Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

ANM MT E5 Libby, MT

Libby Airport, MT
(Lat 48°17′02″N, long. 115°29′25″W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Libby Airport and within 4 miles each side of the 345° bearing from the Libby Airport extending from the 7-mile radius to 10 miles northwest of the airport; that airspace extending upward from 1,200 feet above the surface within an area bounded by a line beginning at lat. 48°19′00″N, long. 115°42′00″W; to lat. 48°19′00″N, long 115°16′00″W; to lat. 48°45′00″N, long. 115°22′00″W; to lat. 48°45′00″N, long. 115°50′00″W, to point of beginning.

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Issued in Seattle, Washington, on May 28, 1996.

Richard E. Prang,

*Acting Assistant Manager, Air Traffic Division, Northwest Mountain Region.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 70, 71, 80, 101, 107, 170, 172, 173, 174, 175, 177, 178, 184, and 1250

**[Docket No. 96N–0149]**

### Food Standards; Reinvention of Regulations Needing Revisions; Request for Comments on Certain Existing Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it intends to review its human food labeling regulations pertaining to: The exemption for soft drinks from requirements for the type size and placement of certain information on the information panel, requirements for listing ''statements of identity,'' and requirements for flavor labeling; its infant formula regulations to ensure that they fully reflect the Federal Food, Drug, and Cosmetic Act (the act); and its regulations pertaining to the discharge of waste aboard casino ships, passenger ships, and ferries. The agency is also conducting a review of its food additive regulations to consolidate existing regulations. As part of this review of agency regulations, the agency is soliciting comments from all interested persons on whether the above regulations should be retained, revised, or revoked. FDA solicits comments on the benefits or lack of benefits of such regulations in facilitating domestic, as well as international, commerce and on the value of these regulations to consumers. The agency also solicits comments on alternative means of accomplishing the statutory objectives that led to the adoption of the subject regulations. This review is in response to the Administration's ''Reinventing Government'' initiative which seeks to ease the burden on regulated industry and consumers.

**DATES:** Written comments by September 10,1996.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Corinne L. Howley, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4272.

**SUPPLEMENTARY INFORMATION:**

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the Administration's ''Reinventing Government'' initiative. In his March 4 directive, the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations to ''eliminate or revise those that are outdated or otherwise in need of reform.''

In response to this directive, FDA issued proposals to revoke a number of regulations (60 FR 53480, October 13, 1995; 60 FR 56513 and 56541, November 9, 1995) and an advance notice of proposed rulemaking (ANPRM) to review standards of identity, quality, and fill of container (60 FR 67492, December 29, 1995). The agency has completed the review of its food regulations in response to the President's initiative and as a result is publishing two documents elsewhere in this issue of the Federal Register. This document is an ANPRM to review regulations that the agency believes may need to be revised. In addition to requesting information on the following issues, FDA requests any other comments relevant to the regulations discussed herein that would assist the agency in fulfilling its mission to protect the interest of consumers.

II. Soft Drinks

Elsewhere in this issue of the Federal Register, FDA is proposing a number of changes in § 101.2 (21 CFR 101.2) pertaining to information that must appear on the information panel of the label. FDA explains in that document that it considers a number of exemptions from the type size and placement requirements in § 101.2 to be obsolete, and the agency is proposing to remove them.[1] The exemptions that FDA is proposing to remove appear in § 101.2(c), but that paragraph also contains a number of exemptions that the agency is not proposing to revoke.

Among the latter exemptions is a provision for soft drinks in § 101.2(c)(4). FDA is undecided about whether to retain this provision because the agency does not know enough about nationwide packing practices for these products. For example, this provision exempts soft drink bottles that were manufactured before October 31, 1975, from the type size and placement requirements. The agency does not know, however, whether any bottles manufactured before that date are still in use. If not, this exemption is obsolete and should be removed. Other soft drink exemptions may also be obsolete, or in need of revision, to respond more efficiently to changes in labeling practices that have resulted from the Nutrition Labeling and Education Act (the 1990 amendments). The agency needs to know more about how firms are presenting newly required information to consumers on labels and on labeling materials other than labels (e.g., counter cards, posters), as well as whether they are encountering any difficulties associated with such presentation, before it can determine whether it should pursue further rulemaking activities for soft drinks. For example, where soft drink manufacturers are using posters for some label information, there may be ample free space to present ingredient

[1] The type size and location requirements apply to all information required to appear on the label of any package of food under certain regulations that are referenced in § 101.2. The information must appear either on the principal display panel or the information panel unless otherwise specified in the regulations. Section 101.2(a) defines the term ''information panel'' as it applies to packaged food, and § 101.2(b) identifies referenced regulations. Section 101.2(c) requires that information required by the referenced regulations be in letters or numbers of at least one-sixteenth inch in height, unless otherwise exempted by regulation.

information in relatively large type size. Would consumers be better informed by such a presentation of this information than they would with smaller type size on the soft drink package itself? If FDA were to permit alternative labeling locations for information required to appear on the information panel, would the current soft drink exemptions still be needed? FDA requests comments on these issues from all interested parties.

