickly as possible.

8. A few comments stated that restaurant menus should comply with FDA's requirements by the same date as labeling on foods from other sources, i.e., May 8, 1994. These comments stated that to delay the effective date for compliance by restaurant menus beyond May 8, 1994, would create an uneven playing field between restaurants and food processors. The comments further argued that any extension for restaurants beyond May 8, 1994, would violate the mandatory effective dates provided by the 1990 amendments. Another comment also tied the effective date for restaurant labeling with the date of applicability for other foods, except that it suggested that restaurants should have an additional 4 months after the May 8, 1994, deadline (i.e., until September 8, 1994) to bring their menus into compliance.

FDA does not agree that it must establish the same effective dates for restaurant menus as for other food labeling. As stated above, FDA must act in an equitable manner in removing the exemption for restaurant menus. Although the agency continues to strive for consistency within the framework of the 1990 amendments, this rulemaking to amend certain provisions of the January 6, 1993, final regulations cannot reasonably impose the same deadlines that the agency imposed in the final regulations implementing the 1990 amendments that it promulgated over 40 months ago. Further, the date of publication of this final rule obviously makes an effective date of May 8, 1994, moot.

9. One comment suggested that compliance with FDA's requirements begin 1 year from the date of the last menu printing. In support of its suggestion, the comment stated that many restaurants change their menus yearly, and that it would be costly for restaurants to change menus in midyear to comply with the new regulations. The comment did not, however, provide data on the number of restaurants that will need to make changes in their menus or on the number of restaurants that do not normally change their menus more than once a year.

FDA notes that restaurants vary widely in the frequency with which they print new menus. Comments to the June 15, 1993, proposed rule, stated that menus may be printed infrequently, annually, daily, or even for each meal. Given the wide variance in practices within the industry, the agency finds that establishing a compliance date that is based on a date that is a given period of time from the last menu printing would be impractical from an enforcement standpoint. It would be extremely difficult to ensure compliance with an application date that varies

from one establishment to another. In such a situation, compliance checks would require not merely looking at the labeling but also determining the date on which labels had last been revised.

Further, establishing an application date that, as it is phased in, affects only some establishments, is inconsistent with the establishment of a single effective date for labels on foods from other sources. As stated in the August 18, 1993, technical amendments (58 FR 44033 at 44035), the nutrition labeling requirements apply to food labeled after May 8, 1994. The agency stated that the term ''labeled'' means the date that the label is affixed to the food. FDA notes that each time a menu is used in a restaurant to convey purchase information about a food served in the restaurant, such use is analogous to affixing a label to a packaged food. Thus, establishing a specific date of applicability for restaurant menus, such that the date applies to the date that any menu is used as labeling in any restaurant, would be consistent with the treatment of labels on foods from other sources.

Finally, confusion could result from a situation in which, for example, two neighboring restaurants use identical claims on identical menus, one restaurant that makes claims would use terms in a manner that complies with FDA's requirements, while the restaurant that printed its menus less than a year earlier would not. Moreover, a restaurant that has not changed its menu in some time because of limited resources could be forced to change its menu sooner than a larger restaurant that had recently printed new menus. Such an outcome would make no sense.

FDA concludes that it is more appropriate to establish an effective date for applying its requirements to menus based on a given amount of time following the date on which this final rule publishes rather than an arbitrary date, such as the date of the last menu change, that may vary between restaurants. This approach will ensure that all restaurants will have a specified amount of time to change menus to comply with any applicable requirements, and that the amount of time will be based on an accommodation of both consumer and industry needs, rather than an arbitrary date that will vary between restaurants.

10. A number of comments agreed with FDA's proposal that the modified effective dates for restaurant menu labeling should allow restaurants to achieve compliance within an amount of time similar to the time that other food producers have had, and that the effective dates should be uniform for all restaurants, regardless of size. These comments stated that all restaurants should be required to comply with health claims regulations 4 months after publication of a final rule and with nutrient content claims regulations 1 year after publication, as proposed. One comment stated that the date of applicability for requirements for menus bearing nutrient content claims should be based on the same amount of time that packaged foods had, i.e., 16 months after publication of the January 6, 1993, final rules.

