Proposed Rules

Federal Register
Vol. 61, No. 246
Friday, December 20, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 96N–0421 and 94P–0453/CP1]

Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations to provide for the use of nutrient content claims on the food label or in labeling based on the reduced availability of fat to the body from the food because of the use of a fat substitute ingredient in the food. This proposal responds, in part, to a citizen petition on the use of digestibility coefficients in determining the quantity of fat declared on a food label. FDA is undertaking this action to encourage innovation on the part of food manufacturers and to foster a situation that will provide increased product choices for consumers in achieving dietary goals.

DATES: Submit written comments by April 21, 1997. Submit written comments on the information collection requirements by January 21, 1997. The agency is proposing that any final rule that may issue based upon this proposed rule become effective 30 days after its date of publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5763.

SUPPLEMENTARY INFORMATION:

I. Background

A. The 1990 Amendments and Implementing Regulations

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) provided for a number of fundamental changes in how food is labeled, including requiring that nutrition labeling appear on most foods and establishing that terms that characterize the level of a nutrient in a food may not be used in food labeling unless defined by FDA.

The 1990 amendments added section 403(q) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)), which requires that most food bear nutrition labeling. In response to this provision, in the January 6, 1993, final rule on nutrition labeling (entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label,'' (the nutrition labeling final rule (58 FR 2079)), FDA prescribed how nutrition labeling is to be provided on the foods that are regulated by the agency. Among other things, the agency required that the nutrition label include information on total calories and calories from fat and on the quantitative amounts of specified nutrients (e.g., total fat, saturated fat, total carbohydrate, and dietary fiber) per serving.

In the nutrition labeling final rule (58 FR 2079 at 2110), FDA recognized that many food ingredients have caloric values substantially different from the general factors of 4, 4, and 9 calories per gram (g) for protein, carbohydrate, and fat, respectively. Therefore, the agency provided a number of options for calculating the energy value of foods. For example, FDA stated that calories may be calculated, under § 101.9(c)(1)(i)(A) (21 CFR 101.9(c)(1)(i)(A)), by using specific Atwater factors given in Table 13 ''Energy Value of Foods-Basis and Derivation,'' U.S. Department of Agriculture (USDA) Handbook No. 74; under § 101.9(c)(1)(i)(C), by multiplying the general factor of 4 calories per g by the amount of total carbohydrate less the amount of insoluble dietary fiber; under § 101.9(c)(1)(i)(D), by using data for specific energy factors for particular foods or ingredients approved by FDA through the food additive or generally recognized as safe (GRAS) petition processes in parts 170 and 171 (21 CFR parts 170 and 171) and provided in parts 172 or 184 (21 CFR parts 172 or 184); or under § 101.9(c)(1)(i)(E), by using bomb calorimetry data.

FDA also defined the basic nutrients that are to be declared as part of the nutrition label (58 FR 2079 at 2086). In particular, FDA defined ''total fat'' as total lipid fatty acids expressed as triglycerides (§ 101.9(c)(2)) and ''saturated fat'' as the sum of all fatty acids containing no double bonds (§ 101.9(c)(2)(i) (58 FR 2079 at 2089)).

In addition to adding section 403(q) on nutrition labeling to the act, the 1990 amendments added section 403(r) on nutrient-related claims and, in particular, section 403(r)(1)(A) of the act, which states that a food is misbranded if it bears a claim in its label or labeling that expressly or implicitly characterizes the level of any nutrient of the type required to be declared in nutrition labeling unless the claim is made in accordance with section 403(r)(2) of the act. Section 403(r)(2)(A)(i) of the act states that a claim may be made only if the characterization of the level made in the claim uses terms that are defined in regulations of the Secretary of the Department of Health and Human Services.

In the Federal Register of January 6, 1993 (58 FR 2302), FDA published a final rule (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,'' hereinafter referred to as ''the nutrient content claims final rule'') that implemented the nutrient content claims provisions of the act by establishing general rules for how such claims are to be made and defining various terms (e.g., ''high,'' ''low,'' ''free,'' and ''reduced'') that could be used to characterize the level of various nutrients in the food.

FDA noted that its approach to developing a system of nutrient content claims emphasized three objectives: (1) Consistency among definitions, (2) claims that are consistent with public health goals, and (3) claims that will help consumers to maintain healthy dietary practices (58 FR 2302 at 2319). The agency stated that it is important for effective consumer education to establish consistent definitions for descriptive terms whenever possible to limit the possibility of consumer confusion (58 FR 2302 at 2319).

B. Citizen Petition

Nabisco Group (Nabisco) (hereinafter ''the petitioner'') submitted a citizen petition (filed December 21, 1994, Docket No. 94P–0453/CP1) requesting that FDA amend its food labeling regulations to permit the use of a ''digestibility coefficient'' or ''food factor'' in determining the quantity of fat to be declared on the nutrition label and to permit nutrient content claims to be based on the quantity of fat declared. According to the petitioner, this action would permit claims on a class of products that contain significantly less available fat compared to an appropriate reference food but that may not qualify to bear a calorie claim or a fat claim based on the total analytically-determined amount of fat in the food. The petitioner asserted that the nutritional benefit of foods with reduced available fat is similar to that of foods with reduced total fat, and that providing for claims on foods that contain significantly less available fat would further FDA's goal of promoting healthier diets by encouraging product innovation. The petitioner noted that the costs of development and reformulation for the use of manufactured fat substitutes, such as salatrim, make them much more expensive to use than fats from traditional sources. The petitioner maintained that, unless manufacturers are able to promote the beneficial aspects of products containing these ingredients, they would have no incentive to develop or use them. Thus, the petitioner continued, it is imperative that manufacturers be able to make claims for foods containing fat substitutes with reduced availability.

Specifically, the petitioner requested that FDA amend§ 101.9(c)(2) by inserting the following language at the end of the first paragraph in that section:

Fat content may be calculated by applying a food factor to the actual amount of fat present per serving, using specific food factors for particular foods or ingredients approved by FDA and provided in parts 172 or 184 of this chapter, or by other means as appropriate.

The requested change would allow the amount of total fat present per serving to be multiplied by a specific factor approved by FDA, to yield the quantity of fat that is to be declared in nutrition labeling, even though the declared value may be less than the actual amount of fat in the food. The approach suggested by the petitioner, that the factor used to calculate available fat content be approved by FDA, is similar to the approach taken by FDA in § 101.9(c)(1)(i)(D), which provides that specific food factors may be used to calculate total caloric content declared in nutrition labeling if they have been approved by FDA and provided for in part 172, part 184, or by other means as appropriate. The petitioner also suggested that the agency could permit self-determination of a food factor for calculating nutrient availability by a manufacturer, pending agency review of a GRAS petition for the ingredient to which the factor applies.

The petitioner noted, for example, that it had filed a GRAS petition for salatrim (GRASP 4G0404) that proposed a food factor of 5/9 for this ingredient.[1] The petitioner maintained that the amount of available (i.e., absorbed/digestible) fat in an ingredient should be reflected in the ''food factor'' or ''digestibility coefficient'' for that ingredient. The petitioner went on to suggest that manufacturers be permitted to make fat reduction claims for products that claim the amount of available fat as opposed to the chemically analyzed quantity of fat in the food.

[1] Dietary fats consist of one, two, or three fatty acid molecules attached to a glycerol backbone (i.e., mono-, di-, or triglycerides). Salatrim is a manufactured fat substitute in which the manufacturer controls the fatty acid composition of the triglyceride. Salatrim is the trade name for a family of triglycerides that contain one or two long chain fatty acids, primarily stearic acid (C18:0, 50 to 60 percent by weight), and one or two short chain fatty acids, primarily acetic acid (C2:0) and propionic acid (C3:0), randomly attached to the glycerol backbone. The stearic acid component is incompletely absorbed, as addressed in the current petition. The short chain fatty acids are fully absorbed, but they have a lower energy value than long chain fatty acids that comprise dietary fats. Thus, the reduction in energy from salatrim compared to conventional dietary fats is derived in part from the incomplete absorption of stearic acid and, in part, from the low energy value of the short chain fatty acids. In combination, these two factors have been estimated by the petitioner to result in a caloric value that is approximately 55 percent (5/9) of the energy value of conventional fats (i.e., a food factor of 55 percent, according to the definition of terms in section II.A. of this document). The digestibility coefficient, which addresses only the availability of fat, would consider only the incomplete absorption of stearic acid from this ingredient.

Additionally, the petitioner requested that FDA amend § 101.9(c)(2) to provide that a food factor be used to calculate the quantity of all fatty acids (i.e., saturated fat, polyunsaturated fat, and monounsaturated fat) declared on the nutrition label.

II. Agency Response

A. Definition of Terms

To understand the issues raised by the petition, and the agency's response to those issues, it is important to distinguish among three terms, ''bioavailability'' or ''availability,'' ''food factor,'' and ''digestibility coefficient.'' These terms are often used interchangeably but have substantially different meanings. The agency's approach to how energy and nutrient values are declared in nutrition labeling is determined by the differences among these terms.

FDA notes that bioavailability is the result of a series of complex events, i.e., digestion, absorption, and metabolism (Ref. 1). Digestion refers to the chemical and physical breakdown of food and its macromolecular components in the gastrointestinal tract (e.g., the breakdown of triglycerides (fats) into fatty acids and glycerol). Absorption refers to the intestinal absorption of the component molecules (e.g., fatty acids). The mechanisms of reduced availability of a fat substitute may vary for different ingredients. Some products are less available because they are resistant to chemical (e.g., enzymatic) digestion (e.g., olestra). Other products exploit less efficient absorption of certain compounds, such as long chain and very long chain fatty acids (e.g., salatrim and caprenin).

FDA will use the term ''available'' to refer to the portion of a fat substitute that is physiologically available from a food, i.e., that portion that is digested, absorbed, and metabolized, or, more simply, the proportion of the consumed fat substitute that can be utilized. The prefix ''bio'' in ''bioavailable'' denotes that a biological attribute is being discussed as opposed to, some other type of availability, e.g., availability within the marketplace. However, based on the context in which the agency expects the term to be used (i.e., fat availability), FDA does not anticipate that the term ''availability'' will be confused with other forms of availability. Thus, for the purposes of this rulemaking, and consistent with current scientific literature, the term ''available'' will be used as a synonym to the term ''bioavailable'' to describe the effects of different mechanisms in

reducing the digestion and absorption of fat substitutes.

The term ''food factor'' will be used to refer to those factors (i.e., Atwater factor, general food factor, and specific food factor) that are used to calculate energy value (total caloric content) of a food or ingredient (§ 101.9(c)(1)(i)) or to calculate the amount of calories in a food that it derives from the fat component of the food (§ 101.9(c)(1)(ii)). It is important to note that energy values vary for different classes of nutrients or ingredients and for ingredients within a class (e.g., different fats). The general factors of 4, 4, and 9 calories per g for carbohydrates, protein, and fat, respectively, are general factors (i.e., a rule of thumb) that may be used to approximate the energy content of foods containing common dietary carbohydrates, protein, and fats. The use of more specific factors to calculate the energy value of a food increases the accuracy of the value (Ref. 2).

