5123 would be designated in order to provide a booster drop zone to contain the reentry and impact of missile boosters after launch from R–5117. R–5123 would extend from the surface to unlimited altitude. R–5119 would be designated as a missile reentry area. R–5119 would extend from FL 350 to unlimited altitude and would be located adjacent to existing WSMR restricted airspace. R–5119 would be required to contain missiles during that portion of the reentry phase of flight prior to the trajectory entering existing WSMR restricted airspace. Missile impact would occur in the existing WSMR impact areas.

When activated, the proposed restricted areas could potentially impact nonparticipating aircraft operations along portions of Federal airways and jet routes, or on direct flights, in the vicinity of the Gallup (GUP), Socorro (ONM), and Truth or Consequences (TCS) navigational aids. It is anticipated that the potential impact of the restricted areas on nonparticipating aircraft operations would be lessened by the limited number of planned test events (6 to 10 per year), and a U.S. Army agreement to complete test activity prior to 9:00 a.m., local time, when the volume of air traffic in the area is normally low. In addition, the entire launch through recovery operation is designed to take less than 15 minutes total, therefore, it is anticipated that the tests would 5 have minimal impact on instrument flight rules traffic. It is possible that activation of the proposed restricted areas may necessitate rerouting of a few aircraft, however, any rerouting should be minimal due to the location, small size, and limited activation time requirements of the areas. The two proposed restricted areas which would extend from the surface, R–5117 and R–5123, would be designated over government-controlled tracts of land.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental impact analysis by the proponent and the FAA prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854;, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

2. Section 73.51 is amended as follows:

§ 73.51 [Amended]

R–5117 Fort Wingate, NM [New]

Boundaries. Beginning at lat. 35°25′51″N., long. 108°30′09″W.; to lat. 35°28′46″N., long. 108°37′14″W.; to lat. 35°28′46″N., long. 108°37′39″W.; to lat. 35°21′27″N., long. 108°36′58″W.; to the point of beginning.
Designated altitudes. Surface to unlimited.
Time of designation. Intermittent by NOTAM 24 hours in advance.
Controlling agency. FAA, Albuquerque ARTCC.
Using agency. Commanding General, White Sands Missile Range, NM.

R–5119 Socorro, NM [New]

Boundaries. Beginning at lat. 33°59′56″N., long. 106°43′29″W.; to lat. 33°59′51″N., long. 106°56′27″W.; to lat. 34°08′16″N., long. 107°05′17″W.; to lat. 34°00′28″N., long. 107°12′04″W.; to lat. 33°46′04″N., long. 107°02′38″W.; to lat. 33°26′49″N., long. 107°02′25″W.; to lat. 33°26′49″N., long. 107°00′00″W.; to lat. 33°32′44″N., long. 106°58′47″W.; to lat. 33°54′10″N., long. 106°46′24″W.; to lat. 33°57′16″N., long. 106°43′58″W.; to the point of beginning.
Designated altitudes. FL 350 to unlimited.
Time of designation. Intermittent by NOTAM 24 hours in advance.
Controlling agency. FAA, Albuquerque ARTCC.
Using agency. Commanding General, White Sands Missile Range, NM.

R–5121 Fort Wingate, NM [New]

Boundaries. Beginning at lat. 35°25′51″N., long. 108°30′09″W.; to lat. 35°21′22″N., long. 108°25′59″W.; to lat. 35°19′18″N., long. 108°28′10″W.; to lat. 35°17′48″N., long. 108°31′41″W.; to lat. 35°21′27″N., long. 108°36′58″W.; to the point of beginning.
Designated altitudes. FL 200 to unlimited.
Time of designation. Intermittent by NOTAM 24 hours in advance.
Controlling agency. FAA, Albuquerque ARTCC.
Using agency. Commanding General, White Sands Missile Range, NM.