III. Statements of Identity

Section 101.3(a) and (b) (21 CFR 101.3(a) and (b)) requires that the principal display panel of the label of food in package form bear a statement of identity of the food product. Specifically, § 101.3 requires that the statement of identity be in terms of the name of the food as required by Federal law or regulation or, in the absence of such, of the common or usual name for the food. If no such common or usual name has been established, the statement of identity must be an appropriately descriptive term. When the nature of the food is obvious, however, a fanciful name commonly used by the public for the food may be used.

This regulation also requires, among other things, that where the food is marketed in optional forms (whole, slices, diced), the particular form be considered a necessary part of the name (§ 101.3(c)). This provision does not affect the required declarations of identity under definitions and standards of identity for foods that specify other ways of declaring the optional forms of the food.

Section 101.3(d) requires that the statement of identity be presented in bold type on the principal display panel of the label, be in a type size that is reasonably related to the most prominent printed matter on such panel, and be in lines generally parallel to the base on which the package rests as it is designed to be displayed. These provisions were established to meet the prominence and conspicuousness requirements of section 403(f) of the act (21 U.S.C. 343(f)).

The requirement that the type size in which the statement of identity appears be reasonably related to the largest type size used on the principal display panel has been informally interpreted by FDA to mean that the statement of identity must appear in type not less than one-half the size of the largest printed matter on the principal display panel. However, the agency has observed that brand name identifications and flavor declarations often appear many times larger than the statement of identity on the food label. The agency requests comments on whether the statements of identity are sufficiently conspicuous in light of other representations on the principal display panel. If they are not, how should the regulation be changed to ensure that the type size used for the statement of identity will be adequate? For example, should FDA's informal guidance be established as a requirement in a regulation? Should a different criterion be established, perhaps related to the area of the principal display panel, similar to the requirement for net contents declaration?

FDA is also aware that some identity statements are not placed parallel to the base on which the container rests. Does this create problems for consumers in reading labels? Are there specific needs for variations from this requirement that should be provided for by special exemptions? For example, do advancements in packaging foods and in displaying them justify exemptions for certain types of packaging?

Section 101.3(e) defines the term ''imitation'' and how it is to be used in the labeling of foods. This provision states that a food shall be deemed to be an imitation, and thus subject to the requirements of section 403(c) of the act, if it is a substitute for and resembles another food but is nutritionally inferior to that food. If the food is an imitation, as so defined, then the label of the food must bear in type of uniform size and prominence, the word ''imitation'' and, immediately thereafter, the name of the food imitated.

When section 403(c) of the act was adopted in 1938, Congress was seeking to protect the consumer from the uninformed purchase of an inferior substitute product that could be mistaken for a traditional food product (38 FR 2138, January 19, 1973). In 1973, in proposed regulations pertaining to imitation foods, the agency noted that vast strides in food technology had taken place since section 403(c) of the act was enacted, and that since 1938 many new wholesome and nutritious food products had entered the marketplace, some of which resembled and substituted for traditional foods (38 FR 2138). The agency stated that it was no longer the case that such products were necessarily substandard compared to the traditional foods for which they substituted. However, FDA still believed that the consumer must be protected from the unwitting purchase of a product that is different from what he or she may reasonably expect (38 FR 2138). FDA proposed that the term ''imitation'' only be applied to substitute foods that are nutritionally inferior to the foods for which they substitute (38 FR 2143 at 2148). In its final regulation (38 FR 20703, August 2, 1973), FDA confirmed this view and defined nutritional inferiority as any reduction in the content of an essential nutrient that is present in a measurable amount.

Over the years, FDA has received questions as to when a food is considered to resemble and substitute for a traditional food, so that it is subject to the provisions of this regulation. The agency has advised that where there is no standard of identity for the food in parts 130 through 169 (21 CFR parts 130 through 169), no common or usual name regulation in part 102 (21 CFR part 102), or no provision for the food in the nutritional quality guideline that appears in part 104 (21 CFR part 104), the product must be evaluated in terms of whether it resembles or purports to be (has similar functional, physical, and organoleptic properties), and whether it substitutes for, a food product that has a commonly understood identity or common or usual name. For example, there are products on the market that are textured, colored, flavored, and shaped to resemble crabmeat. These products resemble and substitute for crabmeat, and when they are nutritionally inferior to crabmeat, they must be labeled ''imitation crabmeat.''

In addition, manufacturers have often sought advice on how a food should be labeled when it resembles and substitutes for a traditional food but is not nutritionally inferior to the traditional food. In some cases, the agency has recommended the use of the term ''substitute'' as part of the name of such a food. For example, the agency has advised that a beverage made by replacing the milkfat in milk with vegetable oil, and which is not nutritionally inferior to milk, could be labeled as a ''milk substitute.'' The agency stated that the name would be followed by a descriptive phrase, such as ''made with skim milk and vegetable oil'' or ''contains 3 percent soybean oil to replace the milkfat,'' to inform the consumer as to the difference between the milk substitute and milk.

In view of these questions, the agency is seeking comment on whether it should develop more in-depth guidance to assist manufacturers in naming new food products. If so, how should this be accomplished: through revision of the regulations in §§ 101.3 or 102.5 (common or usual name), a Compliance Policy Guide, or other less formal guidance, such as an addendum to FDA's Food Labeling Guide? In developing comments on this issue, interested parties should keep in mind that FDA has published an ANPRM seeking comment on whether

and how standards of identity and common or usual name regulations should be revised (60 FR 67492). Many, though not all, of the foods subject to § 101.3(e) resemble and substitute for foods subject to those regulations. FDA will evaluate any proposed changes in its policy on labeling of imitation foods in light of any changes it ultimately decides to make in its approach to standards of identity and common or usual name regulations.