Alternatively, several comments maintained that compliance with the nutrient content claims regulations would be no more difficult than compliance with the requirements for the use of health claims, and that, consequently, restaurant menus should be required to comply with both regulations at the same time. Comments were divided, however, as to whether the single effective date for both nutrient content claims and health claims should be 4 months or 12 months after the date of publication of a final rule.

FDA has carefully considered how much time should be given for restaurant menus to be brought into compliance with the nutrient content claim and health claim labeling requirements. FDA's consideration has been guided by section 10 of the 1990 amendments. That provision made the nutrient content claim and health claim provisions effective 6 months after enactment but gave FDA the authority to delay application of the nutrient content claim requirements for up to 1 year if it found that compliance with those requirements would cause undue economic hardship (section 10(a)) of the 1990 amendments). FDA took advantage of the latter provision. FDA notes that a number of the factors that influenced the agency's decision to delay the application of the nutrient content claims requirements in the January 6, 1993, final rule do not have equal application with respect to this rulemaking.

One factor that influenced FDA's decision to delay the applicability date was the amount of effort that would be necessary to learn about how to come into compliance with the new rules (56 FR 60856 at 60862, November 27, 1991). The agency notes that, since publication of the January 6, 1993, final rules, FDA and other organizations have been active in disseminating information about the new food labeling requirements. Because access to information about these requirements, and the number of resources available to facilitate compliance with these requirements, have grown, the effort required on the part of a restaurateur who is not familiar with the requirements to obtain information about them has been reduced compared to that which was required for makers of other types of food. Moreover, the effort required for compliance by restaurateurs is even further reduced by the flexible provisions that FDA has established specifically for restaurant situations, e.g., providing the ''reasonable basis'' criterion for nutrient content determinations.

A second factor that influenced FDA's decision was the amount of time needed to come into compliance with the labeling requirements (56 FR 60856 at 60862). The type of labeling used in restaurants reduces the amount of time, compared to other food sources, that is reasonably necessary to achieve compliance. For example, for packaged foods that bear nutrient content claims, manufacturers needed time to use up preexisting labels to reduce the cost of complying with the new requirements. Conversely, menu inventory is generally not affected by a food purchase. Further, many restaurants use menus that may be revised, printed, and copied in-house, thereby avoiding the queue at printers that affected many food manufacturers. Therefore, providing time for bringing menus into compliance will not have the same effects on the costs of a restaurateur that it had on the costs of the manufacturer. Consequently, FDA concludes that significant circumstances that justified a1-year delay in the applicability of the nutrient content claims provisions for packaged foods do not apply to restaurant foods.

Moreover, in the June 15, 1993, proposed rule (58 FR 33055 at 33058), FDA cited an informal survey by the National Restaurant Association indicating that up to 89 percent of all printed menus include at least one claim. Based on information in the survey, FDA had assumed that more restaurants were making nutrient content claims than health claims, and that, consequently, a larger effort would be required on the part of restaurants to ensure compliance with requirements for nutrient content claims compared to health claims. The agency tentatively concluded that a date of applicability of 4 months after the publication of a final rule would be sufficient to ensure compliance with the requirements for health claims.

FDA continues to believe that few if any restaurant menus bear express health claims, such as ''a diet low in sodium may contribute to a reduced risk of high blood pressure, a disease associated with many factors,'' on their

menus. However, a number of comments to the June 15, 1993, proposed rule provided examples of menus that bear terms and symbols (e.g., heart symbols and terms such as ''heart healthy'') in a manner that makes them implied health claims under the act. Based on this information, and on information gleaned by FDA from informal inquiries from the industry (Ref. 1), FDA concludes that the number of restaurants making health claims is greater than it had previously assumed.

Furthermore, because of the flexible provisions that FDA has established for restaurant foods, it may be easier for a restaurant to establish that a food qualifies to bear a nutrient content claim (e.g., that a ''low fat'' food contains no more than 3 g of fat per reference amount) than that it qualifies to bear a health claim (i.e., that, in addition to the criterion for the nutrient in the claim, the food contains less than the disqualifying levels for fat, saturated fat, sodium, and cholesterol, and 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount prior to nutrient addition). The agency concludes that the effort required on the part of restaurants that want to make health claims in their menus (e.g., to obtain, read, and understand FDA's regulations; to develop a ''reasonable basis'' for making claims; to generate nutrition information for consumers; and, in some cases, to modify a food or its labeling) will be as great, if not greater, than that required of restaurants making nutrient content claims.