R–5123 Magdalena, NM [New]

Boundaries. Beginning at lat. 34°22′30″N., long. 107°57′00″W.; to lat. 34°25′00″N., long. 107°49′00″W.; to lat. 34°24′45″N., long. 107°37′00″W.; to lat. 34°18′00″N., long. 107°30′00″W.; to lat. 34°15′08″N., long. 107°37′00″W.; to lat. 34°19′00″N., long. 107°40′00″W.; to lat. 34°15′08″N., long. 107°45′20″W.; to lat. 34°14′52″N., long. 107°44′40″W.; to lat. 34°13′00″N., long. 107°48′00″W.; to the point of beginning.
Designated altitudes. Surface to unlimited.
Time of designation. Intermittent by NOTAM 24 hours in advance.
Controlling agency. FAA, Albuquerque ARTCC.
Using agency. Commanding General, White Sands Missile Range, NM.

Issued in Washington, DC, on January 25, 1996.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 96–2273 Filed 2–1–96; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0103]

Food Labeling; Nutrient Content Claims and Health Claims; Special Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require that, in certain circumstances, persons responsible for the labeling of foods with nutrient content and health claims maintain records that support the claims, and that they make those records available to appropriate regulatory officials upon request. FDA has tentatively concluded that the proposed requirements are necessary to ensure that, in the specified circumstances, when a claim is made on the label or in the labeling of a food to characterize the level of a nutrient in that food, or to characterize the relationship between a nutrient in the food and a disease or health-related condition, the claim is made in

accordance with regulations issued by the agency.

DATES: Written comments by April 17, 1996; except that comments regarding information collection requirements by March 4, 1996, but not later than April 2, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Written comments regarding paperwork burden estimates should be sent to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: F. Edward Scarbrough, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration,200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535) amended the act by, among other things, adding section 403(r)(21 U.S.C. 343(r)). This section sets out the circumstances in which nutrient content claims and health claims can be made in food labeling. Under section 403(r) of the act, a food is misbranded if a claim made in its label or labeling that characterizes the level of a nutrient in the food, or characterizes the relationship between a nutrient in the food and a disease or health-related condition, unless the claim is made in accordance with regulations issued by the agency. FDA has adopted regulations implementing the 1990 amendments with respect to nutrient content claims in § 101.13 (21 CFR 101.13) and subpart D of part 101 (21 CFR part 101) of FDA's regulations and with respect to health claims in § 101.14 and subpart E of part 101.

One of the purposes of the 1990 amendments was to encourage the development of new food technologies. (See 136 Congressional Record S 16610, October 24, 1990, statement of Senator Hatch: ''[M]anufacturers should have the economic incentives they need to be creative and innovative so that more and more low-fat, reduced sodium, and high-fiber foods come onto the market.'') The 1990 amendments also addressed ''the need to have consistent, enforceable rules pertaining to the claims that may be made with respect to the benefits of nutrients in foods.'' (See H. Rept. No. 538, 101st Cong., 2d sess., at 8 (1990).) It is likely that new, more healthful products that qualify for claims will be introduced. Yet newly developed foods can present situations that challenge FDA's traditional enforcement tools of inspection and sample analysis.

When FDA issued the regulations implementing the 1990 amendments, the agency determined that, in certain situations, adequate enforcement of the new regulations would be possible only if the agency could review the information that a manufacturer had developed to support the statements on its food labels. One such situation is aeration, a technique now being used to reduce the fat and calorie content of foods. (See the January 6, 1993, final rule on serving sizes (58 FR 2229 at 2271).) Comments on the proposed rule on serving sizes argued that manufacturers of aerated foods should be permitted to substitute a volume-based measure for a weight-based reference amount as the basis for determining the product's serving size. FDA determined that the most reasonable solution was to allow manufacturers to determine a ''density-adjusted reference amount'' for their aerated foods. Under the final regulations, however, manufacturers who choose this approach must have 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)), available for inspection by FDA.

FDA also found it necessary to impose a records requirement for claims such as ''light,'' which compare the amount or percentage of a nutrient in one product to a reference nutrient value derived from one of a variety of sources (e.g., a representative valid data base or an average value determined from the top three national brands). In issuing its final regulation on nutrient content claims, the agency required that:

> to fully inform consumers, firms that use a broad based reference nutrient value as a basis for a claim must be prepared to make information on how they derived the reference nutrient value available to consumers on request. In addition, the information must also be made available to appropriate regulatory officials on request. This additional requirement will assist regulatory officials in determining compliance with the requirements for appropriate reference nutrient values for products bearing a claim to ensure the claim is not false or misleading.