In § 101.3(e)(4), FDA has defined nutritional inferiority to include any reduction in the content of an essential nutrient that is present in a measurable amount. A measurable amount of an essential nutrient under this regulation is 2 percent or more of the Daily Reference Value of protein listed under § 101.9(c)(7)(iii) (21 CFR 101.9(c)(7)(iii)) and of potassium listed under § 101.9(c)(9) and of the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv). In the Federal Register of December 28, 1995 (60 FR 67164), FDA established RDI's for several nutrients and revised the definition of nutritional inferiority to accommodate those new RDI's where practicable. The agency stated that as substitute products proliferate, it is important to ensure that these products contain essential nutrients in amounts consistent with the reference food, so that consumers can continue to have confidence that a varied diet will supply adequate nutrition (60 FR 67164 at 67169).

The agency is requesting comment on the appropriateness of the current definition of nutritional inferiority for the purpose of determining whether a food is an imitation. Fat and calories are currently excluded from the nutrients to be considered when determining nutritional inferiority. The agency did not reevaluate this provision when it revised the definition of nutritional inferiority in the December 28, 1995, final rule. Nonetheless, it now seeks comment on whether that definition should be further revised. Should the definition be changed to take into account current dietary guidelines? For example, should sodium, saturated fat, and cholesterol be excluded from the nutrients to be considered? On the other hand, if a substitute food is modified to achieve a nutrition goal, such as a reduction in the sodium content of the diet, and as a consequence the fat or calorie content of the food is increased to achieve a more palatable product, should such a product be considered to be nutritionally inferior? Is there some other way of highlighting such a change on the label?

FDA notes that the concept of nutritional inferiority is widely used in the agency's regulations and interpretations. For example, FDA relies on this concept in the definition of the term ''substitute'' food in § 101.13 *Nutrient content claims—general principles*. Section 101.13(d) states that a ''substitute'' food is one that may be used interchangeably with another food that it resembles, i.e., to which it is organoleptically, physically, and functionally (including shelf life) similar, and to which it is not nutritionally inferior, unless it is labeled as an ''imitation.'' In addition, the general standard of identity, § 130.10 *Requirements for foods named by use of a nutrient content claim and a standardized term* (21 CFR 130.10), explains how to derive statements of identity for foods that substitute for and resemble traditional standardized foods. This regulation specifically references § 101.3(e) and provides for the addition of nutrients to the new food so that it will not be nutritionally inferior to the traditional standardized food that is named in the statement of identity. Thus, comments that suggest changes in the definition of nutritional inferiority in § 101.3(e) should also consider the effect of such changes on the labeling of foods covered by other regulations such as those mentioned here.

## IV. Flavors

FDA's flavor labeling regulation, § 101.22 (21 CFR 101.22), has generated many questions over the years. Some representatives of the food industry have complained that this regulation is so complex that it is subject to a multitude of differing interpretations. In light of such complaints, FDA believes that it should attempt to revise this regulation to make it more user friendly and, at the same time, to make flavor designations on food labels more meaningful to consumers. Comments on the existing regulation will help the agency to achieve this goal.

Section 101.22 lists a variety of characteristics that would make the flavoring used in a food either ''artificial'' or ''natural.'' The regulation does not, however, contain an adequate definition for either term. Before a firm can decide how to describe the flavoring used in its product, it may have to engage in a rather arduous analysis. For example:

In § 101.22(a), FDA defines an ''artificial flavor'' or ''artificial flavoring'' as any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf, or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. The term ''artificial flavor'' also includes those synthetic flavoring substances and adjuvants listed in §§ 172.515(b) and 182.60 (21 CFR 172.515(b) and 182.60) except where the flavors are derived from natural sources.

This definition would be simpler if FDA could state that the term ''artificial flavor'' generally connotes a synthetic source. However, the agency has traditionally viewed this term as having wider application than simply to synthetic substances. For example, FDA has advised that when a flavor from a natural source is used in a food product to simulate a flavor of a food other than the one from which the flavor is derived, the food to which the flavor is added must be labeled as ''artificially flavored'' (38 FR 20718, August 2, 1973). Thus, a ''lemon'' type pie, made with natural flavor derived predominantly from citrus products, could not be identified simply as ''lemon pie'' without misleading the consumer. It must be labeled as ''citrus pie'' or ''artificially flavored lemon pie.'' This position has led to considerable confusion because often manufacturers do not consider the end use of the flavoring, in addition to its source, in determining whether the food should be labeled as being ''artificially flavored.''

Further, the exception in the definition of ''artificial flavor'' that permits substances that are listed as synthetic flavoring substances and adjuvants in §§ 172.515(b) and 182.60 to be designated as ''natural'' when they are derived from ''natural sources'' has resulted in a very broad category of substances labeled as ''natural flavor.'' There is confusion regarding the interpretation of ''natural source'' in this context. Should this provision be retained? If so, how should it be phrased so that it can be interpreted consistently?

