PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

1. The authority citation for part 200, subpart B, is revised to read as follows:

Authority: 5 U.S.C. 552b; 15 U.S.C. 78d–1 and 78w.

2. Section 200.40 is revised to read as follows:

§ 200.40 Joint disposition of business by Commission meeting.

Any meeting of the Commission that is subject to the provisions of the Government in the Sunshine Act, 5 U.S.C. 552b, shall be held in accordance with subpart I of this part. The Commission's Secretary shall prepare and maintain a Minute Record reflecting the official action taken at such meetings.

§§ 200.41 and 200.42 [Redesignated as §§ 200.42 and 200.43]

3. Sections 200.41 and 200.42 are redesignated as §§ 200.42 and 200.43, and § 200.41 is added to read as follows:

§ 200.41 Quorum of the Commission.

A quorum of the Commission shall consist of three members; provided, however, that if the number of Commissioners in office is less than three, a quorum shall consist of the number of members in office; and provided further that on any matter of business as to which the number of members in office, minus the number of members who either have disqualified themselves from consideration of such matter pursuant to § 200.60 or are otherwise disqualified from such consideration, is two, two members shall constitute a quorum for purposes of such matter.

§ 200.42 [Amended]

4. In newly redesignated § 200.42, in paragraph (a) the reference to ''§ 200.42'' is revised to read ''§ 200.43'' and in paragraph (b) the reference to ''§ 200.41(a)'' is revised to read ''§ 200.42(a)''.

§ 200.43 [Amended]

5. In newly redesignated § 200.43(c)(1), the reference to ''§ 200.42(a)'' is revised to read ''§ 200.43(a)'' and the reference to ''§ 200.41'' is revised to read ''§ 200.42''.

§ 200.401 [Amended]

6. In § 200.401(a), the reference to ''§ 200.41 or § 200.42'' is revised to read ''§ 200.42 or § 200.43''.

Dated: March 30, 1995.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–8259 Filed 4–4–95; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 93N–0283]

RIN 0905–AD89

Food Labeling; Placement of the Nutrition Label on Food Packages

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to provide increased flexibility in the placement of the nutrition label on packaged foods. In situations in which the principal display and information panels cannot accommodate all the required labeling information, and the package has a total surface area available to bear labeling of greater than 40 square inches (sq in), the amendment allows the nutrition label to be placed on any panel that can be readily seen by the consumer. This action is being taken in response to comments received on the final rule of January 6, 1993, entitled ''Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments,'' (hereinafter ''the implementation final rule''), and on the proposed rule of August 18, 1993, entitled ''Food Labeling; Placement of the Nutrition Label on Food Packages.''

EFFECTIVE DATE: May 5, 1995.

FOR FURTHER INFORMATION CONTACT: Arletta M. Beloian, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5430.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Principal Display Panel and Information Panel

Under FDA's regulations (§ 101.1 (21 CFR 101.1)), the part of a label that is most likely to be displayed, presented, shown, or examined by a consumer under customary conditions of display for retail sale is called ''the principal display panel.'' This panel must include the statement of identity for the product and its net weight. In addition, to provide consistency and uniformity in the presentation of label information to consumers, FDA has provided for a second display panel for information that must be included on the label but that is not required to appear on the principal display panel. This alternate panel is called ''the information panel'' (§ 101.2 (21 CFR 101.2)).

The information panel is defined in § 101.2(a) as that part of the label that is immediately contiguous and to the right of the principal display panel. Section 101.2(a)(1) specifies that if the first panel to the right of the principal display panel is too small to accommodate the necessary information, or is otherwise unusable label space, the panel immediately contiguous and to the right of that part of the label may be used as the information panel. Accordingly, FDA's regulations direct manufacturers to move the information required to appear on the information panel as a unit when the first available information panel will not accommodate all the required information. Pursuant to § 101.2(e), all information appearing on the information panel must be presented in one place without other intervening material.