The agency notes that, in establishing a specific effective date, its goal is to ensure that consumers have access to useful nutrition-related information as quickly as possible while providing restaurateurs with sufficient time to make necessary changes. FDA does not believe that all restaurant menus could be reasonably expected to comply with the health claims requirements within the proposed 4-month timeframe. While many restaurants have already begun actions to come into compliance, especially larger restaurants that make claims on non-menu labeling, some restaurants that use only menus to convey purchase information may not be familiar with the requirements or know how to obtain the necessary information to determine whether their menus are in compliance. FDA further notes that an effective date for its requirements for restaurant menus that bear nutrient content claims of 4 months after the publication of this final rule, as suggested by some comments, would provide restaurant foods significantly less time than had been afforded foods from other sources. Thus, a compliance period of 4 months after publication would place restaurants offering improved foods and promoting these foods on their menus at a disadvantage compared to other food manufacturers.

Conversely, FDA concludes that it is not necessary for restaurant menus to have the same amount of time that other food labeling producers were given. Based in part on the amount of time that information on the criteria that will be applied to menus has been available (i.e., since January 6, 1993), and on the flexible rules it has adopted for restaurants, FDA concludes that a compliance period of 12 or 16 months is longer than is necessary for menus, and that such a time period would unduly delay consumer access to useful information.

After considering the foregoing, FDA has decided to establish a single date of applicability for both the nutrient content claim and health claim requirements for menus and to establish that date as May 2, 1997. This date will provide restaurateurs with 9 months to bring their menus into compliance. FDA has decided to provide 9 months based on the following three factors: First, 6 months is the amount of time that Congress provided for compliance with these provisions in the absence of undue economic hardship (section 10 of the 1990 amendments). Second, FDA finds that, based on the economic impact analysis in this rulemaking, unlike for non-restaurant foods, economic hardship does not exist. Consequently, the agency has no basis for providing an additional year for compliance by restaurant menus. Third, in Pub. L. 103–261, Congress provided non-restaurant food manufacturers with an additional 3 months to achieve compliance with the new labeling rules. Consequently, FDA finds that establishing May 2, 1997 as the effective date for the amendments that it is making to §§ 101.10, 101.13(q)(5), and 101.14(d)(2)(vii)(B) and (d)(3), and, thus, as the date that menus must be in compliance, is consistent with the treatment of non-restaurant foods. FDA believes that establishing a single date will benefit both consumers and industry. FDA notes that the different effective dates for nutrient content claims and for health claims in non-menu labeling in small restaurants and in larger restaurants have created a great deal of confusion about what requirements are effective at a given time. The agency concludes that establishing different dates for the use of health claims and of nutrient content claims in menus would only further compound this confusion. FDA finds that, in light of the confusion expressed by comments and in informal communications with the agency (Ref. 1), establishing a uniform date for all types of claims on menus makes the most sense. The agency further finds that a single effective date for menus will prevent the consumer confusion that could result from a restaurant using a menu that bears some types of claims that are consistent with the new requirements and other claims that are not. In addition, a single effective date for all menu claims will aid compliance by giving restaurants a single date by which to make necessary changes, regardless of the kind of statement (e.g., nutrient content claim, health claim, third party endorsement, or dietary guidance) used to present nutrient information to consumers. Thus, a single date will avoid the need to change menus twice within the compliance period. The agency concludes that, for efficient enforcement of the act, establishing a single effective date for both nutrient content claims and health claims on menus is desirable and appropriate.

Moreover, given the amount of time that FDA's labeling rules have been in place, an effective date of May 2, 1997, will provide ample time for restaurants to bring their menus into compliance without unduly delaying consumer access to useful nutrition-related information. An effective date of May 2, 1997, will also provide time for FDA and other regulatory officials to work with restaurants, consumers, dietitians, health professional organizations, and other interested parties to ensure that the agency's regulations are adequately implemented with respect to restaurant menus.