The agency's definition for ''natural flavor'' is also very complex. In § 101.22(a)(3), FDA defines ''natural flavor'' or ''natural flavoring'' as the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, that contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf, or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include natural essence or extractives obtained from plants

listed in 21 CFR 182.10, 182.20, 182.40, and 182.50 and part 184 (21 CFR part 184) and such substances listed in 21 CFR 172.510.

Recognizing that, with advances being made in the technology of flavor development, the distinctions established in its regulations and policy statements may need to be modified, FDA requests comments on whether and, if so, how the definitions of natural and artificial flavor should be revised. For example, if a substance from a natural source is used to produce an intermediate product that is further reacted with another substance from a natural source, e.g., hydrolyzed by use of enzymes or other substances, should the resultant flavor, which obviously differs from its original natural source, be permitted to be labeled as ''natural,'' or should the new flavoring compound be considered to be ''an artificial flavor'' because the new flavor is not native to the natural sources? Should hydrolysates and their reaction products continue to be considered as natural flavors? What about flavors produced by the Maillard reaction? Would it be better to define ''natural flavor'' and simply provide that ''artificial flavor'' constitutes all flavor that does not fall within that definition, or vice versa? Does it make sense to simply abandon the distinction between ''artificial'' and ''natural'' flavoring as no longer being relevant to the interests and understanding of consumers and to simply provide for the use of the term ''flavor added'' on the principal display panel and as part of the ingredient list?

In addition, FDA would like to focus attention on the designation of characterizing flavors on food labels in accordance with § 101.22(i). This matter has provided another source of confusion. Section 101.22(i) provides that if the label or labeling or advertising makes any direct or indirect representations with respect to the primary recognizable flavors of a food, by word, vignette (e.g., by depiction of a fruit) or other means, or if for any reason the manufacturer or distributor of the food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered to be the characterizing flavor and shall be designated in the following way:

1. If the food contains no artificial flavor that simulates, resembles, or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., ''vanilla,'' in letters not less than one-half the height of the letters used in the name of the food.

2. If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in ''strawberry shortcake,'' and the food contains natural flavor derived from such ingredient, but the amount of the characterizing ingredient is insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word ''natural'' and shall be immediately followed by the word ''flavored'' in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ''natural strawberry flavored shortcake'' or ''strawberry flavored shortcake.''

3. If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as ''artificially flavored.''

4. If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor that simulates, resembles, or reinforces the characterizing flavor, the name of the food shall be immediately followed by the words ''with other natural flavor'' in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

5. If the food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food, and the name of the characterizing flavor shall be accompanied by the words ''artificial'' or ''artificially flavored,'' in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ''artificial vanilla,'' ''artificially flavored strawberry,'' or ''grape artificially flavored.''

6. Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by § 101.22(i) shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, with certain exceptions.

These provisions are so complex that it is not surprising that they have frequently been the cause of confusion and varying interpretations by both manufacturers and regulators. The regulation needs to be clarified. In addition, developments in food processing since the regulation was adopted have resulted in the manufacture of more diverse products using natural and artificial flavors.

The agency requests comment on how the use of flavors should be declared on the food label. Some manufacturers have contended that declaration of natural and artificial flavors in the ingredient list is sufficient to inform consumers of their role in the food. FDA's position has been that consumers can be misled unless the characterizing flavor of the food is described as ''flavored'' when flavoring substances are needed to characterize the food. The agency's position has been that the term ''artificial'' should be used to describe the flavor unless it is a natural flavor and is from the same source as the flavor of the food.

What is the best way to inform the consumer of the use and the role of a flavoring substance in a food? How should a combination of natural and artificial flavors be declared? The agency requests suggestions for revisions of § 101.22(i) and substantiating information regarding why the suggested revisions are appropriate, and how they would affect marketing practices.

Further, § 101.22(i) requires that the flavor supplier certify, in writing, that any flavor it supplies that is designated as containing no artificial flavor does not, to the best of the supplier's knowledge and belief, contain any artificial flavor, and that the supplier has not added any artificial flavor to it. Although the agency is not aware of any concerns about labeling of flavors supplied to manufacturers, it requests comments on the suitability of these requirements.

## V. Infant Formula

Part 107 (21 CFR part 107) provides for labeling of infant formulas, for terms and conditions that a manufacturer must meet with respect to exempt infant formulas, for required levels of nutrients in infant formulas as prescribed by statute, and for recalls of infant formulas in appropriate circumstances. Congress passed the Infant Formula Act of 1980 (the 1980 act) (Pub. L. 96–359), which amended the act to add section 412 (21 U.S.C. 350a). In 1985, FDA partially implemented the 1980 act by establishing subparts B, C, and D in part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant

formula, respectively (50 FR 1833, January 14, 1985; 50 FR 48183, November 22, 1985; and 50 FR 45106, October 30, 1985). In 1986, Congress, as part of the Drug Enforcement, Education, and Control Act of 1986 (the 1986 amendments) (Pub. L. 99–570), completely revamped section 412 of the act to address concerns that had been expressed by Congress and consumers about the 1980 act and FDA's implementation of those provisions.

In 1990, Congress passed the 1990 amendments which amended the act to add paragraphs (q) and (r) to section 403. While the 1990 amendments exempt infant formulas subject to section 412 of the act from the nutrition labeling provisions of section 403(q) of the act, only infant formulas subject to section 412(h) of the act (exempt infant formulas) are exempt from the nutrient content and health claims provisions of section 403(r).