Section 101.2(b) states that the ingredient listing; name and place of business of the manufacturer, packer, or distributor; and nutrition information must appear either on the principal display panel or on the information panel, unless otherwise specified by regulation. Section 101.2(d)(1) requires that all information required to appear on the principal display panel or the information panel appear on the same panel unless there is insufficient space, in which case it may be divided between the principal display panel and information panel in accordance with §§ 101.1 and 101.2. In determining the sufficiency of the available space, under § 101.2(d)(1), any vignettes, designs, and other nonmandatory label information are not to be considered.

B. Mandatory Nutrition Labeling

In the **Federal Register** of January 6, 1993, FDA issued a final rule entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (58 FR 2079) (hereinafter referred to as ''the mandatory nutrition labeling final rule''), which included provisions to require nutrition labeling on most foods that are regulated by FDA and to specify a new format for declaring nutrition labeling. FDA took this action, in part, to implement the Nutrition Labeling and

Education Act of 1990 (Pub. L. 101–535), which amended the Federal Food, Drug, and Cosmetic Act. Section 101.9(i) (21 CFR 101.9(i)), which FDA added to its regulations as part of the mandatory nutrition labeling final rule, states that, except as provided in § 101.9(j)(13), the location of the nutrition label must be in accordance with § 101.2.

In recognizing the demands for label space made by nutrition labeling, the agency included a provision in the mandatory nutrition labeling final rule that allows nutrition information to be presented on any label panel on packages that have a total surface area available to bear labeling of 40 sq in or less (see § 101.9(j)(13)(ii)(D)). The flexibility provided by this provision reflects the agency's recognition that it is more important that the nutrition information be presented on the immediate package than that it be presented in any particular place (58 FR 2079 at 2156). FDA stated that given the consistent appearance of the nutrition information that will be produced by the format elements that it adopted, and the educational efforts of government, industry, and consumer organizations, consumers will know to look for, and be able to recognize, nutrition information, even if it is not presented to the right of the principal display panel. Section 101.9(j)(13)(ii)(D) does not provide an exception, however, for the placement of nutrition information on packages of more than 40 sq in when the principal display and information panels of those packages cannot accommodate all of the required information.

On January 6, 1993, the agency published, along with the mandatory nutrition labeling final rule and various other final rules, the implementation final rule (58 FR 2066). This document gave interested persons 30 days to comment on any technical issues that had not been raised in earlier comments. In response to this document, FDA received a number of comments that requested greater flexibility in the placement of the nutrition label because of the increased amount of space needed to meet the type size and spacing requirements of the new nutrition label. These comments included product labels that illustrated the difficulties presented in trying to place the required label information on the information panel.

In the **Federal Register** of August 18, 1993 (58 FR 44091), FDA published a proposed rule, entitled ''Food Labeling; Placement of the Nutrition Label on Food Packages,'' to amend its regulations on the placement of nutrition information on packages having a total surface area for labeling of greater than 40 sq in. For such situations, the agency proposed to add § 101.9(j)(17). Under this provision, when the package cannot accommodate all information required by regulation on its principal display panel and information panel, the nutrition label may be moved to any alternate panel that can be readily seen by the consumer. Furthermore, under proposed § 101.9(j)(17), the space needed for vignettes, designs, and other nonmandatory label information may be considered when determining the sufficiency of available space on the principal display panel. FDA also proposed to revise: (1) § 101.9(i) to make reference to the exemption from § 101.2 for products covered by proposed § 101.9(j)(17), and (2) § 101.2(d)(1) to exclude from its coverage products that are exempt under § 101.9(j)(17). FDA also proposed to make a number of ancillary modifications to all of the regulations that pertain to relative nutrient content claims, specifically to those sections that require that the statement that compares the amount of the subject nutrient in the product per labeled serving with that in the reference food appear either adjacent to the most prominent claim or on the information panel. Under the proposed modification, the comparative quantitative information may be placed either adjacent to the most prominent claim or to the nutrition label, without regard to the panel on which the nutrition label appears. The agency proposed to make this modification to each regulation in part 101 (21 CFR part 101) that pertains to relative nutrient content claims (e.g., ''more,'' ''light'').

In addition, in response to other comments that FDA received on the implementation final rule, the agency proposed to amend § 101.61(c)(2)(iii) to require that the statement ''not a sodium free food'' on foods that are not sodium free and yet whose label bears a claim of ''unsalted'' be placed adjacent to the nutrition label rather than on the information panel.