The term ''digestibility coefficient'' is used extensively in scientific literature to refer to the multiplicand used to calculate the amount of a nutrient that is physiologically available (Refs. 3 and 4). In this document, FDA will use the term ''digestibility coefficient'' to represent the factor used to calculate fat availability.

Food factors and digestibility coefficients do not necessarily refer to the same thing. As noted above, when food factors for specific ingredients are available that are more accurate than the general factors, their use increases the accuracy of the calculation of the total energy value for the food. Specific food factors reflect the different parameters, including but not limited to availability, that affect the amount of energy that may be derived from a particular food or ingredient. It may be possible, under certain circumstances (e.g., when a 50 percent reduction in availability of a fat substitute results in a proportionate reduction in the energy value of the ingredient), to use the same number to calculate both energy value and fat availability for a food or an ingredient. However, the energy values of different food components may vary because of parameters unrelated to reduced availability, such as differences in molecular weight and heat of combustion.

Reduced availability will reduce the amount of calories that derive from a particular food component because only part of the component can be absorbed. However, different nutrients (e.g., fat, carbohydrate, and protein) and different food components within a class (e.g., fats composed of different fatty acids) may be essentially 100 percent available and still have different energy values. Very short chain fatty acids, for example, are at the lower end of the energy value range compared to longer chain fatty acids. In fact, a reduced calorie fat ingredient can be made by combining fat components that have a lower energy value because of reduced availability with components that are naturally lower in energy but that are fully available (as is the case with salatrim). Therefore, when the energy value and the nutrient availability of a fat substitute are reduced, but not proportionately (such as when the fat substitute depends on two different mechanisms to achieve a lower energy value compared to the average value for fat, but only one of the mechanisms relates to the availability of the nutrient), the food factor used to calculate available calories would be expected to differ from the digestibility coefficient used to calculate the availability of the fat.

Comments are requested on these definitions of terms and the tentative conclusions resulting from their use.

B. Current Position

In its discussion of total fat in the nutrition labeling final rule (58 FR 2079 at 2087), FDA responded to a number of comments that requested that fat be defined to exclude various types of long chain fatty acids because of their poor availability. These comments asserted that ''total fat'' should be defined as ''total digestible fat'' to allow for the use of fat-type ingredients that have reduced digestibility and, therefore, provide fewer calories per g than the fats that they replace.

In response to these comments, FDA acknowledged the effect that the use of fats that contain very long chain (longer than 18 carbons) fatty acids with reduced digestibility have on the available fat and calorie content of foods. FDA stated that, in an effort to encourage innovation in the creation of products that provide lower fat and calorie contents, it was willing to consider the digestibility of novel fat compounds (58 FR 2079 at 2087). In fact, as stated above, § 101.9(c)(1)(i)(D) provides for calculating the caloric content of foods and ingredients, including fat substitutes, using a specific food factor approved by FDA. However, FDA concluded that, because of the diversity of possible products, it was not appropriate to modify the definition of ''total fat'' in § 101.9(c)(2) (58 FR 2079 at 2087). That definition, i.e., ''total lipid fatty acids expressed as triglycerides,'' represents all fatty acids obtainable from a total lipid extraction (58 FR 2079 at 2087), and, by maintaining this definition, FDA not only included all sources of fatty acids that provide energy in the amount of fat to be declared in nutrition labeling but the nondigestible fatty acids as well.

Rather than modifying the definition, the agency stated that it would address the digestibility of novel fat compounds on a case-by-case basis. Because the digestibility of a substance is one of the identifying characteristics of the substance, the agency requested that manufacturers who wish to declare adjusted values of total fat based on reduced digestibility include information on the digestibility of the compound, analytical assay procedures for the compound, and data on interference with required methods of analysis, in food additive petitions (part 171) on such substances or in petitions for affirmation that the use of such substances is GRAS (§ 170.35) (58 FR 2079 at 2087).

The agency anticipated including the specific digestibility coefficients that could be used in determining the quantitative declaration of fats and the caloric contribution from fats as part of the statement of identity for the substances in the listing regulations for them in part 172 or in the GRAS affirmation regulations in part 184 for those whose use is affirmed as GRAS. However, FDA also recognized that mechanisms other than food additive or GRAS petitions may be appropriate to bring issues involving the digestibility of a substance to the attention of the agency. Thus, it suggested the mechanism in § 101.9(g)(9) as a possible means of requesting the use of specific digestibility coefficients (58 FR 2079 at 2087).

The agency also responded to a number of comments that stated that fatty acids with carbon chains longer than 18 (i.e., C20–C24) should not be categorized together with those having chain lengths of 12 to 18 carbons as saturated fatty acids because very long chain fatty acids are poorly absorbed and have little or no physiological effect, e.g., they will not contribute to raising serum cholesterol. After reviewing all the comments, FDA was not persuaded to exclude any fatty acids from the definition of saturated fat on the basis of their physiologic effects. Rather, FDA defined saturated fat as ''the sum of all fatty acids containing no double bonds'' (58 FR 2079 at 2089). FDA did not address the issue of digestibility or availability of individual fatty acids in its discussion, but the agency noted that an inclusive chemical definition avoids controversy about which saturated fatty acids are associated with increases in blood

cholesterol, is consistent with general dietary guidelines recommending reduced saturated fat consumption, avoids under-reporting of saturated fat, and is more consistent with international definitions (58 FR 2079 at 2089).

Thus, while FDA's final regulations provide for the use of food factors and other options to calculate more accurately the total energy value of a food (§ 101.9(c)(1)), they do not provide for the use of a mechanism to calculate available fat or available saturated fat for nutrition labeling. The regulations require that nutrition labeling and claims reflect the total amount of fat and saturated fat in a food (i.e., ''all fatty acids obtainable from a total lipid extraction'' (58 FR 2079 at 2087)). The only exceptions to this general requirement are provided in: (1) The voluntary nutrition labeling final rule for raw fruit, vegetables, and fish (61 FR 42742, August 16, 1996) with respect to total fat in orange roughy and (2) the olestra final rule in § 172.867(e)(5).

In regard to orange roughy, FDA notes that this fish is one of the few foods that contains wax esters (i.e., single fatty acids esterified to long chain alcohols). Because wax esters are extracted along with lipids during analysis, under § 101.9(c)(2), nutrition labeling for orange roughy should reflect these wax esters in the total fat declaration. However, the value for fat in cooked orange roughy in Agricultural Handbook 8–15 (1990 Supplement), upon which FDA relied in developing the interim nutrition labeling values for this food, does not include the wax esters in the value of total fat because, as stated in the Handbook, the wax esters do not provide a metabolizable source of energy for humans (Ref. 5). In the Federal Register of July 18, 1994 (59 FR 36379), FDA proposed to revise its guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish, stating its intention to revise the total fat value for orange roughy to include the wax esters should it receive acceptable information in comments on its proposal. While such a revision would have made the orange roughy declaration of total fat consistent with declarations for other foods, FDA did not receive any information that would enable it to change the value of fat for orange roughy to include the wax esters. Accordingly, the nutrient values for orange roughy in part 101 (21 CFR part 101), appendix D continue to exclude the wax esters (61 FR 42742).

With regard to olestra, FDA recently published a final rule establishing conditions of safe use for this substance as a replacement for fats and oils (hereinafter referred to as the ''olestra final rule'' (61 FR 3118, January 30, 1996)). FDA specified that olestra, a sucrose polyester composed of six to eight fatty acids bound to sucrose by ester bonds, need not be considered as a source of fat or calories for purposes of nutrition labeling or nutrient content claims (§ 172.867(e)(5)). This holding was based on the fact that nearly all ingested olestra remains intact and is not absorbed, but is excreted intact in the feces (61 FR 3118 at 3126). Because the fatty acids in olestra are not absorbed and, therefore, are unavailable to the body, FDA decided not to require that the fatty acids be included in the declaration of total fat.

C. Proposal to Allow Nutrient Content Claims Based on Fat Availability

Having carefully considered the Nabisco petition, FDA tentatively concludes that there is merit in providing a generic means of allowing for the digestibility of fat substitutes, rather than in addressing this issue on a case-by-case basis as stated in the nutrition labeling final rule (58 FR 2079 at 2087) and as implemented in the olestra final rule (61 FR 3118).

As noted in the nutrition labeling and nutrient content claims final rules, dietary guidance given in various reports, such as the Surgeon General's ''Report on Nutrition and Health'' (Ref. 6), the National Academy of Sciences' ''Diet and Health: Implications for Reducing Chronic Disease Risk'' (Ref. 7), the National Cholesterol Education Program's ''Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction'' (Ref. 8), and the ''Dietary Guidelines for Americans'' (Ref. 9), recommends reducing the consumption of fat (especially saturated fat) and cholesterol by choosing foods that are relatively low in fat and high in carbohydrates. These recommendations have been carried forward in the recent publication of the fourth edition of the ''Dietary Guidelines for Americans'' (Ref. 10). Read together, these dietary guidance reports make clear that reducing the fat content of the American diet is an important public health goal.

The issue presented by the petitioner thus becomes whether fat-based fat substitutes with reduced availability will play a useful role in helping consumers to construct a healthy diet, and, if so, whether it is appropriate to authorize nutrient content claims based on the amount of available fat from such ingredients. To answer these questions, it is useful to understand the physiological functions of dietary fats and the metabolic processes necessary to achieve these functions. The physiological functions of fats include transporting fat soluble vitamins within the body, serving as structural components in cell membranes, serving as a source of essential fatty acids, and acting as precursors of certain hormones, prostaglandins, and other active substances. While dietary fats are insoluble in water, the digestion processes convert them into free fatty acids and monoglycerides, in which forms they are absorbed from the digestive tract. Products of digestion are absorbed from the intestinal lumen into the enterocytes (i.e., intestinal cells). The form of transport and ultimate fate of fatty acids depends to a large extent on chain length and extent of unsaturation (Refs. 11 and 12).

Long chain fatty acids (>C12) are formed into new triglycerides and transported, bound to protein (i.e., lipoproteins), into intercellular spaces and thus into the lymphatic system. To pass through the capillaries of the organs in which they will ultimately be used or stored (e.g., adipose tissue, heart, skeletal muscle, or mammary gland), triglycerides must be hydrolyzed into fatty acids and glycerol. Shorter chain fatty acids (<C10), which primarily serve as an energy source, are transported from the intestine to the liver as unesterified fatty acids, bound to albumin. Medium chain length fatty acids (C8–C12) may be transported through either mechanism (Ref. 11).

Each of the above processes serves as a gateway or hurdle to the ultimate use or storage of ingested fat. Thus, the availability of a fat will depend on whether, and to what extent, it and its component fatty acids are able to participate in each of these processes (i.e., digestion, absorption, and use or storage). For example, to function as a source of fatty acids, a fat must first be digested to release the fatty acids from the one and three positions on the glycerol molecule. However, even if the fat is digested, not all the resulting free fatty acids may be absorbed (e.g., long chain and saturated fatty acids are less soluble than shorter chain and unsaturated fatty acids and have lower rates of absorption). Also, other dietary components can combine with the free fatty acids to prevent their absorption. The evidence shows that some fats or fatty acids are either not digested or, if digested, are not absorbed into the intestinal tract (Ref. 13). These fats and fatty acids are less available to the body than those that are more efficiently digested and absorbed.