Thus, the deletion of the phrase ''(except for menus)'' that exempted menus from nutrient content claim requirements in §§ 101.10 and 101.13(q)(5) will be effective on May 2, 1997. Likewise, the deletion of the phrase ''(except on menus)'' that exempted menus from health claim requirements in § 101.10 and the phrase ''(except if the claim is made on a menu)'' in § 101.14(d)(2)(vii)(B) will also be effective on that date.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the significant economic impact of that rule on those small entities. FDA finds that this final rule is a significant rule as defined by Executive Order 12866, and finds under the Regulatory Flexibility Act, that the final rule will not have a significant economic impact on a substantial number of small entities.

A. Background

In the Federal Register of January 6, 1993 (58 FR 2927), FDA published a final regulatory impact analysis (RIA) of the final rules implementing the 1990 amendments (hereinafter referred to as the January 6, 1993, RIA). In that document (58 FR 2927 at 2934), FDA presented costs of compliance with the 1990 amendments for food service establishments. Although the agency did not include menus in its regulatory coverage of the nutrient content claims and health claims final rules, it assumed that restaurants would alter their menus to comply with the agency's definitions because of the possibility of enforcement by the States. Consequently, FDA included the cost of altering menus in its assessment.

In the June 15, 1993, proposed rule, FDA proposed to remove the provisions that exempt restaurant menus from the requirements for how nutrient content claims and health claims are to be made. Because the agency originally assumed that restaurants would alter their menus in order to comply with the regulations so as to avoid State enforcement, FDA assumed that the proposed action to include menus in the agency's regulatory coverage would not result in any significant increase in costs to food service establishments beyond that estimated in the January 6, 1993, RIA.

B. Costs of the Final Regulation

The following estimates are based on both quantitative and anecdotal information provided in the comments. However, FDA has previously stated that it lacks in-depth data on a number of issues related to the food service industry (56 FR 60537 at 60554, November 27, 1991). Therefore, while these estimates represent the best information available to the agency, FDA acknowledges that there is uncertainty in these estimates.

In the January 6, 1993 (58 FR 2927 at 2934), RIA, FDA estimated that 75 percent of restaurants, including all small restaurants, would normally alter menus before the applicable compliance date for nutrient content claims and health claims on non-menu labeling (based on a 16-month compliance period). The agency also assumed that, in revising their menus, most restaurants would make changes to comply with the regulations so as to avoid enforcement by the States. Consequently, FDA estimated that only 14,500 commercial establishments would incur costs attributable to the nutrient content claims and health claims final rules. In the June 15, 1993, proposed rule, FDA repeated the assumptions stated in the January 6, 1993, RIA, i.e., that most restaurants would alter their menus in order to comply with the regulations.

FDA received very few comments regarding its economic analysis of the June 15, 1993, proposed rule. However, a few comments indicated that the agency's assumption that most restaurants would alter menus to comply with the agency's requirements because of the possibility of enforcement by the States was not correct. FDA has anecdotal information indicating that at least some restaurants have not yet altered menus to comply with the claims requirements and would, therefore, bear some cost of the agency's action to remove the exemption for menus. However, the comments did not provide information regarding the proportion of the industry that has not yet altered its menus.

FDA notes that the costs of revising menus to comply with the new requirements are one-time costs only. However, costs of ensuring that claims are made on a reasonable basis and are in conformance with FDA rules, and costs of maintaining that information and presenting it to consumers on demand, are on-going costs, changing with new claims only in the former case. FDA does not have information with which to estimate these costs. However, those firms that would normally redesign their menus within the compliance period will not incur costs attributable to FDA's regulations. In the analysis of the proposed rule, FDA estimated that 75 percent of all menus would normally be revised during the compliance period ending in May 1994.

FDA received comments regarding the frequency of menu changes. Comments varied in their estimates of the frequency of menu redesign, ranging from several times a day to once a year. FDA concludes that, taken as a whole, these comments do not significantly alter its original assumptions about the rates at which restaurants alter menus, that is, that an average of 5 percent of all restaurants would normally alter their menus in a month and, thus, 45 percent of all restaurants would normally alter their menus during a 9-month compliance period.

In previous analyses, FDA noted that, because it is requiring only a reasonable basis to support claims in restaurant labeling, no analytical testing is necessary. FDA has described a number of methods by which a restaurant may determine the nutrient content of a food that are less costly than chemical analyses. For example, a claim may be based on nutrient data published in FDA's regulations for the voluntary nutrition labeling of fresh fruits, vegetables, and fish. A claim may also be based on nutrient data provided in USDA's *Handbook 8*, information in a cookbook, or an analysis using a reliable database. However, the cost of determining whether or not a reasonable basis exists to support a claim is not zero. Estimates of the cost of these sources range from $10 to $175 per claim (Ref. 2).