Interested persons were given until October 18, 1993, to comment on the proposal.

II. Comments and the Agency's Response

FDA received 19 letters, each containing 1 or more comments, in response to the proposal from trade associations, food manufacturers, a state government, and a foreign government. The comments unanimously supported the proposal. However, a few comments contained suggestions for clarifying the regulations and for modifying additional related sections that were not covered in the proposal. FDA is responding to these comments in this document. In addition, the agency received a few comments that addressed issues such as type size and leading (i.e., format) requirements and specific problems pertaining to the placement of the ingredient list on multi-packs of ready-to-eat cereals. These issues are outside the scope of the proposal, and therefore FDA will not address them in this document.

A. Flexibility in Placement

1. All the relevant comments supported FDA's proposal in § 101.9(j)(17) to allow consideration of the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel in deciding whether the space on that panel and the information panel is adequate for presentation of the nutrition label. One comment, however, objected to the agency's failure to provide for consideration of nonmandatory information on the information panel as part of the determination as to whether there is sufficient space available for the nutrition label. The comment stated that the agency's position that the nutrition facts box will be so recognizable that consumers will not have difficulty locating it regardless of where it appears on the label seems to support giving consideration to space needs for vignettes, designs, and other nonmandatory information on the information panel as well as on the principal display panel. The comment asked that the agency clarify its intent and permit nonmandatory label information on the information panel to be taken into account when deciding whether there is sufficient space on that panel for the nutrition facts box.

The agency's intent in this rulemaking was not to remove all constraints on the placement of the nutrition label but rather to provide added flexibility when needed by industry to facilitate placing the new nutrition label on food packages. In attempting to accomplish this purpose, the proposal did not address the issue of nonmandatory information on the information panel. The agency did not see a need to alter the current requirement in § 101.2(d)(1) that all required information (including the nutrition label; the ingredient list; the name and place of business of the manufacturer, packer, or distributor; and the percent juice declaration) be placed on the information panel, if not on the principal display panel, when there is sufficient space to do so.

In support of the proposal, FDA noted that the appearance of many packages

could be significantly affected if regulations did not allow vignettes, designs, and other nonmandatory information on the principal display panel to be considered in calculating the amount of available label space. The agency also noted that current industry practice almost never places the nutrition label on the principal display panel unless there is no alternative panel on the package. These two factors, which were the impetus for the subject proposal, do not apply to vignettes, designs, and other nonmandatory information on the information panel. Thus, the interests of consumers will be served best by continuing to have this information appear together wherever possible. Moreover, having the nutrition label, the ingredient list, and the name and place of business of the manufacturer, packer, or distributor appear on the same panel simplifies the consumers' search for this information. The comment did not advance any arguments that suggested a countervailing benefit to the public from allowing nonmandatory label information to replace nutrition labeling on the information panel. Accordingly, the agency is not making the requested change.

2. One comment stated that the second sentence of proposed § 101.9(j)(17) needed to be clarified because there was confusion in trade publications about the significance of nonmandatory information on the information panel.

FDA agrees that it is necessary to clarify the differences in the agency's treatment of nonmandatory information on the principal display panel as opposed to on the information panel. Accordingly, the agency is revising § 101.9(j)(17) to add a sentence at the end of the subparagraph that reads: ''Nonmandatory label information on the information panel shall not be considered in determining the sufficiency of available space for the placement of the nutrition label.''

B. Statements of Ingredients, and Name and Place of Business

FDA did not propose to modify the requirement that manufacturers list ingredient information and the name and place of business of the manufacturer, packer, or distributor on the principal display panel or the information panel. Under § 101.9(j)(13) and proposed § 101.9(j)(17), only the nutrition label could be placed on another panel.

3. Three comments urged that the agency allow the ingredient statement (§ 101.4) and the name and place of business of the manufacturer, packer, or distributor (§ 101.5) to be presented adjacent to the nutrition label on any other label panel that can be readily seen by consumers when the information panel is too small to accommodate all the required information. They argued that, although consumers may now look for the ingredient list and the name and place of business statement on the principal display panel or information panel, it was likely that these statements would be seen if listed on the same panel as the nutrition information, which must be readily observable. Furthermore, the comments argued, consumers are accustomed to seeing all of this information on one panel, and manufacturers often incorporate the ingredient list, the name and place of business statement, and the nutrition label into one design.