The agency is considering what changes need to be made to part 107 in light of the 1986 and 1990 amendments to the act. Subpart D of part 107—Nutrient Requirements was not affected by either the 1986 or 1990 amendments and is not being reconsidered under this review. In 1989, the agency responded to the provisions of the 1986 amendments on recalls by establishing subpart E in part 107—Infant Formula Recalls (54 FR 4006, January 27, 1989). To assist in the update of subparts B (Labeling) and C (Exempt Infant Formulas) of part 107, the agency requests comments on what matters need to be addressed.

Section 412(h)(1) of the act states that ''any infant formula which is represented and labeled for use by an infant—(A) who has an inborn error of metabolism or a low birth weight, or (B) who otherwise has an unusual medical or dietary problem, is exempt from the requirements of * * *'' section 412(a) (adulteration provisions of the act for failure to meet the nutrient requirements of the act, failure to meet the quality factor requirements, and failure to process the infant formula in compliance with the good manufacturing practices and quality control procedures), (b) (quality factors and good manufacturing requirements including quality control procedures), and (c) (registration, submission, and notification requirements). Section 412(h)(2) of the act provides that the Secretary of Health and Human Services (and by delegation FDA) may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of section 412(a), (b), and (c).

In 1980, the House Committee on Interstate and Foreign Commerce stated:

> The Committee recognizes the need to make special formulas available without the imposition of cumbersome regulations which may discourage formula manufacturers from committing resources into this vital public service. Conditions on exemptions promulgated under this authority should not make access to special formulas difficult. Instead, they should insure that such formulas are manufactured to the same high standards of quality required of formulas for normal infants. The Committee recognizes the importance of these products and the continued need to make them and new products like them, readily available to the public.

(H. Rept. 96–936, 96th Cong., 2d sess., 1980, p.10.)

The agency is soliciting comment on what terms and conditions should be set for the exemption of an infant formula from the requirements of section 412(a), (b), and (c) of the act.

In the past, FDA and infant formula manufacturers have disagreed on how to interpret section 412(h) of the act in light of the current regulations on exempt infant formula in § 107.50. One manufacturer stated that the statute and regulations do not envision a premarket designation or clearance for exempt formulas. Another manufacturer asserted that section 412(h)(1) of the act exempts these formulas from section 412(c) (registration and submissions), and that § 107.50(b)(4) only requires notification to FDA of any change in ingredients or processes that may result in an adverse impact on the levels of nutrients or on the availability of nutrients before the first processing of the infant formula. This manufacturer argued that, consequently, there is no requirement to give notice to the agency 90 days before marketing any exempt infant formula that has been changed in formulation or processing.

The agency has deep reservations about both of these industry assertions. The first would mean that infants who need an exempt formula, and who are by definition among the most vulnerable, would receive the least protection from the law. The second would raise significant questions about the agency's ability to carry out its mandate to ''insure that such formulas are manufactured to the same high standards of quality required of formulas for normal infants.'' The agency would be unable to do so unless it receives notification of ''major changes'' in exempt infant formula at least 90 days before the marketing of the changed formula. The agency requests comment on what terms and conditions should be set for the exemption of an infant formula from the requirements of section 412(c) of the act (registration and submissions).

Problems also have occurred in the regulation of infant formulas that meet the statutory definition of an exempt infant formula, i.e., formulas that are intended for infants who have an inborn error of metabolism or a low birth weight, or who otherwise have an unusual medical or dietary problem, but that do not need an exemption from any of the nutrient, quality factor, or good manufacturing requirements (including quality control procedures) of the act. In 1980, the House Committee on Interstate and Foreign Commerce stated that it recognized that infants suffering from special medical disorders, such as phenylketonuria, or severe kidney diseases, require formulas tailored specifically to their medical needs. The Committee recognized also the need to exempt these formulas from the nutritional standards applicable to formulas intended for normal, fullterm infants. (*Id*.)

However, infant formulas are now being developed that meet the nutritional standards applicable to formulas for normal, fullterm infants, i.e, the nutrient requirements of § 107.100, but that are for infants with low birth weight or with unusual medical or dietary problems. Thus, these formulas apparently are exempt infant formulas under section 412(h) of the act. The agency requests comment on what terms and conditions should be set for the exemption of an infant formula from the requirements of section 412(a) of the act. Should infant formulas that are intended for special populations of infants but that meet the nutrient requirements of the act be exempted from being deemed to be adulterated if they do not meet the same quality factor requirements or good manufacturing practices and quality control procedures that are required of infant formulas for normal, fullterm infants? Should infant formulas that meet the definition in the act for an ''exempt infant formula'' be exempted from meeting the quality factor and good manufacturing practice requirements when they are fully capable of meeting these requirements?

Current § 107.50(b)(3) requires the submission of the label and other labeling in the notification required to retain the exempt status of an infant formula. Current § 107.50(b)(3) further states that FDA will review the submitted information under § 107.50(d), and current § 107.50(d)(4) lists the criteria that FDA will use to determine whether a deviation from the requirements of subpart C of part 107 (Exempt Infant Formulas) is necessary and will adequately protect the public

health. One such criterion is whether a deviation from the labeling requirements of subpart B of part 107 is necessary because, without an exemption, the label information, including pictograms and symbols, could lead to inappropriate use of the infant formula (§ 107.50(d)(4)(iii)).