FDA now assumes that approximately 50 percent of the industry has already redesigned menus to comply with the nutrient content and health claims regulations. This rulemaking provides 9 months for menus to come into compliance with the claims requirements. FDA assumes that approximately 45 percent of restaurants will normally alter their menus during this compliance period; those restaurants can incorporate the requirements of this regulation into their normally scheduled menu revisions and, thus, will incur no regulatory costs associated with menu changes.

According to the National Restaurant Association, there are approximately 262,000 commercial establishments and 36,000 institutions with a combined total of approximately 460,000 printed menus. Based on a review of menus entered in the National Restaurant Association's annual menu contest, the association estimated that 89 percent of all printed menus include at least one nutrient content or health claim. Although FDA has not challenged this

number, it has no basis on which to determine whether this number fairly represents the situation in restaurants. Nonetheless, FDA is using the 89 percent survey result as an upper-bound estimate of the likelihood of typical menus bearing claims. The association also indicated that at least 18 percent of the printed menus that it reviewed would require more complex changes, such as the revision of an entire section or symbol program (e.g., programs using a heart logo).

Based on the association's estimates and on the agency's revised estimate of the number of menus that have already been changed to comply with the nutrient content and health claims requirements, FDA estimates that approximately 90,000 individual menus [460,000×(.89 − .18)×(1 − .45)×(1 − .50)] would require simple changes valued at $500 per menu, or $45 million. In addition, approximately 23,000 menus [406,000×.18×(1 − .45)×(1 − .50)] would require more complex changes valued at $1,700 per menu, or $39 million. The cost of establishing a reasonable basis to support a claim ranges between $10 and $175 per claim for each of the 113,000 menus, or a total cost of between $1 and $20 million. FDA estimates that the total cost of compliance for food service establishments would be between $85 million and $104 million if none of the restaurants currently making claims on menus have a reasonable basis to support their claims. However, because significant time has elapsed since publication of the nutrient content and health claims final rules, it is likely that at least one-third of restaurants have a reasonable basis for believing that their foods meet the nutrient requirements for the claims that they are making. Therefore, the total costs of compliance are estimated to be between $57 million and $69 million. However, if as many as 90 percent of restaurants have a reasonable basis to support claims currently being made, the regulations will result in costs of between $8.5 million and $10 million.

C. Benefits

Requiring that health claims and nutrient content claims on menus be consistent with FDA's definitions and with these types of claims made on packaged foods will provide consumers with consistent, reasonably based signals from restaurant menus with regard to health claims and nutrient content claims that they can use to achieve dietary goals. It is possible that information that is now on menus that complies with FDA's requirements and that would aid consumers in meeting dietary goals may be removed if a restaurateur believes that the burden of proof to support a claim is too costly. However, FDA believes that in many circumstances this will not be the case, because the minimum amount of effort that a restaurant would have to go through to validate a claim is not overly burdensome.

D. Regulatory Flexibility

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612).

In this final rule FDA defines small commercial food service establishments consistent with the Small Business Administration's (SBA's) definitions (13 CFR part 121) as firms with $5 million or less in total annual revenue. In addition, small institutional food service establishments defined as those with less than $15 million in sales. FDA estimates that approximately 66 percent of all of the firms affected by this rule are small by SBA's definitions. Using that figure, FDA estimates that there are approximately 173,000 commercial food establishments and 24,000 institutional food establishments that may be defined as small under these definitions. Using the same assumptions as in the previous analysis, i.e., that 89 percent of all printed menus contain at least one nutrient content or health claim, then there are approximately 175,000 small establishments with 270,000 menus that contain claims. Using the same assumptions as above ((1) 50 percent have already revised their menus, (2) 55 percent of the remaining establishments would not normally revise their menus within the compliance period for this rule, and (3) 18 percent of these latter establishments will have to make complex changes), approximately 9,700 small establishments will potentially have one-time costs of $1,700 to make complex changes to each menu. In addition, approximately 38,000 small establishments will potentially have one-time costs of $500 to make simple revisions to each menu.