Among these comments, one recommended revised wording in § 101.4(a)(1) to implement the change, i.e., to state that ingredients are to be listed on either the principal display panel, the information panel, or the label panel on which the mandatory nutrition information appears. The comment stated that because § 101.5(a) requires that the label of a food in package form specify conspicuously the name and address of the manufacturer, packer, or distributor, that regulation need not be amended because it allows manufacturers the option of placing such information in a place where the consumer will see it.

The agency has considered these comments and is not making the requested change because a change of the magnitude of that suggested was not foreshadowed by the proposal. The ingredient statement and the name and place of business statements have appeared on either the principal display or the information panels for nearly 20 years. Allowing the ingredient list and the name and place of business of the manufacturer, packer, or distributor to move off the information panel whenever there is insufficient space for them to appear with the nutrition label would represent a significant redefinition of what constitutes the information panel. While the portion of the food supply that would be affected is unknown, it could be substantial. Companies interested in pursuing this suggestion should submit a citizen petition under § 10.30 (21 CFR 10.30) that would address the possible ramifications of such a change on food packages and on consumers' use of the required label information.

It should be noted, however, that under § 101.2(a)(1), when there is insufficient space on the panel immediately contiguous and to the right of the principal display panel for all required components, the ingredient list; the name and place of business of the manufacturer, packer, or distributor; and the nutrition label may be moved as a unit to the next panel immediately contiguous and to the right of that panel.

C. Clarification

4. One comment requested that FDA allow for the placement of nutrition information on either side of a center-seamed back panel, such as on flexible film bags used for snack foods that do not have information printed on the sides, top, or bottom of the package. The comment argued that the bag is easily rotated from front to back, and that the full center-seamed back panel is in plain view.

Section 101.2(a) states that the ''information panel'' is that part of the label immediately contiguous and to the right of the principal display panel when observed facing the principal display panel. If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information, the next panel immediately contiguous and to the right of the fold may be used (see § 101.2(a)(1)). In the case of flexible film bags of snack foods with folded or pleated side panels that do not provide any additional usable label space, the back panel of the bag is the information panel. FDA interprets the back panel to be the full back panel of the flexible bag, regardless of the presence or absence of a seam. Therefore, the nutrition label may be located on any part of the back panel. Wherever it is placed, however, § 101.2(e) requires that there be no intervening material between it and the other pieces of required information.

III. Other Provisions

5. All comments addressing the aspect of the proposal on relative nutrient content claims supported the proposed requirement that the comparative quantitative information be positioned adjacent to the most prominent claim or to the nutrition label. However, in light of § 101.2(e), which states that all required information on the information panel appear in one place without other intervening material, the agency is concerned that the proposed codified language pertaining to relative claims in §§ 101.54, 101.56, 101.60, 101.61, and 101.62 that would require quantitative information to be ''declared adjacent to the most prominent claim or to the nutrition label * * *'' might be interpreted to mean that when the

nutrition label remains on the information panel, the quantitative information has to be immediately adjacent to the nutrition label rather than being allowed to be placed elsewhere on the information panel in proximity with other required information, as is in fact the case. Such a literal interpretation of the words ''adjacent to the nutrition label'' could have the unintended effect of requiring current labels containing relative claims to be redesigned for the sole purpose of relocating the quantitative information. The same concern exists for § 101.61(c)(2)(iii), which addresses the placement of the statement ''not a sodium free food'' on foods that are not sodium free and yet whose label bears a claim of ''unsalted.''