FDA has held that, for an exempt infant formula to be eligible to make label claims that deviate in any way from the requirements of subpart B of part 107, a firm must show that the labeling claims are necessary to ensure appropriate use of the product (§ 107.50(d)(4)(iii)), and that the public health will be adequately protected if these claims are made (§ 107.50(d)(4)). This showing must be made based on a persuasive medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies) (§ 107.50(b)(5)). The agency has held that failure to submit information that supports that an exemption is necessary to ensure the proper use of a formula, and failure to show that the public health will be adequately protected if such an exemption is continued, provide grounds for revoking the exempt status of a formula. Revoking the exempt status of a formula would mean that its label could not deviate in any way from the labeling requirements of subpart B of part 107, and thus it would not be able to bear the claims in question. The agency solicits comments on any changes that need to be made to § 107.50 (exempt infant formulas) to ensure that the labeling of these products will be consistent with the public health and will not lead to the inappropriate use of the product.

The agency also solicits comments on any changes to subpart B of part 107 (Labeling) that may be necessary to ensure that exempt infant formulas are labeled appropriately. Further, the agency solicits comments on any changes that it needs to make in the regulations governing the labeling of exempt infant formulas to ensure that the representations made for these products are truthful and not misleading. The 1990 amendments exclude exempt infant formulas from the requirements on nutrition labeling, nutrient content claims, and health claims (section 403(q)(5)(A)(iii) and (r)(5)(A) of the act). The regulations issued in response to the 1990 amendments reflect this fact (§ 101.9(j)(7) (nutrition labeling), § 101.13(q)(4) (nutrient content claims), and (§ 101.14(f)(1) (health claims)). The agency solicits comments on any changes that should be made to subpart B of part 107 (Labeling) to ensure that exempt infant formulas are labeled in a manner that will adequately protect the public health and that will ensure appropriate use of the product.

## VI. Food Additive Regulations

The agency has identified the following candidates for changes to make the regulations on food ingredients easier to understand and to consolidate certain existing regulations under a single listing to minimize redundancy.

### *A. Carrageenan, Carrageenan With Polysorbate 80, Salts of Carrageenan, Furcelleran, and Salts of Furcelleran*

In the Federal Register of October 6, 1961 (26 FR 9411 and 9412), FDA published final rules permitting the use of the food additives carrageenan, salts of carrageenan, furcelleran, and salts of furcelleran in food. The agency later published an additional final rule permitting the use of carrageenan processed with polysorbate 80 in food. The original food additive petitions requesting the use of carrageenan and furcelleran in food were submitted to FDA by competing producers of these two additives. Thus, the agency issued separate regulations for these additives even though there are similarities in the structure and functionality of carrageenan and furcelleran. It may now be appropriate to combine the regulations on carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, and carrageenan with polysorbate 80 into a single regulation.

Carrageenan and furcelleran are refined hydrocolloids that are produced by extraction of certain species of red seaweed in aqueous alkali, and they are regulated for use as emulsifiers, thickeners, and stabilizers in food under §§ 172.620 and 172.660 (21 CFR 172.620 and 172.660). The functional properties of carrageenan derive from the sulfated polysaccharide that is the major component of the additive. This polysaccharide is composed of galactose and anhydrogalactose hexose units.

The primary difference between carrageenan as regulated under § 172.620 and furcelleran as regulated under § 172.660 is the degree of sulfation of the hexose units composing the polysaccharide. Furcelleran has a sulfate range of 8 to 19 percent on a dry weight basis, while carrageenan may have a sulfate content of between 20 and 40 weight percent. The degree of sulfation of the additive is believed to be the determining factor regarding the additive's ability to bind to proteins and thus determines the additive's functionality in certain food applications, including dairy applications. In addition, the functionality of the carrageenan complying with § 172.620 is known to vary with the seaweed species used to produce the additive and with the dominant cation in aqueous solutions of the additive. This variation reflects the level of three principal polysaccharide types in commercial carrageenan. These are known as kappa, iota, and lambda carrageenan and differ in the number and location of the sulfate groups on the hexose units.

In commerce, carrageenan may consist of a relatively pure form of one of the three polysaccharides or a mixture of kappa, lambda, and iota polysaccharides along with cellulosic material, protein, and inorganic salts. The relative amounts of polysaccharides can vary naturally based on their content in the native seaweed, or carrageenan can be formulated from relatively pure kappa, lambda, and iota carrageenan either by processing or by seaweed choice. The ability to produce carrageenan consisting of relatively pure forms of one or the other of the polysaccharides facilitates the production of carrageenans with a wide variation in properties. Thus, the industry is able to develop carrageenans with specific properties for specific applications in food.

The only distinguishing characteristics that FDA incorporated into the regulations for furcelleran and carrageenan were a limitation on the degree of sulfation for the polysaccharide that is the functional component of each additive and a listing of the different seaweed sources of the additives. The differing specifications (sulfate content and seaweed source) incorporated into the regulations for carrageenan and furcelleran were included solely to differentiate between these two similar additives. There is no safety concern regarding the sulfate content of the respective additives. Given this fact, there is no reason to distinguish between the additives on the basis of sulfate content, and no reason why the sulfate specifications for the two additives could not be combined in one regulation.