(58 FR 2302 at 2365, January 6, 1993; nutrient content claims, general principles final rule.) The agency codified this requirement at § 101.13(j)(1)(ii)(A).

Another example of the agency's need to examine supporting information arose with respect to the caloric content of new products with reduced digestibility, such as novel fats and carbohydrates (58 FR 2079 at 2111, January 6, 1993; mandatory status of nutrition labeling, final rule). The agency stated that it would consider the digestibility of new products on a case-by-case basis. FDA also said that those manufacturers who wish to declare adjusted values for the energy contribution of a substance, based on reduced digestibility, should include information on the digestibility of the substance, analytical assay procedures for the compound, and data on interference with required methods of analysis in a food additive petition or in a petition for affirmation that use of the substance is generally recognized as safe, or should provide the information to the agency by other appropriate means. (See 58 FR 2079 at 2087 and 2111 and § 101.9(c)(1)(I)(D).)

Nutrient content claims for restaurant foods presented FDA with difficult compliance questions, as well (58 FR 2302 at 2387). In order to provide a way for restaurants to make claims, FDA devised a ''reasonable basis'' standard, under which restaurateurs who make nutrient content claims for their foods on labeling other than menus must be prepared to present to regulatory officials the basis for their belief that pertinent nutrient levels are present in their foods. (58 FR 2302 at 2388 and § 101.13(q)(5)(ii).) By requiring access to information supporting nutrient content claims, FDA sought to encourage the provision of useful dietary information on restaurant foods while maintaining its ability to assure consumers that nutrient content claims made for restaurant foods reasonably reflect the nutrient content of the food (58 FR 2302 at 2387).

Although in some situations, such as those described above, FDA required that access to a manufacturer's information supporting its labeling claims be provided to the agency, the agency declined to adopt the review of nutritional analyses on file at firms as a general investigatory procedure (58 FR 2079 at 2110). The agency set forth compliance criteria in § 101.9(g) that explain how its traditional investigatory procedures will be applied to mandatory nutrition labeling and, by extension, to claims made under section 403(r) of the act. A comment on proposed § 101.9 suggested that FDA substantiate nutrition label information by verifying laboratory analysis results on file at a firm (58 FR 2079 at 2110). The comment cited, as a model for FDA

to follow, the food labeling regulations proposed (and since made final) by the United States Department of Agriculture (USDA) that require firms to maintain records to support the validity of nutrient declarations contained on product labels and to make these records available upon request by USDA. (See 9 CFR 317.309(h)(8) and 381.409(h)(8).) The agency responded:

> To support a misbranding charge for inaccurate nutrient content information, FDA must have accurate, reliable, and objective data to present in a court of law. To obtain that information, FDA relies upon the work performed by its trained employees because it does not have legal authority in most instances to inspect a food manufacturing firm's records.

(58 FR 2079 at 2110.)

This statement reflects the fact that, unlike USDA, FDA does not have explicit, broad statutory authority to inspect food manufacturing records. However, as discussed in greater detail below, FDA may issue regulations for the efficient enforcement of the act, and those regulations may require that access to certain records be provided to the agency. Thus, although the statement that FDA lacks authority to inspect the records of a food manufacturing firm ''in most instances'' is generally accurate, it is also true that FDA may legally inspect a food manufacturing firm's records when it acts under the authority of a regulation that provides for records inspection.

II. Recent Enforcement Concerns

Since the publication of its final regulations implementing the 1990 amendments, FDA has given further consideration to the difficulties it expects to encounter in enforcing the new rules. When it issued the final rules, FDA identified and addressed the particular problems of which it was aware, such as aeration. Although this approach appeared adequate at the time the regulations were developed, the agency now recognizes that there may be situations that are not provided for in its current regulations in which it will need to have access to records in order to enforce the act adequately.

For example, circumstances may arise of the sort foreshadowed in the final rule authorizing health claims associating calcium with a reduced risk of osteoporosis. In that rule, the agency anticipated that:

> * * * instances may develop in which the bioavailability of the calcium source has not been shown, including the use of new fortificants or food products in which the combination of the component nutrients raises concerns about the assimilability of calcium from the product (e.g., a new bread rich in a novel high phytate fiber source and fortified with calcium).