If the fat or its fatty acid components are digested and absorbed (as are most naturally occurring fats), they are available for use by the body (Ref. 11).

Conversely, if an ingested fat, or the fatty acid components of that fat, cannot be absorbed or digested, then the fat or fatty acids are not available for use or storage and thus pass through the gastrointestinal tract and are excreted.

FDA is aware that several manufacturers have started to formulate fat-based fat substitutes that are structured to minimize the amount of fat and fatty acids that will be available to the body but that have other characteristics that allow them to be substituted for other fats that are more available. The agency tentatively concludes that foods that contain these less available fat-based fat substitutes will have an impact on many physiological processes that is similar to that of foods that contain less total fat. Because less fat is available for use or storage from these ingredients, less fat will be available to have the physiological effects that increase risk of disease. Consequently, consuming less available fats appears to be consistent with the public health goal of reducing dietary fat intake.

Based on the tentative conclusion that, for most consumers, substituting foods made with fat-based ingredients that have reduced availability for foods whose fats have normal availability is effectively the same as reducing total fat intake, the agency tentatively concludes that claims based on declared levels of available fat will be truthful and not misleading and will assist consumers in maintaining healthy dietary practices. Such claims will help consumers to identify foods that will help them to achieve the public health goal of reducing their level of fat intake. For most consumers, the need for information about the fat content of the diet is related to weight control and to increased risk of chronic diseases, such as cardiovascular disease, diabetes, stroke, and cancer. As stated above, to a large extent, fat must be available to the body to affect the risk of these diseases, i.e., it must be digested and absorbed. Therefore, FDA tentatively concludes that it is appropriate to authorize claims that describe the level of available fat in a food product.

In its final rules to implement the 1990 amendments, the agency acknowledged the possible usefulness of novel fat compounds in enabling the consuming public to have a healthier diet and to meet dietary recommendations for reducing fat consumption (58 FR 2079 at 2987). However, as stated earlier, the agency concluded that, because of the diversity of possible products, it was not appropriate to modify the definition of total fat in § 101.9(c)(2), but that the agency would address the digestibility of new ingredients (e.g., fat substitutes) on a case-by-case basis. Tight time constraints and resource limitations precluded FDA from taking further action at that time.

FDA is aware that food technology pertaining to fat-based fat substitutes is advancing, and that more companies are developing ingredients formulated to limit the availability of fat to the body (e.g., olestra and salatrim). These products appear to offer significant advantages to consumers in that they should result in more foods appearing in the marketplace with less available fat, leading to the consumption of diets lower in fat. However, the petitioner has stated that it is imperative to the commercial viability of fat substitutes that manufacturers be permitted to make reduced fat claims based on the use of such products.

Because of the apparent advantages to consumers, FDA has tentatively decided that it is appropriate to foster the development and use of fat-based fat substitutes and to authorize nutrient content claims based on their use. To do this, FDA is proposing to add a new § 101.63 *Nutrient content claims for fat and fatty acids based on use of ingredients formulated to reduce amount of available fat.* This provision, if adopted, will define nutrient content claims for fat and fatty acids in a way that will allow such claims to be made for foods containing fat-based fat substitutes that have been formulated to limit the amount of fat and fatty acids that can be absorbed and digested from them by the body, thereby reducing the availability of the fat.

1. Coverage

In proposed § 101.63(a), FDA states that this new section defines the circumstances in which claims can be made for foods that contain manufactured fat-based fat substitutes that have been formulated to provide functional characteristics of fat and to reduce or eliminate absorption and digestion of fat from the substance by the body. The agency recognizes that providing for claims based on availability raises the question of whether claims for all fats should be based on availability. FDA is aware that certain conventional food fats are less available than others (e.g., fats rich in stearic acid, e.g., cocoa butter, are not well absorbed relative to other fats (Refs. 14 and 15)). However, the agency is reluctant to include conventional fats under proposed § 101.63(a) because few, if any, such fats have undergone testing to determine a digestibility coefficient, i.e., availability. Moreover, including such fats in the coverage of the proposed regulation would create inconsistencies among nutrition label values, standard food composition tables, and data bases used by consumers and health professionals. In addition, if some food products continue to declare total analytically determined levels of fat, while other similar food products chose to declare only the amount of available fat, additional inconsistencies would become apparent. The agency tentatively concludes that these inconsistencies could lead to so much consumer confusion that it would outweigh any benefits from providing this information.

FDA requests comment on whether the declaration of available, rather than total, fat from conventional fat ingredients that contain less available fat without the benefit of special processing (e.g., cocoa butter) would be beneficial to consumers and should be allowed. What would be the effect of doing so on standard food composition tables and on data bases? What would be the effect of doing so on dietary guidance? What will be the affect of any inconsistencies created by limiting the foods for which fat content is determined by availability? While FDA will consider comments on this issue, it considers the inclusion of conventional fats under proposed § 101.63 outside the scope of this rulemaking. Thus, if FDA were to be convinced by the comments that it is appropriate to declare all fats based on availability, it would institute a new rulemaking to effect this change.

2. Proposed Method for Providing for Claims Based on Availability

In the nutrition labeling final rule (58 FR 2079 at 2111), FDA recognized that innovations in food technology have resulted in reduced calorie foods that utilize various soluble dietary fibers and other modified carbohydrates, proteins, and fats to achieve the calorie reduction. As noted above, the agency stated that manufacturers or users of ingredients with reduced availability may petition the agency for use of alternative energy factors in nutrition labeling through established procedures for food additive or GRAS petitions. FDA also stated that the burden for establishing the actual energy value for the food is appropriately with the manufacturer. FDA determined (58 FR 2079 at 2112) that the petition process was an appropriate mechanism for establishing specific food factors (energy values) for these ingredients. The regulations require that the factor for calorie determination be approved by the agency (§ 101.9(c)(1)(i)(D)) and provided

for in parts 172 or 184, or by other means, as appropriate.

The petitioner requested that FDA amend its regulations to specifically provide that data on fat availability may be submitted as part of a food additive or GRAS petition or ''by other means as appropriate,'' similar to the agency's treatment of specific food factors in § 101.9(c)(1)(i)(D). The petitioner also requested that the agency provide for self-determination of digestibility coefficients pending agency review of data submitted.

It would be most useful to the public if factors such as food factors and digestibility coefficients were listed in the food additive or GRAS affirmation regulations in parts 172 or 184 of the Code of Federal Regulations so that all information about a compound is located in one place. However, not all ingredients that are used in food are listed in the food additive or GRAS regulations (see § 182.1(a)). The statute does not preclude the use of an ingredient based on a manufacturer's self-determination that the use is GRAS. In some cases, manufacturers have started using an ingredient based on such a determination, even though they have also filed a petition for GRAS affirmation. Furthermore, based in part on limited agency resources, final FDA action on such petitions may take a significant amount of time. For this reason, even though the recent final rule on olestra did include a statement of the digestibility coefficient for this substance (in § 172.867(e)(5), FDA states that olestra shall not be considered as a source of fat for purposes of nutrition labeling or nutrient content claims), FDA recognizes that there may not be a regulation in part 172 or part 184 in which to list the digestibility coefficient.

Therefore, FDA recognizes that, at least under the current state of affairs, it may not be possible to list all digestibility coefficients for fat and fatty acids in parts 172 and 184. Nonetheless, FDA considers that there should be some method by which digestibility coefficients are brought to FDA's attention before these coefficients are used in labeling food. Consequently, under its authority in sections 403(r)(2)(A)(i) and 701(a) of the act (21 U.S.C. 371(a)), FDA is proposing in § 101.63(b) to provide that claims based on the amount of available fat and fatty acids may be made in food labeling if: (1) Appropriate notification procedures are followed and the agency has not objected to the digestibility coefficient suggested by the manufacturer, (2) the food meets the criteria for the claim as specified in § 101.62, and (3) the food bears nutrition labeling in accordance with provisions in § 101.63(e), as proposed.

3. Notification Procedure

In § 101.63(c), the agency is proposing to require that a manufacturer of a fat-based fat substitute notify the agency of its intention to market the ingredient. FDA tentatively concludes that a notification requirement is necessary for a number of reasons. First, notification will enable the agency to identify foods that bear fat or fatty acid claims based on the use of a manufactured fat-based fat substitute. Thus, the agency will not be alarmed if it finds in a compliance check conducted in accordance with § 101.9(g) that the food contains more fat and fatty acids than is declared on the label. Second, notification will enable FDA to evaluate the basis for the reduced availability claim and to object if it appears that the claim is not valid.

One of the objectives of the 1990 amendments was to ensure that when nutrient content claims are made in food labeling, they provide consumers with useful information that will assist them in maintaining healthful dietary practices. For FDA to ensure that the digestibility coefficient for a fat does not underestimate the amount of fat that will be absorbed into the body, and thereby contribute to the fat intake that Americans are encouraged to limit (Ref. 10), FDA must be able to review the data that support the digestibility coefficient that the manufacturer believes should be used in calculating the amount of fat available from the ingredient.

To do this, the agency must have sufficient time to evaluate the evidence that supports the claim of reduced availability and to decide whether there is any reason to object to the suggested digestibility coefficient. FDA tentatively concludes that the 120-day notification procedure in proposed § 101.63(c) will satisfy FDA's needs while imposing a minimal burden on manufacturers who will be able to proceed to market with products that bear the claims unless FDA objects.

Finally, as stated above, FDA may not have reviewed the safety of some manufactured fat substitutes. A notification requirement will mean that the agency will have an opportunity to ensure that the evidence supports the claim of reduced availability without passing on the use of the ingredient. Thus, a notification requirement provides a nonintrusive way for the agency to protect the public trust in nutrition label information and in nutrient content claims without creating the unwarranted impression that the ingredient is necessarily safe.

In § 101.63(c)(1) through (c)(5), FDA is proposing the elements that must be included in the notification to the agency. The agency is proposing to require in § 101.63(c)(1) through (c)(3) that the manufacturer provide the firm's name and address, the identity of the substance, and descriptive information about the substance. This descriptive information must include the method of analysis for quantifying the amount of the fat-based fat substitute in the food and should include appropriate information on validation. Also, where the fat substitute is not a single compound, but a family of similar structured fats, a statement about the possible need for separate values for the availability of each of the various formulations would help the agency review the data in a timely fashion.

These elements of the notification are necessary to: (1) Allow unambiguous communications between the manufacturer and the agency about the substance, (2) assist the agency in understanding the data provided in support of the digestibility coefficient, and (3) allow the agency to determine whether the data were obtained using adequate analytical methodology. In situations where analytical methodologies have been supplied to FDA as a part of a food additive or GRAS petition, or through some other means, it would be sufficient to state where the information may be found in the agency's records.

In § 101.63(c)(4) and (c)(5), the agency is proposing that the manufacturer specify the digestibility coefficient that is expected to be used for the fat and fatty acids present in the fat substitute and provide FDA with data that it believes establish the appropriateness of the digestibility coefficient. As explained above, FDA must be assured that there is strong scientific support for the appropriateness of a digestibility coefficient to ensure that any claims made on the basis of the declared amounts of fat and fatty acids are not false or misleading or are not contrary to the stated public health objectives.