The first detailed specifications that FDA adopted for furcelleran and carrageenan were the specifications included in the first edition of the Food Chemicals Codex (FCC). The specifications for furcelleran in the first edition of the FCC were identical to those for carrageenan except for the percent sulfate content of the additive and the listed seaweed sources. Subsequent editions of the FCC did not include a separate specification for

furcelleran, in part because the additive was so similar to carrageenan that it was generally considered as a form of carrageenan, and in part because the total use level of furcelleran was only a fraction of the use level of carrageenan. Indeed, the current specification for carrageenan adopted by the Food and Agriculture Organization/World Health Organization Joint Expert Committee on Food Additives (JECFA) includes the additive regulated in the United States as furcelleran. Therefore, inclusion of furcelleran under the U.S. regulation for carrageenan would be a step toward harmonizing U.S. regulations with the JECFA specification recognized internationally.

When FDA issued separate regulations for salts of carrageenan and salts of furcelleran, the agency was primarily concerned about the possibility of economic deception resulting from an artificial increase of one or more of the inorganic salts that are typically components of these additives. In addition, the agency's concern in issuing a separate regulation for carrageenan with polysorbate 80 was to ensure that carrageenan processed with polysorbate 80 would be properly labeled. At the time the regulations for carrageenan, furcelleran, salts of carrageenan, salts of furcelleran, and carrageenan with polysorbate 80 were issued, the chemistry of carrageenan and of furcelleran was well known. At that time, it was known that the addition of salts containing one or another cation would alter significantly the gelation properties of given forms of the additive.

The level of sophistication with which carrageenan and carrageenan-like substances such as furcelleran are developed, marketed, and used reflects a high degree of understanding in the industry regarding the identity and functionality when used in food. Therefore, it may well be advantageous to simplify the regulation of salts of carrageenan, furcelleran, salts of furcelleran, and carrageenan with polysorbate 80 by eliminating the separate regulations for these substances and by providing for all of them to be marketed as carrageenan. The agency is specifically soliciting comments regarding whether such a change should be made, and, if so, what changes to existing specifications, and what additional specifications, may be required in a regulation to permit the combining of referenced regulations.

*B. Use of Metals in Contact With Food*

FDA is considering publishing a proposal to list, in 21 CFR part 182, certain metals as generally recognized as safe (GRAS) for use in contact with food. In addition, FDA is considering ways to make publicly available those uses of metals that have been the subject of a favorable opinion letter issued by agency employees because of the insignificant potential for the metals to migrate into food.

Historically, the use of metals as components of food-contact articles has generally resulted in low dietary exposure. The chemical inertness and hardness of many metals is such that there is little or no likelihood that the metal will migrate to food in other than insignificant amounts. In addition, because metals are typically used in the manufacture of repeat-use articles, the concentration of any migrant would be extremely low because of the large volume of food processed.

While FDA employees have issued opinion letters over the past three decades on the agency's lack of safety concern about the low exposure from such uses of metals, this information has not been made publicly available in any sort of systematic and widespread way. As a result, the agency continues to receive inquiries on the same metals that have been previously found to be acceptable for use in contact with food, either because their use is GRAS, or because the potential for them to migrate to food is insignificant.

To help alleviate this situation, the agency is considering whether to list in part 182 those metals that FDA has stated in opinion letters are GRAS for use as indirect food additives. FDA has reviewed its files and is aware of opinion letters stating that the following metals are GRAS for use in contact with food: Aluminum and aluminum foil; stainless steel (grades 302, 303, 304, 304F, 316, 321); 416 and 440C stainless steel for use as a ring on filter bags; tin plate; and iron for food contact use in breweries.

The agency is interested in information on whether other metals are GRAS when used in contact with food and the basis for such a finding.

In addition to the metals listed above, the agency is aware of opinion letters that have been written by agency employees on various metals agreeing that their use as a component of food-contact articles would not require a food additive petition or regulation because of an insignificant potential for migration to food. FDA has considered that, in some cases, the composition of some of the metal alloys that have been the subject of such letters may be confidential information. The agency is interested in comments on what procedures for making such letters publicly available would be most effective as well as in information that would help it to determine whether data in such letters, such as the composition of alloys, are confidential, and thus not releasable, or are common information that can be made public.

FDA invites public comment on all of these matters.

VII. Interstate Conveyance Sanitation (21 CFR Part 1250)

FDA regulates the construction and operation of conveyances (trains, planes, buses, and vessels) in interstate traffic under parts 1240 and 1250 (21 CFR parts 1240 and 1250) of its regulations. These regulations cover environmental health and food safety requirements for the conveyances themselves, including their water and waste systems. They also cover the conveyance servicing areas and vehicles used for boarding drinking water and food and for offloading wastes.

In § 1250.93, FDA focuses on vessels operating in fresh water lakes and rivers and specifically prohibits the discharge of sewage and ballast or bilge water within areas adjacent to domestic water intakes.

*C. Concerns*

1. FDA regulates vessels in interstate traffic that operate in both fresh and salt waters.

2. These vessels generate several waste streams involving both liquid and solid wastes. Improper disposal of some of these wastes have important public health implications beyond the possible contamination of public drinking water supplies addressed by the existing regulation. One example is the possible contamination of molluscan shellfish growing and harvesting areas, which is of concern because shellfish are often consumed raw.