(See 58 FR 2665 at 2667, January 6, 1993). In the Federal Register of January 6, 1994, the agency also stated that ''[c]alcium sources whose bioavailability has not been shown would be at risk for * * * enforcement action.''

Having further considered this type of situation, the agency believes that it would be a far more appropriate and efficient use of its resources to require the manufacturer of a new food product labeled with a health or nutrient content claim, such as the bread described above, to provide the agency with access to the information that the manufacturer has developed to support a claim. Where a company has developed a product and labeled it with a health or nutrient content claim, and elaborate testing is required to provide the basis for the claim (e.g., animal tests for bioavailability, 58 FR 2665 at 2667), the agency should not have to duplicate those tests. Indeed, it would be unlikely that the agency would have the resources to do so. Thus, unless FDA were able to review the underlying data, companies could make certain claims on newly developed foods that the agency effectively would be unable to verify. Companies would then be in a position to make false labeling statements with virtual impunity.

FDA is also concerned that the development and use of new testing methods may place it in the position of not having sufficient information to assess the accuracy of a claim. The agency has recognized that advances are being made in the area of nutrient testing. For example, in issuing its final regulation on nutrition labeling, the agency noted that testing for certain nutrients is being actively researched (see 58 FR 2079 at 2112 (cholesterol)), and that new testing methods are being developed (see 58 FR 2079 at 2113 (sugars)). The agency said that it would not ''preclude [companies'] use of emerging technologies * * * as they are developed and validated,'' (58 FR 2079 at 2113), but that, for compliance purposes, it would continue to use the methods of the Association of Official Analytical Chemists (AOAC) International or other validated procedures (58 FR 2079 at 2109). However, FDA now expects that there may be situations in which this approach is inadequate; for example, where there is no AOAC or other validated method applicable to a particular food, and a manufacturer has used a new testing method to determine that its food qualifies to bear a claim. Such a case might involve a novel form of fat that requires the use of unconventional analytical methods (58 FR 2079 at 2087).

New foods and new testing techniques are two matters about which the agency has enforcement concerns. The agency does not wish to stand in the way of the development of new technology and of new foods by limiting companies to conventional manufacturing techniques and analytical methods, and FDA believes that to do so would be fundamentally inconsistent with the purpose of the 1990 amendments. (See 136 Congressional Record, S 16610, October 24, 1990, statement of Senator Hatch, stating that Congress ''should not deter'' the benefits of new, more healthful foods for the consumer.) However, the only way that the agency can avoid doing so, and still enforce the act effectively, is if it is able to examine certain relevant records.

The agency also has concerns about claims that are based on information about a food that is available only to the food manufacturer and without which the agency would be unable to evaluate the truthfulness of the claim. ''Light'' provides an example of this type of claim. Without information on what the company has used as its reference nutrient value, FDA cannot determine whether the claim accurately describes the food. An inflexible approach would be to prohibit these claims altogether. However, FDA believes that it is consistent with the 1990 amendments to permit certain useful nutrition-related information in food labeling if the agency can be assured that the information accurately describes the labeled food.

Under section 403(r)(2)(C) and (r)(2)(D) of the act, certain foods bearing nutrient content claims as part of their brand names are exempt from requirements contained in section 403(r)(2) of the act, if the brand name was in use for the food before October 25, 1989 (§ 101.13(q)(1) and (q)(2)). Without access to company records, FDA will often not be able to determine whether a food that is asserted to qualify for this ''grandfather'' provision actually qualifies; i.e., whether the name was in use prior to October 25, 1989, and whether the food is unchanged. As with the claim ''light,'' this information may be available only to the food manufacturer. FDA's tentative view is that companies that take advantage of this exemption should be prepared to demonstrate to FDA that the food for which they claim the exemption qualifies for it.