The value specified for the digestibility coefficient is critical because it will determine the amount of fat and fatty acids declared on the label and thus the claims that can be made for the foods in which the product is used. If a digestibility coefficient is incorrectly calculated, or if its use is inappropriate for a particular ingredient or food application, the amount of fat or fatty acids in a food could be over- or underreported by a large margin. Underreporting the amount of available fat or fatty acids in a food would seriously misbrand the food because the

consequences of consuming the food would be misrepresented by the label. Overreporting of fat or saturated fat content would not be as big a problem, because it would mean that consumers who structure their diets based on nutrition label values will have an extra measure of assurance that their diets contain the level of these nutrients that they wish to receive. Thus, if this proposal is adopted as proposed, FDA intends to work with manufacturers to arrive at digestibility coefficients for fat substitutes that do not underestimate the amount of fat or saturated fat that will be available to most consumers from consuming the product in question.

While FDA tentatively agrees with the petitioner that the available level of fatty acids, as well as of fat, should be declared on the nutrition label when a manufactured fat-based fat substitute is used, the agency does not expect that the same digestibility coefficient will necessarily apply to all types of fatty acids in a fat substitute. For example, it is possible that the entire reduction in total fat could reside in one subcategory of fat, e.g., saturated fat. An approach that involves applying an appropriate digestibility coefficient to each fatty acid is consistent with the approach embodied in the agency's statement in the August 18, 1993, technical amendment to the nutrition labeling final rule (58 FR 44063 at 44073). This approach involved applying a specific energy value to component fats to the extent that the fatty acids that constitute the fat ingredient in question belong to that specific subcategory (e.g., saturated fat) to which the value applies. Accordingly, the agency expects that manufacturers who wish to declare adjusted values of saturated fat, polyunsaturated fat, or monounsaturated fat based on reduced availability of a fat substitute will submit information on the digestibility coefficients for each of those fatty acids in addition to the digestibility coefficient for fat.

FDA seeks comments, with supporting data, on its tentative conclusion that digestibility coefficients need to be specified and applied to each type of fatty acid if the amounts declared in the nutrition label for those fatty acids are to represent only the available amounts.

In proposed § 101.63(c)(5), the agency outlines the types of information that will need to be submitted to establish the digestibility coefficients for total fat and for the fatty acids. FDA has drafted this provision to suggest the types of questions that the agency is likely to raise in its evaluation of data submitted in support of digestibility coefficients. It is based on the concerns that have arisen when the agency has considered digestibility coefficients and on the types of evidence from adequate and well-controlled studies that would be useful in addressing them. It is also based on what the agency learned in evaluating the food additive petition for olestra.

In proposed § 101.63(c)(5)(i), FDA is proposing to require that the data submitted demonstrate the reduced absorption of the substance. The agency is not proposing to prescribe specific types of evidence that need to be submitted because it wants to provide a degree of flexibility, and because it recognizes that fat availability is a relatively new matter. There is no commonly accepted method (e.g., an Association of Official Analytical Chemists International validated method) for measuring availability in humans or for determining a digestibility coefficient for fat in a particular food or ingredient. To enable it to evaluate availability, FDA considers it important for the agency to have information on factors such as: Individual variability in absorption; the relationship between the amount of the fat substitute ingested and the rate of absorption of components of the fat (i.e., dose-response); the relative usefulness of animal data for the determination of availability of an unconventional fat source; the representativeness of the sample of subjects tested to the general population for whom the fat substitute is intended; the need for special testing in vulnerable subpopulations; the completion rate in clinical studies; and any adverse events occurring during the study.

As stated above, it is important that the declared value for fat not underestimate the amount of fat that is available. Thus, the range of responses reported for various individuals, described in proposed § 101.63(c)(5)(i)(A), is of particular concern. The agency has traditionally considered safety assessments based on estimates of consumption at the 90th percentile of exposure. For nutrition labeling modifications based on changed availability, however, it is not clear that the 90th percentile of absorption should be used. The agency welcomes comments on these elements for determining the digestibility coefficient.

Proposed § 101.63(c)(5)(ii) requests information about foods or diets that may affect the digestibility coefficient. Responses to this request would be information about possible interactions between the ingredient and other components of the food or diet that could affect the digestibility coefficient, steps in processing the types of foods expected to contain the fat substitute that could affect the digestibility coefficient, the impact of the amount of substance used in feeding studies on the digestibility of the substances in the study, and the duration of feeding studies and any changes in the digestibility coefficient over time. As the agency has gained experience with the determination of the availability of fat, it has found the types of information highlighted in proposed § 101.63(c)(5)(ii) to be important. Research suggests that a number of factors, including the food matrix, the percent fat in the food, and the processing conditions and temperatures affect the availability of fat (and other nutrients) (Refs. 4 and 16). Tristearin, for example, has reduced availability when food is ''cold processed,'' but its availability goes up dramatically if the food is heated at temperatures of 80 to 85 °C (Ref. 14). When there is reason to believe that the amount of the fat substitute used in the food, the food matrix, or the processing method may bear on the availability of fat from the fat substitute, FDA may find it necessary to limit the application of the digestibility coefficient to only those conditions for which reliable data are provided.

Other factors also appear to affect the digestibility coefficient. For example, a comment to the docket of the subject petition suggests that high levels of calcium and magnesium in experimental diets may contribute to a reduced absorption of some fats (Ref. 17). In addition, FDA's evaluation of the data submitted in the petitioner's GRAS petition suggests an important inverse dose-response relationship between the amount of stearic acid in a food and the fraction of stearic acid that is absorbed (Ref. 18). Consequently, the level of feeding of a fat substitute in a diet may materially affect the digestibility coefficients. Similarly, FDA has determined that there is substantial variability among individuals (animals or humans) in the amount of stearic acid that they absorb from a particular diet (Ref. 18). The agency requests comment on additional factors that may affect digestibility and on how digestibility coefficients should be adjusted to reflect these factors and the other factors mentioned.

Because of the tight time constraints that will be on FDA if it is to review the notification within 120 days, the agency is proposing in § 101.63(c)(6) to require that the notification include a certification that the manufacturer is

submitting all data of which it is aware that pertain to the digestibility of the fat substitute that is the subject of the notice. With this certification in hand, FDA can begin its review immediately, without having to spend time searching for all available materials on the compound.

FDA is also proposing in § 101.63(c)(6) to require that the manufacturer certify that, for as long as it markets the ingredient, it will submit any new data about the digestibility of the ingredient as it becomes available. Most fat substitutes that will be the subject of a notice are quite new, and thus it seems likely that at least some additional information about them and their availability to the body will be forthcoming after their introduction into the marketplace.

Proposed § 101.63(c)(7) states that the materials being submitted in the notification are to be sent to the Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

The agency welcomes comments on issues that it is proposing be addressed, and on the material that it is proposing to require be included in the notification. Are there other types of studies that should be required as a part of the notification? If so, are there validated methodologies for those studies?[2]

4. FDA Review

Proposed § 101.63(d) provides that FDA will review the notifications of digestibility coefficients that it receives, and that, if the agency does not object in writing within 120 days of its receipt of a notification, the firms that use that fat substitute in their products may begin to make nutrient content claims based on the specified digestibility coefficients. To ensure that both FDA and the firm are clear on that date, FDA will notify the firm submitting the notification of the date on which it received the notification.

The agency anticipates that 120 days will be sufficient time for it to determine whether there is reason to question the scientific basis for a digestibility coefficient. While FDA anticipates that the information to be reviewed will be complex because of the inclusion of clinical studies, the scope of the task is limited to the demonstration of the appropriateness of the digestibility coefficients without concerns for other factors, such as safety or toxicity. Therefore, the agency expects that the information in the notification can be reviewed expeditiously.

Even with premarket review, the agency recognizes that new information may become available, or that there may be a new understanding of data of which the agency is already in receipt, that could show that a particular digestibility coefficient is in error. In such a case, what mechanism should be used to respond to such developments? Is it sufficient to notify the manufacturer, who would then be responsible for notifying all users of the product? Should FDA publish a notice in the Federal Register? What amount of time should be provided for making label corrections before products introduced into interstate commerce would be considered misbranded?

There is likely to be considerable interest from a broad segment of the public (including members of the regulated industry; other Federal, State, and local government agencies; international government agencies; and public interest groups) in information submitted. Such groups may wish to review the data and offer comments to the agency. The agency tentatively concludes that making the information publicly available is the most direct and administratively efficient way of informing the public, including the scientific community, of the data that support a particular digestibility coefficient. FDA requests comment on this tentative judgment.

To meet the expected public interest and to provide guidance about the contents of a notification found acceptable by the agency, FDA is considering establishing a procedure in which it will place all notifications about which it has not objected in a file at Dockets Management Branch once the 120-day review period has passed. Is there a need to call attention to material placed in a docket, perhaps through a mechanism such as a notice of availability published in the Federal Register? Should the information be made available before the completion of FDA's review? Are there reasons why any of these materials should not be made publicly available? Should FDA review be based only on published research on the digestibility coefficient? FDA is also interested in comments on whether there is a need for a compiled listing of digestibility coefficients, including those that may be included in a regulation in part 172 or 184, in a format that is readily available to the public.

5. Levels of Fat or Saturated Fat

As stated above, proposed § 101.63(b) specifies that nutrient content claims for fat and saturated fat may be made on a food product label or labeling if, based on the digestibility coefficient, the amount of available fat or saturated fat meets the quantitative level requirements for the claim in § 101.62.

While the petition spoke only of ''reduced fat'' claims, its premise that nutrient content claims can be based on the quantity of available fat would permit use of ''fat free,'' ''low fat,'' and similar saturated fat claims when the digestibility coefficient for the fat substitute is small enough to result in amounts of available fat or available saturated fat that meet the criteria for the claim (e.g., because olestra is unavailable, foods that contain olestra as the only source of analytically measured fat may be eligible to bear a ''fat free'' claim). Accordingly, proposed § 101.63(b) provides for the use of all fat and saturated fat claims defined in § 101.62 to be based on available fat or available saturated fat.

To provide for claims based on availability of fat and saturated fat, FDA is proposing to revise § 101.62(b)(1)(i), (b)(2)(i)(A) and (b)(2)(i)(B), (b)(3)(i), (b)(4)(i), and (b)(5)(i) by revising the term ''fat'' to state ''total fat or, as provided in § 101.63, available fat'' and § 101.62(c)(1)(i), (c)(2)(i), (c)(3)(i), (c)(4)(i), and (c)(5)(i) by revising the term ''saturated fat'' or ''saturated fatty acids'' to state ''saturated fat or, as provided in § 101.63, available saturated fat''.