To prevent such a misunderstanding, FDA is modifying the codified language pertaining to relative claims (i.e., ''more'' claims: § 101.54(e)(1)(iii)(B) and (e)(2)(iii)(B); ''light'' claims: § 101.56(b)(3)(ii), (c)(1)(ii)(B), (c)(2)(ii)(B), and (g); calorie claims: § 101.60(b)(5)(ii)(B), (b)(6)(ii)(B), (c)(4)(ii)(B), and (c)(5)(ii)(B); sodium claims: § 101.61(b)(6)(ii)(B) and (b)(7)(ii)(B); and fat, fatty acid, and cholesterol claims: § 101.62(b)(4)(ii)(B), (b)(5)(ii)(B), (c)(4)(ii)(B), (c)(5)(ii)(B), (d)(1)(ii)(F)(*2*), (d)(2)(iii)(E)(*2*), (d)(2)(iv)(E)(*2*), (d)(4)(i)(C)(*2*), (d)(4)(ii)(D)(*2*), (d)(5)(i)(C)(*2*), and (d)(5)(ii)(D)(*2*)) and the general principles governing nutrient content claims in § 101.13(j)(2)(iv)(B) (21 CFR 101.13(j)(2)(iv)(B)) to state that the quantitative information ''shall appear adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.'' (For clarity, FDA is making a small change in the placement of the illustrative example in these regulations and, for consistency, is adding an example to § 101.62(d)(4)(i)(C)(*2*).) Likewise, the agency is modifying § 101.61(c)(2)(iii), which pertains to the placement of the statement ''not a low sodium food,'' to state that the statement shall appear ''adjacent to the nutrition label of the food bearing the claim, or, if the nutrition label is on the information panel, it may appear elsewhere on the information panel in accordance with § 101.2 of this chapter.''

IV. Environmental Impact

The agency previously considered the environmental effects of this rule as announced in the proposed rule of August 18, 1993 (58 FR 44091). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of the final 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 believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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 this final rule will allow for increased flexibility in complying with labeling rules, and therefore results in positive net benefits, the agency certifies that the final 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.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

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

PART 101—FOOD LABELING

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

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (5 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 101.2 is amended by revising paragraph (d)(1) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(d)(1) Except as provided by § 101.9(j)(13) and (j)(17), all information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as provided by § 101.9(j)(17), any vignettes, designs, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

* * * * *

3. Section 101.9 is amended by revising paragraph (i) and by adding new paragraph (j)(17) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(i) Except as provided in paragraphs (j)(13) and (j)(17) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(j) * * *

(17) Foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition label. The space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered in determining the sufficiency of available space on the principal display panel for the nutrition label. Nonmandatory label information on the information panel shall not be considered in determining the sufficiency of available space for the nutrition label.

* * * * *

4. Section 101.13 is amended by revising paragraph (j)(2)(iv)(B) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(j) * * *

(2) * * *

(iv) * * *

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information

panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

5. Section 101.54 is amended by revising paragraphs (e)(1)(iii)(B) and (e)(2)(iii)(B) to read as follows:

§ 101.54 Nutrient content claims for ''good source,'' ''high,'' and ''more.''

* * * * *

(e) * * *

(1) * * *

(iii) * * *

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces (e.g., ''Fiber content of white bread is 1 gram (g) per serving; (this product) 3.5 g per serving'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(2) * * *

(iii) * * *

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., ''The fiber content of 'X brand of product' is 2 g per 3 oz. This product contains 4.5 g per 3 oz.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

6. Section 101.56 is amended by revising paragraphs (b)(3)(ii), (c)(1)(ii)(B), (c)(2)(ii)(B), and (g) to read as follows:

§ 101.56 Nutrient content claims for ''light'' or ''lite.''

* * * * *

(b) * * *

(3) * * *

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference food that it replaces (e.g., ''lite cheesecake—200 calories, 4 grams (g) fat per serving; regular cheesecake—300 calories, 8 g fat per serving'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2; and

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food that it replaces (e.g., ''lite soy sauce 500 milligrams (mg) sodium per serving; regular soy sauce 1,000 mg per serving'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(2) * * *

(ii) * * *

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food that it replaces (e.g., ''lite canned peas, 175 mg sodium per serving; regular canned peas 350 mg per serving'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(g) The term ''lightly salted'' may be used on a product to which has been added 50 percent less sodium than is normally added to the reference food as described in § 101.13(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not ''low in sodium'' as defined in § 101.61(b)(4), the statement ''not a low sodium food,'' shall appear adjacent to the nutrition label of the food bearing the claim, or, if the nutrition label is on the information panel, it may appear elsewhere on the information panel in accordance with § 101.2 and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 101.13(j)(2).