The regulations that FDA is now proposing are designed both to ensure that the agency's ability to enforce the 1990 amendments is not compromised and to avoid significant interference with the development of new food technologies and more healthful foods. The circumstances described above establish a need for FDA to have access to records in particular situations; this rule is intended to address those situations. The agency expects that the concerns it has identified will arise primarily with respect to foods bearing claims (e.g., a new food designed specifically to meet the requirements of a nutrient content claim). Therefore, although the proposed regulations are limited in scope to health and nutrient content claims, the agency expects that they will be sufficient to enable it to enforce the provisions of the 1990 amendments and the regulations implementing those amendments, and it does not at this time anticipate extending these proposed requirements to other situations.

III. Legal Authority

When Congress enacted the 1990 amendments, it sought to ensure that the rules pertaining to health and nutrient content claims would be enforceable (see H. Rept. 538, 101st Cong., 2d sess. 8, 9 (1990)). Health and nutrient content claims are intended to make the consumer aware of the nutritional attributes of the labeled food. Because these claims are meant to help consumers maintain healthful dietary practices, it is of the utmost importance that they accurately reflect the nutritional composition of the labeled food. (See 136 Congressional Record, H 12953, October 26, 1990, statement of house floor managers: ''There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims.'')

The agency expects that many advances in food technology will occur that will provide the basis for claims, as food products are designed to meet the requirements for particular health and nutrient content claims. These developments, although beneficial, have the potential, as stated above, to outstrip the agency's traditional enforcement tools. This proposal is intended to address this problem. By enabling manufacturers to provide valuable information to consumers, while ensuring that the agency has the ability to verify that information, the regulations being proposed will serve the interests of both manufacturers and consumers. Food manufacturers will be able to profit from the advances that they make by marketing foods with claims that make the foods attractive to consumers, yet consumers and competitors can be confident that the agency has the tools to ensure that the claims appropriately appear on the foods that bear them. Thus, consumers will be able to rely on the claims to structure their diet in a manner that allows them to achieve their dietary goals.

FDA may require records to be maintained in specific instances and may inspect those required records, despite the act's lack of express, general statutory authority to inspect records. The Supreme Court has recognized that FDA has authority that ''is implicit in the regulatory scheme, not spelled out in haec verba'' in the statute. (See *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).)

> Indeed: it is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the statutes, but include, also, all of the powers that may fairly be implied therefrom. * * * In the construction of a grant of powers, it is a general principle of law that where the end is required the appropriate means are given and that every grant of power carries with it the use of necessary and lawful means for its effective execution.

(*Morrow* v. *Clayton*, 326 F.2d 35, 44 (10th Cir. 1963).)

Under section 701(a) of the act (21 U.S.C. 371(a)), the agency may issue regulations for the efficient enforcement of the act. Courts have recognized that FDA may impose recordkeeping requirements where they effectuate the act's goals. (See *Toilet Goods Association* v. *Gardner*, 387 U.S. 158, 163–64 (1967); and *National Confectioners Association* v. *Califano*, 569 F.2d 690, 693 & n.9 (D.C. Cir. 1978).) The agency has required that records be maintained and made available for inspection by FDA employees in a number of situations. (See, e.g., 21 CFR 108.25(g) and 114.100 (acidified foods); 108.35(h) and 113.100 (thermal processing of low-acid foods); part 129 (21 CFR part 129) (bottled drinking water); 172.320 (amino acids); 176.170 (components of paper and paperboard in contact with aqueous and fatty foods); and 179.25(e) (food irradiation).)

FDA has tentatively determined that the proposed requirements, which would cover only those health and nutrient content claims that pose particular enforcement difficulties, are necessary for the efficient enforcement of the act. Ensuring the accuracy of claims was an overriding concern of Congress in passing the 1990 amendments. Congress envisioned that, under the act as amended, ''only truthful claims may be made on foods'' (136 Congressional Record H 12953, October 26, 1990, statement of Representative Waxman. See also 136 Congressional Record H 12954, statement of Representative Moakley: ''This bill will help curb misleading claims * * *.''; and H. Rept. 538, 101st Cong., 2d sess. 21 (1990): ''The [health] claim on the food label or labeling would have to be stated in a manner which accurately represented the substance of the regulation * * *.'') By its terms, section 403(r) of the act (21 U.S.C. 343(r)(1)) applies to claims made ''for'' a food ''in the label or labeling of the food.'' In order for a claim ''for'' a food to be truthful, it must accurately describe the labeled food. A food labeled ''low fat'' must meet the definition of ''low fat'' in 21 CFR 101.62(b) and any other applicable requirements. Similarly, a food bearing a health claim relating calcium intake to the risk of osteoporosis must, among other things, actually provide the consumer with a ''high'' amount of calcium (§ 101.72(c)(2)(ii)).