Although the petitioner did not specifically address cholesterol nutrient content claims, there are a number of references to ''total fat'' and ''saturated fat'' in § 101.62(d). Section 101.62(d) defines when cholesterol nutrient content claims can be made for products containing specific levels of total fat (e.g., 13 g or less per reference amount customarily consumed) and includes limits on the amounts of saturated fat that may be in a product for it to bear a cholesterol nutrient content claim. FDA requests comment on whether, for consistency, the terms ''total fat'' and ''saturated fat'' in § 101.62(d) should be revised to specify ''available fat'' or ''available saturated fat.'' The agency also requests comment on the implications of such revisions. Specifically, the agency is interested in whether such changes are appropriate,

[2] FDA's review of the extensive data in the olestra food additive petition led the agency to conclude that nearly all of the ingested olestra remains intact and is not absorbed (61 FR 3118 at 3127). Given the extensive data in the olestra petition and given the agency's tentative conclusion above that unabsorbed fats are not available for use or storage in the body, and therefore are consistent with public health goals of reducing dietary fat intake, if the agency adopts proposed § 101.63, it will consider the notification requirements to have been met for olestra, and its evaluation of the information to have been completed.

and in whether such changes will facilitate the wider use of cholesterol nutrient content claims. The paragraphs in § 101.62(d) under consideration for revision include the following: § 101.62(d)(1)(i) and (d)(1)(i)(C); (d)(1)(ii), (d)(1)(ii)(C) and (d)(1)(ii)(D); (d)(2)(i) and (d)(2)(i)(B); (d)(2)(ii) and (d)(2)(ii)(B); (d)(2)(iii), (d)(2)(iii)(B), and (d)(2)(iii)(C); (d)(2)(iv), (d)(2)(iv)(B), and (d)(2)(iv)(C); (d)(3); (d)(4)(i) and (d)(4)(i)(B); (d)(4)(ii), (d)(4)(ii)(B), and (d)(4)(ii)(C); (d)(5)(i) and (d)(5)(i)(B); and (d)(5)(ii), (d)(5)(ii)(B) and (d)(5)(ii)(C). Should the agency conclude after its review of the comments that these changes are consistent with the goals of the nutrient content claims provisions, it will include such changes in the final rule.

Similarly, the disclosure levels for the nutrient content claims provisions found in § 101.13(h)(1), (h)(2), and (h)(3); the health claims disqualification levels found in § 101.14(a)(5), (a)(5)(i), and (a)(5)(ii); the criteria for fiber claims found in § 101.54(d)(1); and the criteria for ''light'' and ''lite'' nutrient content claims in § 101.56 also include references to total fat and saturated fat. The agency requests comment on the implications of changing these sections of the regulations to reflect ''available fat'' and ''available saturated fat.'' Again, the agency will revise these sections of the regulations if it concludes, based on comments, that such changes are useful in helping consumers to construct healthy diets.

6. Nutrition Labeling

Nutrient content claims based on fat availability could be confusing unless § 101.9 is modified so that the levels of fat and fatty acids declared in the nutrition label reflect the basis for claims. Accordingly, FDA is proposing to require in § 101.63(e) that, when a claim is made for fat or saturated fat under § 101.63, the nutrition label declare the amount of available fat or fatty acids in accordance with the format requirements in proposed § 101.9(d)(15). In addition, to provide the necessary flexibility FDA is proposing to add § 101.9(d)(15), which is discussed below, and to modify § 101.9(c)(2), (c)(2)(i), (c)(2)(ii), and (c)(2)(iii) to provide that foods that bear a claim that is made in compliance with § 101.63 may declare the grams of available fat, saturated fat, polyunsaturated fat, or monounsaturated fat, respectively, in lieu of the usual declaration in the nutrition label. This proposed action will provide consistency between the amount of available fat or saturated fat that is the basis for the claim and the amount of fat and saturated fat that is declared in the nutrition label, thereby preventing the consumer confusion that would likely occur if declared amounts do not meet the criteria for claims made. Additionally, if poly- or monounsaturated fat is declared on the label, it will ensure that the sum of all fatty acid subcomponents does not exceed the declared amount of total fat.

FDA has considered, but tentatively rejected, the option of allowing claims based on levels of available fat and saturated fat, while continuing to require that the analytically-determined amount of total fat and saturated fat be declared in the nutrition label, with a footnote outside of the nutrition label explaining that the product contains a fat substitute that is only partially used by the body, thereby reducing the amount of available fat and saturated fat. While FDA is aware of two products on the market that are using this approach (Ref. 19), the agency is concerned that this approach is cumbersome and confusing to consumers and may reduce consumer confidence in the accuracy of the values declared in the nutrition label. In addition, this approach is internally inconsistent in that it provides for nutrient content claims based on the premise that fat affects the body only to the extent that it is available but does not use the same basis for the declaration of fat in nutrition labeling. FDA requests comment on its tentative judgment.

a. *Terminology.* The agency is proposing to continue to use the term ''total fat'' within the nutrition label of products containing a fat substitute and for which the amount of fat declared has been calculated in accordance with proposed § 101.63 using a digestibility coefficient. FDA considered proposing to require the use of a different term, such as ''available fat,'' with a footnote stating that the product contains a specified fat substitute that is not absorbed (or is poorly absorbed) and possibly listing the amount of fat present in the food that is not used by the body. However, the agency is concerned about consumers' reactions to the introduction of a new term on the nutrition label and about their ability to understand and use the additional information. Consumers have had just over 2 years to adjust to new food labels that resulted from the implementation of the 1990 amendments. While recent consumer studies have shown a very positive consumer response and increased use of nutrition labeling (Ref. 20), this consumer confidence and trust in the nutrition facts panel needs to be nurtured rather than challenged by the introduction of new terms and concepts.

The agency is concerned that some persons may believe that the term ''total fat'' is misleading if the amounts declared represent only the amounts of available fat, not analytically determined levels of total fat. However, when scientific studies show that a fat substitute is not absorbed or metabolized by the body, the resulting declared value for fat would represent the total fatty acids providing energy. In the nutrition labeling final rule, FDA stated that the definition of ''fat'' that it had adopted included all sources of fatty acids providing energy (58 FR 2079 at 2087). Additionally, the Food and Agriculture Organization of the United Nations and the World Health Organization Expert Consultation on Fats and Oils in Human Nutrition, consistent with guidelines provided by the Codex Alimentarius Commission, recommends that fat be defined for nutrition labeling purposes as the ''sum of all fatty acids providing energy'' (Ref. 21). Because the portion of the fat source that is not available to the body is not providing energy, FDA tentatively concludes that it is not misleading to use the term ''total fat'' to represent the amount of fat available for use by the body. FDA seeks comment on this tentative conclusion. For example, what are its implications for how the amount of fat from other, natural sources is declared?

b. *Declaration of percent of Daily Value (DV) for fat.* Current § 101.9(d)(7)(ii) states that the percent DV shall be calculated ''by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV [Daily Reference Value] for the nutrient * * *.'' Inasmuch as FDA is proposing to revise § 101.9(c)(2) to allow for the declaration of available fat, the agency does not consider it necessary to modify § 101.9(d)(7)(ii) to allow the percent DV declaration to represent the available amount of fat.

c. *Footnote and format requirements.* The agency is proposing that, when a digestibility coefficient has been used to calculate the amount of fat declared in nutrition labeling, a footnote be included within the nutrition label stating that the declared amount of fat represents an adjusted amount based on the digestibility of the fat source. The footnote will serve the purpose of informing both consumers and FDA that the amount declared has been adjusted to account for digestibility. During a compliance check, this notification will alert the agency to adjust analytically determined values for fat and fatty acids

according to digestibility coefficients submitted in compliance with the notification procedure in proposed § 101.63.

A number of different possible footnote statements could be used to signal the fact that ''total fat'' and any fatty acid content declarations have been adjusted to reflect reduced availability. For example, direct reference to the adjustment could be made with statements such as ''Fat content adjusted for reduced availability of fat from [*name of ingredient*],'' ''Adjusted for reduced absorption of [*name of ingredient*],'' or ''Represents an amount adjusted for absorption of [*name of ingredient*].'' It may be that mention of the fat substitute and the fact that it has limited availability would be sufficient to alert consumers to the fact that total fat and any fatty acid contents have been adjusted. Such a statement might be ''This product contains [*name of ingredient*], which is only partly available.'' Alternatively, consumers may be better informed by statements that include the quantitative amount of the fat substitute and the digestibility coefficient, through use of statements such as ''Each serving contains 9 g of [*name of ingredient*], which is only ____% absorbed by the body.'' FDA is seeking comment on the type of statement that will most simply and understandably communicate the fact that the declared values for total fat and any fatty acids have been adjusted to represent the amount of fat and fatty acids available to the body. The agency urges commenters to test the utility of a variety of possible statements and to submit the results of such tests during the comment period.

To assist consumers in locating the footnote, FDA is proposing in § 101.9(d)(15) that the declaration of the number of grams of available fat and of any fatty acids each be followed by an asterisk or other symbol that refers consumers to the footnote. To increase its prominence, the agency is proposing that this footnote be placed above the percent DV footnote required by § 101.9(d)(9) and separated from that footnote by a hairline (see FIGURE 1 sample label).

BILLING CODE 4160–01–F

Figure 1

Fudge Covered Sandwich Cookies

Reduced Fat
25% less fat than leading fudge covered sandwich cookie

These cookies: 4.5g fat
Leading brand: 6g fat

Nutrition Facts
Serving Size 1 cookie (25g)
Servings Per Container 24

Amount Per Serving	
Calories 100	Calories from Fat 40
	% Daily Value**
Total Fat 4.5g*	**7%**
Saturated Fat 3g*	**15%**
Polyunsaturated Fat 0g*	
Monounsaturated Fat 1g*	
Cholesterol 0mg	**0%**
Sodium 65mg	**3%**
Total Carbohydrate 13g	**4%**
Dietary Fiber 1g	**4%**
Sugars 8g	
Protein 1g	

Vitamin A 0%	•	Vitamin C 0%
Calcium 0%	•	Iron 2%

*Fat content adjusted for reduced availabilty of fat from *(name of ingredient)*.

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

BILLING CODE 4160–01–C

Short phrases, such as those discussed above, should be sufficient to inform both consumers and FDA that the amount declared has been adjusted to account for digestibility. However, it is likely that health professionals and some knowledgeable consumers may wish to obtain more information, such as the percent digestibility of the fat substitute or the amount of that ingredient in a serving of the food. The agency requests comments on how such information could best be provided if this proposed rule is adopted. Should the additional information be contained in the footnote? If not, is it sufficient for manufacturers of products containing such fat substitutes to provide a phone number or address for consumers and health professionals to use to obtain desired information?

In regard to the calorie conversion footnote provided for in § 101.9(d)(10) (i.e., ''Calories per gram: fat 9, carbohydrate 4, protein 4''), the petitioner argued that the requested action, i.e., allowing a digestibility coefficient to be applied to total fat and to other labeled fat values, would resolve an inconsistency in the nutrition label that could exist when manufacturers use a food factor other than 9 to calculate the calories from declared levels of total fat. FDA agrees that the proposed action could resolve this inconsistency. However, the agency points out that, in the August 18, 1993, technical amendments to the nutrition labeling final rule (58 FR 44063 at 44067), FDA amended § 101.9(d)(10) to make the calorie conversion footnote voluntary. Therefore, the petitioner's concerns about inconsistency in the nutrition label are easily addressed by omitting the calorie conversion footnote from the nutrition label. The agency requests comment on whether, to prevent any confusion on the consumer's part, the optional calorie conversion footnote, in fact, should be prohibited where the amount of fat declared is adjusted to reflect availability, and attention is drawn to

that fact by the presence of an explanatory footnote.

