administrative changes were initiated by the Department of the Air Force to reflect its reorganization. Because this action is a minor technical amendment in which the public is not particularly interested, I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Section 73.25 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8A dated March 3, 1993.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This action is an administrative change and does not affect the boundaries, altitudes, times of use, or activities of the restricted areas. Accordingly, this action will have no effect on current air traffic procedures or routing of civil aircraft operations in the area. The FAA, therefore, finds that there will be no significant impact on the environment as a result of this action.

List of Subjects in 14 CFR Part 73

Aviation safety, Navigation (Air).

Adoption of the Amendment

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

PART 73—[AMENDED]

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

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510, 1522; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 73.25 [Amended]

2. Section 73.25 is amended as follows:

R–2516 Naval Missile Facility Point Arguello, CA—[Amended]

By removing the title "R–2516 Naval Missile Facility Point Arguello, CA," and substituting "R–2516 Vandenberg AFB, CA," and by removing the present controlling agency and using agency and substituting the following:

"Controlling agency. FAA, Los Angeles ARTCC. Using agency. U.S. Air Force, Commander, 30th Space Wing (30 SPW/CC), Vandenberg AFB, CA."

R–2534A Point Arguello, CA—[Amended]

By removing the title "R–2534A Point Arguello, CA" and substituting "R–2534A Vandenberg AFB, CA."

R–2534B Point Arguello, CA—[Amended]

By removing the title "R–2534B Point Arguello, CA," and substituting "R–2534B Vandenberg AFB, CA."

Issued in Washington, DC, on May 11, 1993.

Willis C. Nelson,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 93–12068 Filed 5–20–93; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 163

[Docket No. 86P–0297]

Cacao Products; Amendment of the Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend the standards of identity for certain cacao products. The amendments will: Provide for the use of safe and suitable nutritive carbohydrate sweeteners, neutralizing agents, and emulsifiers in these products; revise the current milkfat content requirements for milk chocolate, buttermilk chocolate, skim milk chocolate, and mixed dairy product chocolates; eliminate the current nonfat milk solids-to-milkfat ratio for certain cacao products; and revise the standards for coatings. The final rule will also update the language and format of the standards. The amendments will promote honesty and fair dealing in the interest of consumers and, to the extent practicable, will achieve consistency with the Codex Alimentarius Commission (the Codex) International Standards for Chocolate and for Cocoa Powders (Cocoas) and Dry Cocoa—Sugar Mixtures.

DATES: July 20, 1993, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 163.5, effective July 20, 1993.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5106.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 5, 1992 (57 FR 23989), FDA published a tentative final rule to amend the standards of identity for cacao products in part 163 (21 CFR part 163). This tentative final rule addressed comments received in response to a proposed rule on the cacao product standards that was published in the **Federal Register** of January 25, 1989 (54 FR 3615), and that responded to a citizen petition submitted by the Chocolate Manufacturers Association of the United States of America (CMA).

This rulemaking, based on the CMA petition, was initiated under authority of section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)) which required formal rulemaking in any action for the issuance, amendment, or repeal of a food standard. However, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535), enacted November 8, 1990, removed rulemakings on food standards (except for actions for the amendment or repeal of food standards of identity for dairy products or maple sirup) from the coverage of 21 U.S.C. 371(e). To ensure that no one was prejudiced by this change in procedure, and to ensure that FDA was apprised of all relevant concerns before deciding on a final rule, the agency prepared the June 5, 1992, document as a tentative final rule. In addition, during the time between the proposed rule and the tentative final rule, a number of issues were raised that were outside the scope of the original proposal. Therefore, FDA divided the June 5, 1992, tentative final rule into two sections: Section II.A. *Tentative Final Rule*; and section II.B. *Issues for Future Rulemaking*. (FDA published a notice in the **Federal Register** (57 FR 54195, November 17, 1992) announcing that it was reopening until May 17, 1993, the comment period for those issues in section II.B. of the tentative final rule.)

The agency announced that it intended to issue a final rule on section

II.A. of the June 5, 1992, tentative final rule as expeditiously as possible. Interested persons were given until July 6, 1992, to comment on section II.A. The agency received 11 letters, each containing one or more comments, from trade associations, chocolate manufacturers, and ingredient suppliers. Most comments supported the proposed amendments and urged FDA to proceed to a final rule on the issues in section II.A. as quickly as possible. Several comments requested further clarification of certain issues (e.g., whether certain ingredients would be nutritive carbohydrate sweeteners) or suggested modification of various provisions of the tentative final rule to amend the standards for cacao products. A summary of the specific comments and the agency's responses follow.