7. Section 101.60 is amended by revising paragraphs (b)(4)(ii)(B), (b)(5)(ii)(B), (c)(4)(ii)(B), and (c)(5)(ii)(B) to read as follows:

§ 101.60 Nutrient content claims for the calorie content of foods.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(B) Quantitative information comparing the level of the nutrient per labeled serving size with that of the reference food that it replaces (e.g., ''Calorie content has been reduced from 150 to 100 calories per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(5) * * *

(ii) * * *

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., ''Calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(B) Quantitative information comparing the level of the sugar in the product per labeled serving with that of the reference food that it replaces (e.g., ''Sugar content has been lowered from 8 g to 6 g per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(5) * * *

(ii) * * *

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., ''Sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

8. Section 101.61 is amended by revising paragraphs (b)(6)(ii)(B), (b)(7)(ii)(B), and (c)(2)(iii) to read as follows:

§ 101.61 Nutrient content claims for the sodium content of foods.

* * * * *

(b) * * *

(6) * * *

(ii) * * *

(B) Quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces (e.g., ''Sodium content has been lowered from 300 to 150 mg per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information

panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(7) * * *

(ii) * * *

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference food that it replaces (e.g., ''Sodium content has been reduced from 217 mg per 3 oz to 150 mg per 3 oz.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(c) * * *

(2) * * *

(iii) If the food is not sodium free, the statement, ''not a sodium free food'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition label of the food bearing the claim, or, if the nutrition label is on the information panel, it may appear elsewhere on the information panel in accordance with § 101.2.

* * * * *

9. Section 101.62 is amended by revising paragraphs (b)(4)(ii)(B), (b)(5)(ii)(B), (c)(4)(ii)(B), (c)(5)(ii)(B), (d)(1)(ii)(F)(*2*), (d)(2)(iii)(E)(*2*), (d)(2)(iv)(E)(*2*), (d)(4)(i)(C)(*2*), (d)(4)(ii)(D)(*2*), (d)(5)(i)(C)(*2*), and (d)(5)(ii)(D)(*2*) to read as follows:

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

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(B) Quantitative information comparing the level of fat in the product per labeled serving with that of the reference food that it replaces (e.g., ''Fat content has been reduced from 8 g to 4 g per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(5) * * *

(ii) * * *

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference food that it replaces (e.g., ''Fat content has been reduced from 7.5 g per 3 oz to 5 g per 3 oz.'') is declared adjacent to the most prominent claim, to the nutrition label, or, if the nutrition label is located on the information panel, it may appear elsewhere on the information panel in accordance with § 101.2.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving with that of the reference food that it replaces (e.g., ''Saturated fat reduced from 3 g to 1.5 g per serving'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(5) * * *

(ii) * * *

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference food that it replaces (e.g., ''Saturated fat content has been reduced from 2.5 g per 3 oz to 1.7 g per 3 oz.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label in on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(F) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., ''Contains no cholesterol compared with 30 mg cholesterol in one serving of butter. Contains 13 g of fat per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(2) * * *

(iii) * * *

(E) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., ''Cholesterol lowered from 30 mg to 5 mg per serving; contains 13 g of fat per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(iv) * * *

(E) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., ''Cholesterol lowered from 30 mg to 5 mg per serving; contains 13 g of fat per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(4) * * *

(i) * * *

(C) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., ''[labeled product] 50 mg cholesterol per serving; [reference product] 30 mg cholesterol per serving'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(ii) * * *

(D) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., ''Cholesterol lowered from 55 mg to 30 mg per serving. Contains 13 g of fat per serving.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

(5) * * *

(i) * * *

(C) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces (e.g., ''Cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(ii) * * *

(D) * * *

(*2*) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces (e.g., ''Cholesterol lowered from 30 mg to 22 mg per 3 oz of product.'') is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

* * * * *

Dated: March 24, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–8067 Filed 3–31–95; 4:32 pm]

BILLING CODE 4160–01–P

---

21 CFR Part 876

[Docket No. 92N–0382]

Gastroenterology-Urology Devices; Effective Date of Requirement for Premarket Approval of Testicular Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the testicular prosthesis, a generic type of a surgically implanted medical device intended to simulate the presence of a testicle within the male scrotum. Commercial distribution of this device must cease, unless a manufacturer or importer has filed with FDA a PMA or a notice of completion of a PDP for its version of the testicular prosthesis within 90 days of the effective date of this regulation. This regulation reflects FDA's exercise of its discretion to require a PMA or notice of completion of a PDP for preamendments devices.