7. Compliance

FDA notes that this proposal would require that manufacturers provide the agency with data in support of a digestibility coefficient for a specific fat-based fat substitute. However, if the proposal is adopted, the basis for calculating declared amounts of available fat and fatty acids in a food in which a fat substitute is used in combination with other conventional fat ingredients will be known only by the manufacturer of the finished food. If FDA is to be able to determine whether the amount of available fat declared in nutrition labeling accurately reflects the amount of fat actually available from the food, the agency will need to know the amount of the fat substitute in the finished food.

Accordingly, FDA is proposing in § 101.9(g)(10) to require that, when a food bears a claim in accordance with proposed § 101.63 and declares available fat and fatty acids in nutrition labeling, records and underlying data that support the amounts declared in nutrition labeling be made available by the manufacturer of the finished food to appropriate regulatory officials upon request. This requirement is similar to that proposed by FDA on February 2, 1996 (61 FR 3885) which, if finalized as proposed, would require, in specified circumstances, that records be retained and be made available for inspection when certain nutrient content and health claims are made.

Such records inspection would allow the agency to evaluate the declared amounts of available fat by using company records, identifying the amount of the fat substitute in the product, subtracting that amount from analytically determined amounts of total fat, and applying the digestibility coefficient to the amount of the fat substitute present in a serving of the food. The sum of the amount of total fat remaining after subtraction of the weight of the fat substitute plus the amount of the digestible portion of the fat substitute should equal the weight of available fat declared on the label.

FDA notes that it has, on a number of occasions, determined that adequate enforcement of labeling rules would be possible only if the agency can review the information that a manufacturer has developed to support the statements on its food labels. For example, in the January 6, 1993, final rule on serving sizes (58 FR 2229 at 2271), FDA provided that manufacturers of aerated foods could substitute a volume-based measure for a weight-based reference amount as the basis for determining a product's serving size. However, manufacturers who choose this approach must make available upon request certain information, including a detailed protocol and records of all data used to arrive at the density-adjusted reference amount (58 FR 2272, § 101.12(e)). In the nutrient content claims final rule, FDA also imposed a records requirement on firms that use a broad based reference nutrient value for claims such as ''light'' (58 FR 2302 at 2365, § 101.13(j)(1)(ii)(A)).

The agency tentatively concludes that a similar records requirement for foods declaring available fat in the nutrition label is necessary for efficient enforcement of the act. Compliance with this records inspection provision would not entail the creation of any new information or the compilation of any special records. Rather, firms would simply need to provide the agency with access on request to information that they should already possess.

FDA advises that if information on the amount of the fat substitute in a serving of food is not forthcoming because, for example, firms believe the agency has no authority to obtain this information, it may well decide not to adopt this proposal. Without this information, FDA cannot ensure that the quantitative claims are valid. Without such assurance, the risks of consumer deception would outweigh any gain from the availability of claims based on the amount of available fat.

8. Misbranding

Proposed § 101.63(f) provides that a food product will be deemed to be misbranded under section 403(r)(1)(A) of the act if it bears a claim based on availability of fat or fatty acids from a fat substitute, and FDA has written an objection based on its review of the notification submitted under § 101.63(c), or if a product is marketed bearing claims based on the available level of fat or fatty acids without the fat substitute having been the subject of a notification procedure in § 101.63. Section 403(r)(1)(A) of the act requires that claims that characterize the level of nutrients in a food use terms that are defined in regulations. In this proposal, FDA has structured the definition of fat and fatty acid claims that are based on fat availability to include compliance with the notification procedures in § 101.63(c). In addition, proposed § 101.63(f) reflects the fact that products that make a claim based on fat availability, but for which there has not been compliance with § 101.63, would be misbranded under section 403(a) of the act because their label would be misleading.

D. Conforming Amendment

The agency is proposing to revise § 101.13(o) to clarify that, when a fat source is used in compliance with proposed § 101.63, under which FDA is notified of the digestibility coefficient, compliance with the requirements for nutrient content claims for fat and fatty acids may take the coefficient into account rather than just the fat measured by the analytical methodologies prescribed for determining compliance under§ 101.9(g).

E. Overview of Issues Related to Availability

While FDA has decided to grant the petition in part and to proceed with this rulemaking to provide for the use of claims based on available fat content and the declaration of available fat in nutrition labeling, an opportunity for public comment is being provided to address wider issues regarding the use of availability as the basis for nutrient content claims and nutrition labeling as follows: (1) Will the proposed action discourage innovation in the development of nonfat fat substitutes (i.e., protein- and carbohydrate-based fat substitutes)? (2) Are there greater health benefits in replacing all or part of the fat in a traditional food with a protein- or carbohydrate-based fat substitute? (3) How will the replacement of conventional fats with a fat substitute with reduced availability affect dietary goals, such as encouraging consumers to choose foods that are high in complex carbohydrates? (4) Will providing for the declaration of amounts of available fat on the nutrition label promote a significant increase in the use of very long chain (>C18) fatty acids in place of common dietary fatty acids (C12–C18)? (5) Are there any safety concerns associated with such a shift?

Additionally, if the proposed action does not become a final rule because of objections to the principle of providing for claims and nutrition labeling based on availability, are there other, more appropriate ways to inform consumers of the amount of available fat in a food product? Comments are requested on these issues.

FDA has, on a number of occasions, raised the issue of nutrient availability. For example, in the Federal Register of August 29, 1978 (43 FR 38575 at 38576), the agency stated that it intended to publish a proposal on availability requirements of iron sources used to fortify foods. At the time, however, FDA did not have sufficient information on

availability of iron from different sources or on how to best measure iron availability in foods. Consequently, the agency did not publish a proposal. Since that time, significant research has been done to evaluate availability of different nutrients and food components. Basing fat claims on amounts of available fat could set a precedent for doing so with other nutrients, such as iron and calcium. Is there sufficient data to consider labeling issues based on the availability of nutrients other than fat, and, if so, how might consumers be affected?

III. Analysis of Impacts

FDA has examined the economic implications of the proposed 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. Similarly, it has been determined that this rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

FDA is proposing to allow the declaration of available amounts of fat and fatty acids in nutrition labeling when fat-based fat substitutes are used. FDA also is providing for definitions for claims based on amounts of available fat and fatty acids in a food. Currently available fat-based fat substitutes include such substances as salatrim, caprenin, and olestra. This rule will not result in any changes for manufacturers of products containing olestra because, in the food additive approval, FDA determined that olestra will not be counted as a fat.

A. Benefits

If finalized, the proposal to provide an expanded definition of fat claims based on available fat would give manufacturers a way to promote products containing novel fat ingredients, thereby encouraging innovation and increasing consumers' product choices in planning healthy diets.

B. Costs

There are two different ways in which the rule imposes costs: (1) Revising existing labels to reflect the new regulations; and (2) data gathering and premarket notification.

Any food manufacturer currently using claims based on available fat for foods containing fat-based fat substitutes may have to change their labels to reflect the new regulations. Such labels may be changed to reflect proper wording of the claim as allowed by FDA. To continue to use the claims, manufacturers will have to alter the nutrition facts panel on their products so that the amount of fat that is reported reflects the amount that is available. FDA is aware of very few products containing fat-based fat substitutes on the market. FDA is aware of two manufacturers marketing products containing a fat-based fat substitute (other than olestra) for which claims are made. However, because of recent emphasis on reducing intakes of fat, FDA expects that many products containing fat-based fat substitutes will be marketed in the future. Because of the small number of such products currently in existence, few if any labels will be modified as a result of this proposed regulation if made final. Therefore, the label revision costs of this proposed regulation will be minimal.

The second way in which the rule imposes costs is in the premarket notification requirements for the digestibility coefficient. If this proposal is adopted, producers of fat substitutes will be required to notify FDA of their intent to market fat substitutes that could provide the basis for nutrient content claims based on availability and to provide the agency with data supporting a digestibility coefficient. Thus, the fat substitute will be tested to determine the digestibility coefficient. FDA estimates that the cost of testing a fat substitute to determine digestibility will be in excess of $100,000 and perhaps as high as $1 million. It is not clear that the costs of the initial notification will be significantly more than the current cost of FDA approval of a substitute. However, FDA is also proposing to require the notifier to continue to submit any information related to the availability of the fat substitute of which it becomes aware to FDA as long as the ingredient is marketed. Therefore, producers will continue to bear the costs of informing FDA of any new information pertaining to the digestibility of the fat substitute that becomes available. FDA is not proposing to require that firms continue to generate or actively seek out new data, only that they provide FDA with any data of which they become aware. Therefore, although not zero, the costs will not be significant.

C. Regulatory Options

1. Approval of the Nutrient Content Claim

One option available to FDA is to deny the petition for nutrient content claims based on the availability of fat. Because the marketability of fat-based fat substitutes depends on the manufacturers ability to market the food containing them as lower in fat, if FDA were to select this option, firms would not have any reason to develop fat substitutes that are less bioavailable. Therefore, FDA would be stifling innovation. Also, if FDA were to deny the petition, consumers would not benefit from the availability of lower available fat foods.

2. Premarket Approval

As an alternative to premarket notification, FDA considered the options of premarket approval of the digestibility coefficient and postmarket notification. A premarket approval of the digestibility coefficient would result in the manufacturer not being able to market a food containing a fat-based substitute until FDA has published in the Federal Register its approval of the coefficient. This option could result in great delays in marketing a product and would be more costly to all parties involved—the firms, the consumer, and the government. However, this option would provide all parties with greater certainty about the information provided on the label.

3. Postmarket Notification

In contrast to a premarket notification, under a postmarket notification requirement the manufacturer can market the food prior to notifying FDA. However, although a postmarket notification clearly does not cause a delay in placing the product in the marketplace, it is not clear that a premarket notification requirement would cause any delay in marketing the food because manufacturers would account for the FDA review period in their timeframes. FDA requests comments on whether the options of postmarket notification and premarket notification are significantly different

with respect to delays in marketing foods.

A postmarket notification might result in greater uncertainty about the nutritional content of the food. Also, if FDA were to determine that the digestibility coefficient is inaccurate or inappropriate after the product is marketed, then the manufacturer will incur significant costs to remove the product from the market, reanalyze the digestibility, revise the labeling, and try again to market the product. Similarly, if the digestibility coefficient is wrong, then consumers could be harmed if the foods they believe are low fat are not in fact low fat.

4. Sunset Provision

Another regulatory option available to FDA would be to limit the length of the time for which the notifier is required to continually submit information to FDA. This option would reduce costs by reducing the amount of information that must be provided to FDA. Although significant information may be generated with experience in marketing the product, at some point in time, the marginal cost of that information may exceed the marginal benefit. FDA requests comments on this option, including how long the manufacturer should be required to update the notification.