It is implicit in the 1990 amendments that a manufacturer who places a health or nutrient content claim in food labeling must have knowledge that the food qualifies to bear the claim. Congress expected that manufacturers would have to ascertain the nutritional attributes of their food products, through laboratory analysis or otherwise, in order to label those products properly. (See H. Rept. 538, 101st Cong., 2d sess. 14 (1990), stating that nutrient definitions will enable manufacturers to ''know the type of analysis to conduct on the food.'') FDA has previously stated that a food manufacturer is responsible for the accuracy of its food labels (58 FR 2079 at 2163 and 2165). Indeed, placing a claim in food labeling that calls the consumer's attention to the food's nutritional characteristics is a representation that the manufacturer has evidence that the food meets the requirements for the claim.[1] Thus, making a claim without such a basis

[1] Cf. Aerosolized food, drug, and cosmetic products, proposed rule; 38 FR 6191 at 6192, March 7,, 1973, (''[W]ith respect to the safety of cosmetics, [the act] necessarily contemplates that the manufacturer or distributer has obtained all data and information necessary and appropriate to substantiate the product's safety before marketing. Any cosmetic product whose safety is not adequately substantiated prior to marketing may be adulterated and would in any event be misbranded unless it candidly and prominently warns that the safety of the product has not been adequately determined.'') *Thompson Medical Co., Inc.* v. *FTS*, 791 (1987) (''[I]n general an advertisement is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it.''

would be misleading, in violation of section 403(a) of the act.

The agency anticipates, and hopes, that in some instances companies will be amenable to demonstrating to FDA how particular values were calculated, regardless of the existence of these regulations. In the mandatory status of nutrition labeling final rule, the agency noted that: ''A few comments expressed the position that FDA should not declare a product misbranded until the manufacturer has had an opportunity to establish that the variations are reasonable under the circumstances'' (58 FR 2079 at 2162). Moreover, the agency considers that, when a product bears a claim based on information available solely to the manufacturer, it is reasonable for the agency to have access to that information. (See *United States* v. *An Article of Device*, 731 F.2d 1253, 1261–62 (7th Cir. 1984) (upholding regulation requiring makers of prescription devices to be able to prove that their devices work safely for their intended purposes and stating that ''[w]here the government's access to the necessary information may be limited * * * it seems not inappropriate to put the burden of persuasion on the party who * * * presumably has better access to the relevant information''.) (See also *Trans-American Van Service, Inc.* v. *United States*, 421 F. supp. 308, 331 (N.D. Tex. 1976).)

In section 3(b) of the 1990 amendments, Congress specifically directed FDA to issue regulations implementing section 403(r) of the act, and FDA has done so. Congress clearly contemplated that, in these regulations, the agency would not only define certain terms used in claims but would also determine the circumstances when claims can be made (see 136 Congressional Record H 5841, July 30, 1990, (''[T]he secretary is required, in the regulations, to define the circumstances under which statements disclosing the amount and percentage of nutrients in food will be permitted.''); 136 Congressional Record H 12953, October 26, 1990, (defined terms ''will have to be used in a manner that is consistent with the FDA's definition.''); and 136 Congressional Record S 16609, October 24, 1990, statement of Senator Metzenbaum:

> [T]he bill does not specify how the term 'light' should be defined or how the Secretary should permit the term to be used. However, the bill gives the Secretary broad authority to develop an appropriate definition, so the Secretary certainly could consider permitting the term 'light' to be used in the manner * * * describe[d].)

FDA is now proposing to amend the general requirements for nutrient content and health claims in § § 101.13 and 101.14 so that manufacturers who choose to place certain claims on the food label or in labeling may do so only if they keep the information on which the claim is based and make it available to appropriate regulatory officials upon request. Failure to meet the requirements by maintaining appropriate records and complying with an agency request to examine those records will be a violation of section 403(r) of the act, misbranding the food bearing the claim.