EFFECTIVE DATE: April 5, 1995.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of January 6, 1989 (54 FR 550), the agency identified the testicular prosthesis as one of the high-priority devices that would be subject to PMA or PDP requirements. This rulemaking is consistent with FDA's stated priorities and Congress' requirement that class III devices are to be regulated by FDA's premarket approval review. This action is being taken under the Medical Device Amendments of 1976 (Pub. L. 94–295). The preamble to this rule responds to comments received on the proposal to require the filing of a PMA or a notice of completion of a PDP.

This regulation is final upon publication and requires a PMA or a notice of completion of a PDP for all testicular prostheses classified under § 876.3750 (21 CFR 876.3750) and all devices that are substantially equivalent to them. A PMA or a notice of completion of a PDP for these devices must be filed with FDA within 90 days of the effective date of this regulation. (See section 501(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(f)(1)(A)).)

In the **Federal Register** of November 23, 1983 (48 FR 53012 at 53024), FDA issued a final rule classifying the testicular prosthesis into class III (premarket approval). Section 876.3750 of FDA's regulations setting forth the classification of the testicular prosthesis intended for medical use applies to: (1) Any testicular prosthesis that was in commercial distribution before May 28, 1976, and (2) any device that FDA has found to be substantially equivalent to a testicular prosthesis in commercial distribution before May 28, 1976.

In the **Federal Register** of January 13, 1993 (58 FR 4116), FDA published a proposed rule to require the filing, under section 515(b) of the act (21 U.S.C. 360e(b)), of a PMA or notice of completion of a PDP for the classified testicular prosthesis and all substantially equivalent devices (hereinafter referred to as the January 1993 proposed rule). In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and (2) the benefits to the public from use of the device (58 FR 4116 at 4118).

The preamble to the January 1993 proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings and, under section 515(b)(2)(B) of the act (21 U.S.C. 360e(b)(2)(B)), provided the opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the testicular prosthesis was required to be submitted by January 28, 1993. The comment period initially closed on March 15, 1993. Because of one request, FDA extended the comment period for 60 days to May 14, 1993, to ensure adequate time for preparation and submission of comments (58 FR 15119, March 19, 1993).

FDA did not receive any petitions requesting a change in the classification of the testicular prosthesis. The agency did receive a total of five comments in response to the January 1993 proposed rule. These represent comments from individuals, manufacturers, and professional societies. The comments primarily addressed issues relating to the significant risks associated with the use of testicular prostheses, and the preclinical and clinical data needed to support a future PMA application.

II. Summary and Analysis of Comments and FDA's Response

A. General Comments

1. One comment stated that it appears that FDA has chosen solid silicone elastomer testicular implants for disparate treatment from other silicone implants, even though the basic chemistry, ingredients, and many manufacturing steps are very similar to other class II implantable silicone products. The comment requested that FDA describe the differences between silicone gel-filled and solid silicone elastomer testicular implants, and between silicone gel-filled mammary prostheses and solid silicone elastomer testicular prostheses.

FDA disagrees with this comment. The testicular prosthesis was classified into class III in 1983 because insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide this assurance. The possible risks identified at the time of classification included: (1) The possible migration of silicone gel from the interior of the prosthesis to adjacent tissue (with or without rupture of the silicone elastomer shell), and (2) possible long-term toxic effects of the silicone polymers from which the prosthesis is fabricated. Therefore, requiring premarket approval for the testicular prosthesis is consistent with the intent to regulate this device as a class III device even in 1983. FDA notes that no requests for a change in