5. Multiple Digestibility Coefficients

FDA is raising questions about whether it is appropriate to establish one digestibility coefficient for fat and its fatty acid subcomponents for all approved uses of a fat substitute, or whether different digestibility coefficients should be established for each fatty acid subcomponent and for different uses. If different food components and different processing methods significantly affect the digestibility of fat, then different coefficients may be appropriate for different foods or different conditions of use. If one digestibility coefficient is appropriate for all approved uses, then the necessary tests will be conducted once as a part of the initial development and approval of the fat substitute.

The ability to make a nutrient content claim based on the availability of the fat then will apply to all producers of foods that include the fat substitute. However, if FDA determines that one digestibility coefficient for all uses is not appropriate, then the digestibility of the fat substitute will need to be tested, and a new notification submitted, as appropriate when the fat substitute is used under conditions that would change its digestibility. Because there are no official methods for determining the digestibility of a fat substitute, FDA cannot estimate the costs of performing new tests for each use. The agency is aware however that, animal tests are relatively costly, in excess of $100,000 per test and perhaps as high as $1 million. The digestibility of the fat substitute is likely to be tested only for those uses for which the expected revenues will exceed the costs of the tests and premarket notification. Because testing is a high fixed cost, digestibility coefficients would only be determined for products with a sufficiently high volume.

D. Regulatory Flexibility

FDA has also considered the impact of the premarket notification on small entities. None of the firms currently marketing fat-based fat substitutes, or the foods that contain them, are small. Therefore, the only potential for impact on small entities would be if this rule creates barriers to entry into markets for either fat-based fat substitutes or the products that contain them. The incremental cost of developing digestibility data and submitting it to FDA is not expected to be large relative to the cost of seeking approval for fat substitutes. In fact, because fat-based fat substitutes are developed specifically because of their reduced digestibility, digestibility testing for the initial intended uses may be a part of the development of the fat substitute. FDA requests comments on whether the incremental costs of the notification requirements themselves are likely to create barriers for the ability of small firms to develop or manufacture fat-based fat substitutes.

However, whether or not the notification requirements will create barriers for the ability of small entities to develop or manufacture foods that contain fat-based fat substitutes depends on whether or not one digestibility coefficient is determined to be appropriate for all approved food uses. If one coefficient is appropriate, then this rule is not expected to create any significant difficulties for small firms. However, if a separate digestibility coefficient is required for each approved use of a fat substitute, then this rule may create barriers to entry for small firms. As stated previously, the cost of testing the fat-based fat substitute for a particular use and submitting a notification will be prohibitive if the potential use is of sufficiently low volume. This situation will primarily occur in niche markets, which are dominated by small firms. Certain small firms might not be able to take advantage of the opportunity to market their product based on the amount of available fat. FDA cannot predict how many small firms, if any, might be prevented from using nutrient content claims based on available fat should different digestibility coefficients be required for each approved use of a fat substitute. However, given recent interest in reducing intakes of fat, it is likely that many small firms will have a desire to use fat-based fat substitutes and make claims based on available fat.

FDA requests comments, especially from small firms, on the economic implications of this proposal, specifically with respect to barriers to entry that might be created by a provision for different coefficients for each approved use.

Because of concerns regarding potential barriers to entry, if different digestibility coefficients are necessary for different uses of a fat-based fat substitute, it may cause a significant impact on small entities.

IV. The Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 and 3507). Therefore, in accordance with 5 CFR part 1320, a description of the information collection requirement is given below with an estimate of the annual collection of information burden. Included in the estimate is the time for reviewing instructions, gathering necessary information, and completion and submission of the notice. Also included is the time necessary for retaining records and making them available to appropriate regulatory officials.

FDA is soliciting comments to: (1) Evaluate 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) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) evaluate the quality, utility, and clarity of the information to be collected; and (4) 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.

Title: Notification of fat substitute digestibility coefficient.

Description: Section 403(r) of the act requires that food bearing nutrient content claims be labeled in compliance with regulations issued by FDA. FDA

has issued regulations in § 101.62(b) and (c) for nutrient content claims that may be used to characterize the level of fat and fatty acids in food products. Among other things, § 101.62(b) and (c) define specific levels of fat that may not be exceeded for a food product to bear specific nutrient content claims concerning fat or fatty acids.

The regulations set forth in this proposed rule provide that the digestibility of fat or fatty acids can be used as a basis for determining whether a food complies with the level requirements established in § 101.62(b) and (c) for nutrient content claims for fat or fatty acids. The proposed rule requires that manufacturers that intend to market a fat-based substitute whose reduced availability can be relied upon as the basis for nutrient content claims for fat or fatty acids notify FDA at least 120 days before marketing the substance. Such notification shall include data and other appropriate information to establish the appropriateness of the digestibility coefficients to be used for the substance and a certification that all data of which the firm is aware that pertains to the digestibility of the fat-based fat substitute is being submitted, with assurances that any new data will also be promptly submitted as it becomes available. Firms that use the substance in their food products may proceed to use claims based on the digestibility coefficient for the substance if FDA does not object to the digestibility coefficient within the 120-day review period. The proposed rule also requires that manufacturers of food products whose labeling bears nutrient content claims based in part or whole on digestibility of a fat-based fat substitute retain the all records that support the quantitative declaration of fat and any fatty acid components declared for as long as the product is marketed. The manufacturer of such a food product would be required to make those records available for review and copying by appropriate regulatory officials upon request.

Descriptions of Respondents: Persons and businesses, including small businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.63(c)	2	1	2	100	200
101.9(g)(10)	25	1	25	1	25
Total					225

There are no capital costs or operating and maintenance costs associated with this collection.

FDA believes that the information that would be submitted in a notification would be that information that a prudent business would obtain as a normal part of doing business.

The agency has submitted copies of the proposed rule to OMB for its review of these requirements. Interested persons are requested to submit written comments regarding information collection requirements by January 21, 1997, to the Office of Information and Regulatory Affairs, OMB (address above), ATTN: Desk Officer for FDA.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) 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.

VI. Comments

Interested persons may by April 21, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal and may by January 21, 1997, submit comments on the information collection requirements. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bender, A. E., ''Nutritional Significance of Bioavailability,'' in *Nutrient Availability: Chemical & Biological Aspects*, edited by D. Southgate, I. Johnson, and G. R. Fenwick, The Royal Society of Chemistry, Thomas Graham House, Cambridge, England, pp. 3 to 9, 1989.

2. Merrill, A. L., and B. K. Watt, ''*Energy Value of Foods—Basis and Derivation*,'' U.S. Department of Agriculture, Agriculture Handbook No. 74, U.S. Government Printing Office, Washington, DC, revised February 1973.

3. Allison, R. G., and F. R. Senti, ''A Perspective on the Application of the Atwater System of Food Energy Assessment,'' Life Sciences Research Office, FASEB, Bethesda, MD, 1983.

4. Apgar, J. L., C. A. Shively, and S. M. Tarka, ''Digestibility of Cocoa Butter and Corn Oil and Their Influence on Fatty Acid Distribution in Rats,'' *Journal of Nutrition*, 117:660–665, 1987.

5. U.S. Department of Agriculture, ''Composition of Foods: Finfish and Shellfish Products,'' Agriculture Handbook Number 8–15, Human Nutrition Information Service, USDA, page 91, 1987.

6. U.S. Department of Health and Human Services, *The Surgeon General's Report on Nutrition and Health*, DHHS (Public Health Service) Publication No. 88–50210 (Government Printing Office Stock N. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.

7. National Research Council, *Diet and Health—Implications for Reducing Chronic Disease Risk*, National Academy Press, Washington, DC, pp. 206–210, 654–656, 669–672, 1989.

8. National Heart, Lung, and Blood Institute, ''Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction,'' NCEP, PHS, National Institutes of Health, DHHS, Washington, DC; NIH Publication No. 90–3046, 1990.

9. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Nutrition and Your Health, Dietary Guidelines for Americans,'' Washington, DC, Home and Garden Bulletin No. 232, 3d edition, U.S. Government Printing Office, 1990.

10. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Nutrition and Your Health, Dietary Guidelines for Americans,'' Washington, DC, Home and Garden Bulletin No. 232, 4th edition, U.S. Government Printing Office, 1995.

11. Brindley, D. N., ''Absorption and Metabolism of Fats,'' in *Health Effects of Dietary Fatty Acids*, edited by G. L. Nelson, The American Oil Chemists' Society, Champaign, IL, pp. 35–47, 1991.

12. Carey, M. C., D. M. Small, and C. M. Bliss, ''Lipid Digestion and Absorption,'' *Annual Review of Physiology*, 45:651–677, 1983.

13. Vanderveen, J. E., N. D. Heidelbaugh, and M. J. O'Hara, ''Study of Man During a 56-day Exposure to an Oxygen-Helium

Atmosphere at 258 mm. Hg Total Pressure IX. Nutritional Evaluation of Feeding Bite-size Foods,'' *Aerospace Medicine*, 37:591–594, 1966.

14. Emken, E. A., R. O. Adolf, W. K. Rohwedder, and R. M. Gulley, ''Influence of Linoleic Acid on Desaturation and Uptake of Deuterium-labeled Palmitic and Stearic Acids in Humans,'' *Biochimica et Biophysica Acta*, 1170:173–181, 1993.

15. Chen, I. S., S. Subramaniam, G. V. Vahouny, M. M. Cassidy, I. Ikeda, and D. Kritchevsky, ''A Comparison of the Digestion and Absorption of Cocoa Butter and Palm Kernel Oil and Their Effects on Cholesterol Absorption in Rats,'' *Journal of Nutrition*, 1569–1573, 1989.

16. Erdman, J. W., C. L. Poor, and J. M. Dietz, ''Factors Affecting the Bioavailability of Vitamin A, Carotenoids, and Vitamin E,'' *Journal of Food Technology*, 42(10):214–221, 1988.

17. Letter from Stephen A. Brown to Dr. F. Edward Scarborough, Office of Food Labeling, FDA, May 29, 1996.

18. Memo from John Wallingford, Office of Special Nutritionals to the Director, Office of Food Labeling, FDA, September 30, 1996.

19. Labels of Hershey's Reduced Fat Baking Chips and Snackwell's Fudge Dipped Granola Bars.

20. The American Dietetic Association, ''1995 Nutrition Trends Survey, Executive Summary,'' Chicago, IL, 1995.

21. Food and Agriculture Organization of the United Nations and the World Health Organization, ''Fats and Oils in Human Nutrition, Report of a Joint Expert Consultation,'' FAO Food & Nutrition Paper 57, Rome, October 19 to 26, 1993.