IV. The Proposal

FDA is now proposing that manufacturers who place certain types of claims on the labels or labeling of food be required to maintain the information upon which they have relied in determining that the food meets the requirements for the claims and to make it available to the agency upon request. The agency proposes that the claims covered by this requirement will be those based on new food technology (e.g., novel ingredients such as fat substitutes) or a new use of a food technology (e.g., manufacturing methods such as aeration), those based on the results of novel or nonstandardized testing procedures (e.g., where there is no applicable AOAC or other validated method), and those which the agency cannot evaluate without such information (e.g., because they are based on information available only to the manufacturer). The agency believes that these three categories encompass the areas of enforcement difficulty that it has already encountered in developing its new food labeling regulations and those that it can expect in the future, as advances in food technology are made.

Compliance with the proposed regulations would not entail the creation of any new information or the compilation of any special records. Rather, the proposed recordkeeping requirement would obligate manufacturers simply to keep and provide FDA with information that they should already possess. Adequate records may consist of results of direct product analyses, data base values or recipe calculations, or a combination of direct analyses, data base values, and recipe calculations.

The agency anticipates that manufacturers may have concerns about the confidentiality of the information inspected by the agency under this regulation. Manufacturers should be assured that FDA does not and would not release information that would provide a competitive advantage to another manufacturer (21 CFR 20.61). For example, if a company's records that support the validity of a labeling statement contain confidential information describing product formulation, manufacturing processes, or unique testing methods, the agency would protect this information from public disclosure (21 CFR 20.61). (See also 5 U.S.C. 552(b)(4); 18 U.S.C. 1905; and 45 CFR 5.65.)

V. Environmental Impact

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

VI. Analyis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency estimates that this proposed rule would cause some incremental cost of developing, maintaining, and storing information above what food firms would normally experience. However, the agency anticipates these costs will be small. Therefore, the agency finds that the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because any records or necessary documents would be ones that any responsible firm would create and maintain in the normal course of business, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains record retention requirements that are subject to public comment and to 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 record retention requirements 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 data, and maintaining the required records.

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: Record Retention Requirements for Nutrient Content Claims and Health Claims.

Description: FDA has previously issued regulations that prescribe nutrient content claims (§ 101.13 and subpart D) and health claims (§ 101.14 and subpart E) that may be used on the label or labeling of a food. The proposed rule would establish a requirement that, in certain circumstances, persons responsible for the labeling of foods with nutrient content claims and health claims maintain the records upon which they rely as the basis for those claims. The proposal would also require that those records be made available to appropriate regulatory officials upon request. The proposed regulation does not specify the records that must be retained or the format in which they must be retained but proposes that they be the ones which form the basis for the claims. Thus, the agency believes that the proposed provisions will add only a minor additional record retention burden for firms subject to the proposed provisions.

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

Estimated Annual Reporting and Recordkeeping Burden

21 CFR Section	No. of Responses Per Respondents	Total Annual Responses	Hours Per Response	Total Annual Hours	Total Operating/ Maintenance Costs
101.13 and 101.14	10	1,000	1	1,000	$46,000

The agency has submitted copies of the proposed rule to OMB for its review of these recordkeeping requirements. Interested persons are requested to send comments regarding information collection by March 4, 1996, but not later than April 2, 1996 to the Office of Information and Regulatory Affairs, OMB, rm. 1035, New Executive Bldg., Washington, DC 20503, ATTN: Desk Officer for FDA.

VIII. Comments

Interested persons may, on or before April 17, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

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 101.13 is amended by revising paragraph (o) and by adding new paragraph (s) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(o) Except as provided in § 101.10 and in this paragraph, 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. With respect to those foods covered by paragraph (s) of this section, compliance may be determined by reviewing the records required to be kept under paragraph (s) of this section.