In addition, firms will have initial and recurring costs of ensuring that health claims and nutrient content claims are supported by a reasonable basis and are in conformance with FDA's definitions of terms. For each claim, a firm must establish via books, databases, or by some reasonable means that the claim falls within FDA's definition. The supporting information must be kept as long as the claim appears on the menu and must be presented to customers on demand. Thus, as menu items and claims change, the cost of establishing a reasonable basis is incurred.

FDA has no data on how often firms change claims or how often restaurant customers will ask to see the nutrition information for foods that bear these claims. However, as stated earlier, cost estimates of establishing a reasonable basis for a claim run between $10 and $175 per claim. Assuming one future claim change or addition per menu per year and an average of 1.5 menus per firm, costs to determine a reasonable basis per firm will be between $15 and $260 per year. As stated earlier, for existing claims, many firms already have or would be likely to have established a reasonable basis for such claims, and this analysis will continue to presume that at least one third to as much as 90 percent of all firms would do so. Thus, average total cost per small firm may range from as high as $2,135 to as low as $765 in the first year for those who have menus with claims and between $15 and $260 per firm for each subsequent year. Firms that neither have claims nor would be expected to have them on their menus in the future will not incur cost.

It is important to note that this rule provides flexibility for restaurateurs in how they determine the nutrient content of a food and in how they communicate this information to consumers, as described above in the preamble. That is, for enforcement purposes, restaurateurs need only show that they have a reasonable basis for the claim and that the method of preparation does not violate the basis for the claim. Therefore, the costs of this regulation for small businesses have been minimized. Accordingly, under the Regulatory Flexibility Act, 5 U.S.C. 605(b) the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

E. Summary

FDA has examined the impact of the final rule in accordance with Executive Order 12866 and has determined that, while it is a significant rule, it is not an economically significant rule. The rule will result in total costs to restaurants of between $8.5 million and $69 million, depending on the number of restaurants that can provide a reasonable basis to support the claims currently in use.

FDA has also examined the impact of the final rule on small entities in accordance with the Regulatory Flexibility Act and has determined that it will not result in a significant burden on a substantial number of small entities.

V. Paperwork Reduction Act

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the collection of information are shown below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, gathering necessary information, maintaining records of that information, and making that information available upon request.

Title: Food Labeling: Nutrient Content Claims and Health Claims; Restaurant Foods.

Description: This regulation removes the provisions that exempt restaurant menus from the requirements for how nutrient content claims and health claims are to be made and from therequirements for the provision of nutrition information with respect to the nutrients that are the basis of the claim, when claims are made. Once it becomes effective, §§ 101.13(q)(5) and 101.14(d)(2)(vii)(B) will require that nutrient content claims and health claims appearing on menus comply with FDA's regulations for nutrient content claims in § 101.13 and subpart D of part 101 of this chapter and for health claims in § 101.14 and subpart E of part 101. Restaurants using nutrient content claims or health claims on menus will be required by § 101.10 to provide nutrition information for the food that bears the claim. Information on the nutrient that is the basis of the claim may serve as the functional equivalent of complete nutrition information as described in § 101.9.

Because of the flexibility provided for restaurants in determining the nutrient content of a food (they need only have a reasonable basis that provides assurance that the food meets the requirements for the claim) and in how this information may be communicated to consumers, a wide range of options is available to restaurants in meeting the information collection requirements imposed by this rule. For example, a restaurant may choose to run a full nutrient profile analysis on a group of items listed under a heading of ''low fat'' on its menu. alternatively, it may chood to offer an item purchases from a commercial manufacturer where the item is appropriately labeled by the manufacturer as ''low fat.'' In such a case, the restaurant requirement for the provision of nutrituin information with respect to the nutrients that are the basis of the claim, when claims are made. Once it becomes effective, § § 101.13(q)(5) and 101.14(d)(2)(vii)(B) will require that nutrient content claims and health claims appearing on menus comply with FDA's regulations for nutrient content claims in § 101.13 and subpart D of part 101 of this chapter and for health claims in § 101.14 and subpart E of part 101. Restaurants using nutrient content claims or health claims on menus will be required by § 101.10 to provide nutrition information for the food that bears the claim. Information on the nutrient that is the basis of the claim may serve as the functional equivalent of complete nutrition information as described in § 101.9.