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, it is proposed that 21 CFR part 101 be 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 101.9 is amended by revising paragraph (c)(2), and by adding new paragraphs (d)(15) and (g)(10) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides, except that, for a food that bears a claim that is made in compliance with § 101.63, a statement of the grams of available fat may be declared instead in accordance with paragraph (d)(15) of this section. Amounts shall be expressed to the nearest 0.5-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that, for a food that bears a claim that is made in compliance with § 101.63, a statement of the grams of available saturated fat may be declared instead in accordance with paragraph (d)(15) of this section. However, a label declaration of saturated fat content is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat or cholesterol content, and if ''calories from saturated fat'' is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement ''Not a significant source of saturated fat'' shall be placed at the bottom of the table of nutrient values in the same type size. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat in a serving defined as cis,cis-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of polyunsaturated fat is required. When a food bears a claim that is made in compliance with § 101.63, the grams of available polyunsaturated fat may be declared, in accordance with paragraph (d)(15) of this section, as the amount of polyunsaturated fat. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat in a serving defined as cis-monounsaturated fatty acids may be declared voluntarily except that when polyunsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of monounsaturated fat is required. When a food bears a claim that is made in compliance with § 101.63, the grams of available monounsaturated fat may be declared, in accordance with paragraph (d)(15) of this section, as the amount of monounsaturated fat. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

* * * * *

(d) * * *

(15) For food products that bear a claim that is made in compliance with § 101.63, and that contain an ingredient for which a digestibility coefficient is used to calculate the number of grams of total fat or fatty acids that are available from the ingredient, there shall be, in the nutrition label, following the quantitative declaration of fat (and saturated fat, polyunsaturated fat, or monounsaturated fat, if declared) and again immediately preceding the footnote required by paragraph (d)(9) of this section, an asterisk (*) or other similar cross-reference symbol. The asterisk or other symbol shall be followed by a statement that the declared amount of ''total fat'' has been adjusted to reflect reduced digestibility of the ingredient (e.g., ''*Total fat content adjusted for reduced availability of fat from [name of ingredient]''). The footnote required by paragraph (d)(9) of this section shall be separated by a hairline from the footnote required under this paragraph.

* * * * *

(g) * * *

(10) Each person responsible for the labeling of a food that bears a claim that is made in compliance with § 101.63, and for which available fat is declared in accordance with paragraph (d)(15) of this section, shall retain, for as long as the food is marketed, all records that support the quantitative declaration of fat and any fatty acid subcomponents declared. Such records shall be made available for authorized inspection and copying by appropriate regulatory officials and shall be submitted to those regulatory officials upon request.

* * * * *

3. Section 101.13 is amended by revising paragraph (o) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(o) Except as provided in §§ 101.10 and 101.63, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9.

* * * * *

4. Section 101.62 is amended by revising paragraphs (b)(1)(i), (b)(2)(i)(A), (b)(2)(i)(B), (b)(3)(i), (b)(4)(i), (b)(5)(i), (c)(1)(i), (c)(2)(i), (c)(3)(i), (c)(4)(i), and (c)(5)(i) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(b) * * *

(1) * * *

(i) The food contains less than 0.5 g of total fat or, as provided in § 101.63, available fat per reference amount customarily consumed and per labeled serving or; in the case of a meal product or main dish product, less than 0.5 g total fat, or as provided in § 101.63, available fat per labeled serving; and

* * * * *

(2) * * *

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 3 g or less of total fat or, as provided in § 101.63, available fat per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less, or 2 tablespoons or less, and contains 3 g or less of total fat or, as provided in § 101.63, available fat per reference amount customarily consumed and per 50-g of food (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the ''as prepared'' form); and

* * * * *

(3) * * *

(i) The product contains 3 g or less of total fat or, as provided in § 101.63, available fat per 100 g and not more than 30 percent of calories from fat; and

* * * * *

(4) * * *

(i) The food contains at least 25 percent less total fat or, as provided in § 101.63, available fat per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

* * * * *

(5) * * *

(i) The food contains at least 25 percent less total fat or, as provided in § 101.63, available fat per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

* * * * *

(c) * * *

(1) * * *

(i) The food contains less than 0.5 g of saturated fat or, as provided in § 101.63, available saturated fat and less than 0.5 g *trans* fatty acid per reference amount customarily consumed and per labeled serving, or in the case of a meal product or main dish product, less than 0.5 g of saturated fat or, as provided in § 101.63, available saturated fat and less than 0.5 g *trans* fatty acid per labeled serving; and

* * * * *

(2) * * *

(i) The food contains 1 g or less of saturated fat or, as provided in § 101.63, available saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

* * * * *

(3) * * *

(i) The food contains 1 g or less of saturated fat or, as provided in § 101.63, available saturated fat per 100 g and less than 10 percent of calories from saturated fat; and

* * * * *

(4) * * *

(i) The food contains at least 25 percent less saturated fat or, as provided in § 101.63, available saturated fat per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

* * * * *

(5) * * *

(i) The food contains at least 25 percent less saturated fat or, as provided in § 101.63, available saturated fat per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

* * * * *

5. New § 101.63 is added to subpart D to read as follows:

§ 101.63 Nutrient content claims for fat and fatty acids based on use of ingredients formulated to reduce amount of available fat.

(a) *Coverage.* This regulation defines the circumstances in which nutrient content claims for fat and fatty acids can be made for foods that contain manufactured fat-based fat substitutes that have been formulated to provide functional characteristics of fat but to limit or eliminate absorption and digestion of the fat from the substance by the body, thereby restricting the availability of the fat to the body.

(b) *Claims.* The terms defined in § 101.62 may be used on the label or in the labeling of foods that contain an ingredient that is covered under this paragraph, provided that:

(1) There has been compliance with the notification provisions of paragraph (c) of this section, and FDA has not objected (see paragraph (d) of this section);

(2) The level of available fat or available saturated fat in the food meets the applicable level in § 101.62; and

(3) The food is nutrition labeled in accordance with paragraph (e) of this section.

(c) *Notification.* The manufacturer of an ingredient covered under paragraph (a) of this section shall notify FDA at least 120 days before such ingredient is introduced into or delivered for introduction into interstate commerce. Such notification shall be signed by a responsible person and shall include:

(1) The name and address of the manufacturer and a contact person;

(2) The common or usual name of the fat substitute that is the subject of the claim (i.e., the notified substance);

(3) Descriptive information that characterizes the substance, including its chemical structure and physical characteristics, its purity and homogeneity, and a detailed description of the analytical methodology for determining the amount of the substance present in a food or a statement that refers the agency to where this analytical methodology can be found in its records (e.g., in a filed food additive petition or in a petition for affirmation that use of a substance is generally recognized as safe). Where the substance is part of a family of similar structured fats, information should be submitted on the applicability of the digestibility coefficient to other forms of the substance;

(4) The digestibility coefficient that is expected to be used to adjust the amount of total fat or of fatty acids contributed by such an ingredient to reflect the amount of fat and fatty acids available from the finished food product;

(5) Data that establish the appropriateness of the digestibility coefficient to be used including, but not limited to:

(i) Evidence demonstrating the reduced absorption of the substance or its components, such as:

(A) An estimate of the biologic variability in the availability of the substance in humans and in the relationship between the amount of the substance ingested and the rate of absorption (i.e., dose-response);

(B) A statement of the relevance, and limit to relevance to the human, of any animal model used to estimate human digestion and absorption of the substance; and

(C) For any clinical studies that are relied on to demonstrate reduced absorption or digestion, information on the characteristics of the subjects studied and the manner in which they are representative of the population for whom the substance is intended. For example:

(*1*) An accounting of subjects enrolled in the study including those who did not complete the study, reasons for any noncompletion, and an assessment of the effect that noncompletion of subjects had on the results of the study; and

(*2*) A description of any adverse events that occurred during the study, and a comparison of the frequency and type of effects as a function of the feeding of the substance;

(ii) Information about foods or diets that may affect the digestibility coefficient, such as:

(A) Interactions of the substance with other components of foods or the diet that could significantly affect the digestibility coefficient;

(B) Steps in processing of the types of foods expected to contain the fat substitute that could affect the digestibility coefficient;

(C) The amount of the substance used in feeding studies, the relationship of that amount to expected levels of intake, and the dose-response relationship between the amount of the substance and the digestibility coefficient; and

(D) The duration of feeding studies and changes in the digestibility coefficient with continued exposure;

(6) A certification that all data of which the firm is aware that pertain to the digestibility of the fat substitute have been submitted, and that any new data will be promptly submitted as it becomes available for as long as the ingredient is marketed; and

(7) Such notification shall be submitted to the Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St., SW., Washington, DC 20204.

(d) *FDA review.* Upon receipt, FDA will notify the submitting firm that it has received the notification and will commence its review. If firms do not receive written objections from FDA within 120 days of FDA's receipt of the notification, nutrient content claims based on the digestibility coefficient submitted may be used.

(e) *Nutrition labeling.* When a claim is made for fat or saturated fat under this section, the nutrition label shall declare the amount of available fat or saturated fat in accordance with § 101.9(d)(15).

(f) *Misbranding.* Any food product containing ingredients that are covered under paragraph (a) of this section that bears a claim based on available levels of fat for which supporting data have not been provided to FDA in accordance with this section or to which FDA has objected in response to the notification filed in accordance with paragraph (c) of this section will be deemed to be misbranded under section 403(a) and (r)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

Dated: December 11, 1996.

William B. Schultz,

Deputy Commissioner for Policy

[FR Doc. 96–32124 Filed 12–19–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–209672–93]

RIN 1545–AS16

Credit for Employer Social Security Taxes Paid on Employee Tips

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws the notice of proposed rulemaking relating to the credit for employer FICA taxes paid with respect to certain tips received by employees of food or beverage establishments. The proposed regulations were published in the Federal Register on December 23, 1993. Changes to the law made by the Small Business Job Protection Act of 1996 have made these proposed regulations obsolete.

FOR FURTHER INFORMATION CONTACT: Jean M. Casey at (202) 622–6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 23, 1993, the IRS issued proposed regulations (EE–71–93) (58 FR 68091) under section 45B of the Internal Revenue Code relating to the credit for employer FICA taxes paid with respect to certain tips received by employees of food or beverage establishments. Amendments made by section 1112(a) of the Small Business Job Protection Act of 1996 (Public Law 104–188) render the proposed regulations obsolete. Therefore, proposed regulation § 1.45B–1 is being withdrawn.

On December 23, 1993, the IRS also published temporary regulations (TD 8503) (58 FR 68033) under section 45B of the Code. These temporary regulations are being removed in a separate document.

List of Subjects in 26 CFR Part 1

Income taxes, Penalties, Reporting and recordkeeping requirements.

Withdrawal of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, the notice of proposed rulemaking that was published in the Federal Register on December 23, 1993 (58 FR 68091) is withdrawn.

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 96–32250 Filed 12–19–96; 8:45 am]

BILLING CODE 4830–01–P

Financial Crimes Enforcement Network Proposed Amendments to the Bank Secrecy Act Regulations Regarding Reporting and Recordkeeping by Card Clubs

31 CFR Part 103

RIN 1506–AA18

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Financial Crimes Enforcement Network (''FinCEN'') is proposing to amend the regulations implementing the statute generally referred to as the Bank Secrecy Act to include certain gaming establishments, commonly called ''card clubs,'' ''card rooms,'' ''gaming clubs,'' or ''gaming rooms'' within the definition of financial institution subject to those regulations.

DATES: Written comments must be received on or before March 20, 1997.

ADDRESSES: Written comments should be submitted to: Office of Regulatory Policy and Enforcement, Financial Crimes Enforcement Network, Department of the Treasury, 2070 Chain Bridge Road, Vienna, Virginia 22182, Attention: NPRM—Card Clubs.

SUBMISSION OF COMMENTS: Comments on all aspects of the proposed regulation are welcome and will be considered if submitted in writing prior to March 20,