* * * * *

(s) Each person responsible for the labeling of a food that bears a nutrient content claim defined in subpart D of this part that is based on:

(1) A new food technology (e.g., novel ingredients such as fat substitutes) or a new use of a food technology (e.g., manufacturing method such as aeration);

(2) Novel or nonstandardized testing procedures (e.g., where there is no applicable Association of Official Analytical Chemists method or other reliable and appropriate analytical procedure); or

(3) Information available only to the person responsible for the labeling, and which the agency cannot evaluate without such information, shall maintain, for as long as the food is marketed, all records that demonstrate that the food meets the requirements in this section and in the applicable regulation in subpart D of this part. These 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 101.14 is amended by adding new paragraph (h) to read as follows:

§ 101.14 Health claims: general requirements.

* * * * *

(h) Records. Each person responsible for the labeling of a food that bears a health claim provided for in subpart E of this part that is based on:

(1) A new food technology (e.g., novel ingredients such as fat substitutes) or a new use of a food technology (e.g., manufacturing method such as aeration);

(2) Novel or nonstandardized testing procedures (e.g., where there is no applicable Association of Official Analytical Chemists method or other

reliable and appropriate analytical procedure); or

(3) Information available only to the person responsible for the labeling, and which the agency cannot evaluate without such information, shall maintain, for as long as the food is marketed, all records that demonstrate that the food meets the requirements in this section and in the applicable regulation in subpart D of this part. These records shall be made available for authorized inspection and copying by appropriate regulatory officials and shall be submitted to those regulatory officials upon request.

Dated: December 12, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–2153 Filed 2–1–96; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI41–01–6999b; FRL–5409–9]

Approval and Promulgation of Implementation Plan; Michigan

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: The USEPA proposes to approve a revision to the Michigan State Implementation Plan (SIP) for the general conformity rules. The general conformity SIP revisions enable the State of Michigan to implement and enforce the Federal general conformity requirements in the nonattainment or maintenance areas at the State or local level in accordance with 40 CFR part 93, subpart B—Determining Conformity of General Federal Actions to State or Federal Implementation Plans.

DATES: Comments on this proposed action must be received by March 4, 1996.

ADDRESSES: Written comments should be sent to: Carlton T. Nash, Chief, Regulation Development Section, Air Toxics and Radiation Branch (AT–18J), USEPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590.

FOR FURTHER INFORMATION CONTACT: Michael G. Leslie at (312) 353–6680.

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final rule which is located in the Rules section of this Federal Register. Copies of the request and the USEPA's analysis are available for inspection at the following address: USEPA, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590. (Please telephone Michael G. Leslie at (312) 353–6680 before visiting the Region 5 office.)

Authority: 42 U.S. C. 7401–7671q.

Dated: December 13, 1995.

Gail Ginsberg,

Acting Regional Administrator.

[FR Doc. 96–1851 Filed 2–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[GA–28–1–6955b; GA–30–1–7009b; FRL–5318–4]

Approval and Promulgation of Implementation Plans State: Georgia; Approval of Revisions to the State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revision submitted by the State of Georgia through the Department of Natural Resources, Environmental Protection Division (GA EPD) for the purpose of realphabetizing and updating definitions, updating volatile organic compounds (VOCs) reasonably available control technology (RACT) rules, stationary source monitoring and testing procedures, and regulations for the prevention of significant deterioration of air quality (PSD). In the final rules section of this Federal Register, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by March 4, 1996.

ADDRESSES: Written comments on this action should be addressed to Laura Thielking at the EPA Regional Office listed below.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4, Air Programs Branch, 345 Courtland Street, NE, Atlanta, Georgia 30365.

Division for Air Quality, Department for Environmental Protection, Natural Resources and Environmental Protection Cabinet, 316 St. Clair Mall, Frankfort, Kentucky 40601.

FOR FURTHER INFORMATION CONTACT: Laura Thielking, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347–3555, X4210. Reference files GA–28–1–6955 and GA–30–1–7009.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this Federal Register.

Dated: September 29, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 96–1929 Filed 2–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[GA–21–3–64881b; FRL–5319–6]

Approval and Promulgation of Implementation Plans Georgia: Approval of Revisions to the State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the state implementation plan (SIP) revision submitted by the State of Georgia for the purpose of establishing regulations governing emission statements, inspection and maintenance procedures, new source permitting requirements and stage II vapor recovery regulations. In the final rules section of this Federal Register, the EPA is approving the State's SIP revision as a direct final rule without prior proposal