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Description of Respondents: Businesses or other for profit organizations.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR	No. of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeping	Total hours
§§ 101.10, 101.13(q)(5), and 101.14 (d)(2)(vii)(B) and (d)(3)	265,000	1.5	397,500	1	397,500

Note: There are no operation and maintenance costs or capital costs associated with this information collection.

Although the June 15, 1993, proposed rule provided a 60-day comment period, and this final rule incorporates the comments received, FDA is providing an additional opportunity for public comment under the Paperwork Reduction Act of 1995, which applies to this final rule but which was enacted after the expiration of the comment period for the June 15, 1993, proposal. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, when appropriate. Individuals and organizations may submit comments on the information collection requirements by October 1, 1996. Comments should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, make revisions as necessary to the information collection requirements, and submit the requirements to OMB for review and approval. FDA will publish a notice in the Federal Register when the information collection requirements are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Additional time will be allotted for public comment to OMB. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or

disapprove the information collection requirements. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Smith, M.A., communications regarding labeling of restaurant foods that bear a claim or other nutrition information, memorandum to file, November 9, 1994.

2. Bush, L.M., communication regarding the cost of establishing a reasonable basis for a claim, memorandum of telephone conversation, September 14, 1994.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.10 is revised to read as follows:

§ 101.10 Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., ''low fat, this meal provides less than 10 grams of fat'') may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

3. Section 101.13 is amended by revising the introductory text of paragraph (q)(5) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(q) * * *

(5) A nutrient content claim used on food that 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 shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

* * * * *

4. Section 101.14 is amended by revising paragraphs (d)(2)(vii)(B) and (d)(3), introductory text, and adding paragraph (d)(3)(i) to read as follows:

§ 101.14 Health claims; general requirements.

* * * * *

(d) * * *

(2) * * *

(vii) * * *

(B) Where the food that bears the claim is sold in a restaurant or in other establishments in which food that is ready for immediate human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section and provides that basis upon request.

* * * * *

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements of vitamins or minerals, in accordance with § 101.36. The requirements of this paragraph are effective as of May 8, 1993, except:

(i) For menus, for which the requirements of paragraph (d)(3) of this section will be effective May 2, 1997.

* * * * *

Dated: July 25, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–19645 Filed 7–30–96; 12:21 pm]

BILLING CODE 4160–01–U

ARMS CONTROL AND DISARMAMENT AGENCY

22 CFR Part 602

Freedom of Information Policy and Procedures

AGENCY: Arms Control and Disarmament Agency.

ACTION: Final rule.

SUMMARY: The United States Arms Control and Disarmament Agency (ACDA) is revising and restating in their entirety its rules that govern the availability and release of information. Clarifying these rules will help the public to interact better with ACDA and is part of ACDA's effort to update and streamline its regulations.

EFFECTIVE DATE: August 2, 1996.

FOR FURTHER INFORMATION CONTACT: Frederick Smith, Jr., United States Arms Control and Disarmament Agency, Room 5635, 320 21st Street, N.W., Washington, DC 20451, telephone (202) 647–3596.

SUPPLEMENTARY INFORMATION: On May 30, 1996, ACDA published a notice of proposed rulemaking (61 FR 27031–27036) with a 39-day comment period. No comments were received during the comment period. Accordingly, the rules are adopted as proposed.

List of Subjects in 22 CFR Part 602

Freedom of Information Act.

Chapter VI of Title 22 of the Code of Federal Regulations is amended by revising part 602 to read as follows:

PART 602—FREEDOM OF INFORMATION POLICY AND PROCEDURES

Authority: 5 U.S.C. 552; 22 U.S.C. 2581; and 31 U.S.C. 9701.

Subpart A—Basic Policy

Sec.
602.1 Scope of part.
602.2 Definitions.
602.3 General policy.

Subpart B—Procedure for Requesting Records

602.10 Requests for records.
602.11 Requests in person.
602.12 Availability of records at the ACDA Office of Public Affairs.
602.13 Copies of records.
602.14 Records of other agencies, governments and international organizations.
602.15 Overseas requests.
602.16 Responses and time limits on requests.
602.17 Time extensions.
602.18 Inability to comply with requests.
602.19 Predisclosure notification for confidential commercial information.