3. The National Research Council's Marine Board and its Committee on Shipborne Wastes, on September 6, 1995, released a new report entitled ''Clean Ships, Clean Ports, Clean Oceans: Controlling Garbage and Plastic Wastes at Sea.'' The report concludes that U.S. activities to implement the provisions of the International Convention for the Prevention of Pollution from Ships (1973) and its 1978 protocol are far from complete and effective.

The report recommends interagency cooperation among relevant Federal agencies to promote a systems approach to enhance total management and control of vessel wastes in nine specific maritime sectors. One of these sectors is passenger day boats, casino ships, and ferries, over which FDA has regulatory

responsibility under the Public Health Service Act.

Lead Federal agencies in the matter of controlling shipborne wastes include the U. S. Coast Guard and the Environmental Protection Agency. Other Federal agencies involved include the Department of State, the National Oceanic and Atmospheric Administration and its National Marine Fisheries Service, the United States Department of Agriculture's Animal and Plant Health Inspection Service, and the Maritime Administration.

*D. Request for Information*

FDA is considering proposing to revise § 1250.93 of the Interstate Travel Sanitation regulations to prohibit discharges that would pollute salt water and shellfish growing areas as well as fresh water. Other agency objectives include harmonizing FDA's vessel waste control requirements with those of other Federal agencies and contributing to meeting U. S. obligations under ratified international agreements. FDA requests information on what changes could be made to § 1250.93 to assist the agency in establishing standards for discharges of waste from passenger boats, casino ships, and ferries. The agency requests information on the effects that any suggested changes would have on the waste discharge practices of affected vessels.

VIII. Comments

Interested persons may, on or before September 10, 1996, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. 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.

Dated: May 31, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 96–14888 Filed 6–7–96; 12:17 pm]

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**21 CFR Parts 101 and 730**

**[Docket No. 96N–0174]**

**RIN 0910–AA69**

## Food and Cosmetic Labeling; Revocation of Certain Regulations; Opportunity for Public Comment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revoke certain regulations that appear to be obsolete. These regulations have been identified for revocation as a result of a page-by-page review of the agency's regulations that FDA conducted in response to the Clinton administration's ''Reinventing Government'' initiative, which seeks to streamline Government to ease the burden on regulated industry and consumers. The agency is providing an opportunity for comments on this proposed rule.

**DATES:** Written comments by August 26, 1996. The agency is proposing that any final rule that may issue based upon this proposal become effective 75 days following date of publication of the final rule.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Corinne L. Howley, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–205–4272.

**SUPPLEMENTARY INFORMATION:**

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the administration's ''Reinventing Government'' initiative. In his March 4, 1995, directive, the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations to ''eliminate or revise those that are outdated or otherwise in need of reform.''

In response to this directive, FDA issued proposals to revoke a number of regulations (see, e.g., 60 FR 53480, October 13, 1995; 60 FR 56513 and 56541, November 9, 1995) and an advance notice of proposed rulemaking (ANPRM) to review standards of identity, quality, and fill of container (60 FR 67492, December 29, 1995). The agency has completed its review of its food and cosmetic regulations in response to the President's initiative and as a result is publishing two documents in this issue of the Federal Register. This document announces additional regulations that FDA is proposing to eliminate or revise, and the second document is an ANPRM that seeks information on other food and cosmetic regulations that appear to be in need of revision.

II. The Proposal

*A. Food Labeling Regulations*

FDA has identified several food labeling regulations in part 101 (21 CFR part 101) as candidates for revocation or revision and is seeking comments from interested parties regarding its tentative conclusions on these matters. The following is a list of those regulations and the agency's tentative conclusions concerning the needed changes:

1. Section 101.2 Information panel of package form food

In § 101.2, paragraph (a) defines the term ''information panel'' as it applies to packaged food, and in paragraph (b), the regulation provides that all information required to appear on the label of any package of food under certain referenced regulations appear either on the principal display panel or on the information panel unless otherwise specified in the regulations. The referenced regulations are: § 101.4 *Food; designation of ingredients*, § 101.5 *Food; name and place of business of manufacturer, packer, or distributor)*, § 101.8 *Labeling of food with number of servings*, § 101.9 *Nutrition labeling of food*, § 101.12 *Reference amounts customarily consumed per eating occasion*, § 101.13 *Nutrient content claims general principles*, § 101.17 *Food labeling warning and notice statements*, Part 101—Subpart D—Specific requirements for nutrient content claims, and Part 105—Foods for special dietary use (21 CFR 105). Paragraph (c) of § 101.2 requires that information required by the referenced regulations be in letters or numbers of at least one-sixteenth inch in height, unless otherwise exempted by regulation. Paragraph (c) of § 101.2 also provides exemptions to this type size requirement. FDA tentatively concludes that certain of these exemptions are obsolete.

*a. Exemptions for small packages*

There are exemptions in paragraphs (c)(1) through (c)(3) of § 101.2 for small packages (defined according to the surface area available to bear labeling). These exemptions were established before the enactment of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). They were designed to encourage firms to provide nutrition information in accordance with § 101.9, as well as a full list of ingredients in accordance with the regulations in § 101.4 and the agency's policy regarding declaration of ingredients on standardized foods as set out in § 101.6 (see 39 FR 15268, May 2, 1974). Before the enactment of the 1990