II. Sweeteners

In the June 5, 1992, tentative final rule, FDA proposed to amend the standards of identity for certain cacao products to include the functional group designation "nutritive carbohydrate sweeteners" rather than listing specific permitted sweeteners. To minimize possible confusion, the agency included in the preamble of that rule a discussion of the characteristics that, when used collectively, describe the class of sweeteners commonly known as "nutritive carbohydrate sweeteners." In its discussion, FDA stated that nutritive carbohydrate sweeteners: (1) Are relatively low molecular weight saccharides; (2) can be metabolized (i.e., have greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity); and (3) have sufficient sweetening power to function as sweeteners. FDA also stated that, under the proposed amendment, these sweeteners would have to be "safe and suitable."

In addition, the agency responded to comments requesting clarification on whether certain ingredients would be considered nutritive carbohydrate sweeteners. In its discussion, FDA stated that maltodextrin, which is defined in § 184.1444 (21 CFR 184.1444) as a "nonsweet nutritive saccharide polymer," is not a sweetener for the purpose of these standards. FDA also stated that the comments did not provide sufficient information concerning the nature of fruit juice concentrate and maltodextrin or dextrin mixtures to justify consideration of these combinations of ingredients as nutritive carbohydrate sweeteners that are suitable for use in the manufacture of cacao products.

1. One comment argued that "nutritive carbohydrate sweeteners" should not necessarily consist only of low molecular weight saccharide components. The comment cited the agency's position (57 FR 23989 at 23991) that glucose sirup (defined in § 168.120 (21 CFR 168.120)) as the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch) is a nutritive carbohydrate sweetener. The comment also noted that the listing of nutritive carbohydrate sweeteners approved by the Codex and tentatively approved by FDA for use in cacao products is not limited to pure saccharides. The comment maintained that the Codex list includes foods such as honey, glucose sirup, and dried glucose sirup that, like fruit juice concentrate, contain nonsaccharide components. The comment conceded that some concentrated flavor and acid components of certain sweeteners may be too strong or unpleasant to meet with consumer acceptance and, thus, would not be suitable for use in cacao products. However, the comment maintained that the presence of fruit flavors, acids, and fruit juice solids should not, by itself, make a sweetener unsuitable for use in chocolate confections. The comment further stated that some fruit juice concentrates, such as apple juice and white grape juice concentrate, are very bland and are naturally low in acid and nonsaccharide fruit juice solids.

FDA agrees that nutritive carbohydrate sweeteners may contain other components in addition to low molecular weight saccharides. FDA notes that because the saccharides in some nutritive carbohydrate sweeteners are produced from the partial hydrolysis of edible starch, the nutritive carbohydrate sweeteners also contain other components in addition to low molecular weight saccharides. Of course these sweeteners must still have significant sweetness. In glucose sirup, the extent of hydrolysis controls the ratio of low-to-high molecular weight saccharides. Varying the extent of hydrolysis or degree of conversion of starch to sugars affects the characteristics (e.g., sweetness and viscosity) of the product. However, § 168.120(b)(1) requires that glucose sirup contain sufficient low molecular weight saccharides (i.e., not less than 20 percent dextrose equivalent) to ensure sufficient sweetening properties for the ingredient to be considered a sweetener. The higher molecular weight saccharides present in glucose sirup are bland in flavor and are a naturally occurring component of the food. As such, their presence does not preclude the use of glucose sirup as a nutritive carbohydrate sweetener.

FDA noted in the tentative final rule (57 FR 23989 at 23992) that products such as "decolorized, decharacterized grape juice concentrates," which are essentially concentrated solutions of sugars from fruit, are nutritive carbohydrate sweeteners.

Based on the argument supplied by the comment, the agency has further considered the use of fruit juice concentrate-based sweeteners in cacao products. FDA has concluded that to be consistent with its treatment of other nutritive carbohydrate sweeteners that contain higher molecular weight saccharide or nonsaccharide components, the presence of naturally occurring fruit flavors, acids, and fruit solids should not preclude the use of fruit juice concentrates as nutritive carbohydrate sweeteners in cacao products. Therefore, FDA agrees with the comment that fruit juice concentrates, such as apple juice and white grape juice concentrate, would be nutritive carbohydrate sweeteners, suitable for use in certain cacao products.

2. Another comment pointed out that maltodextrin, dextrins, or rice syrup solids are added to fruit juice concentrate-based sweeteners as a carrier or drying aid for the fruit juice concentrate. The comment stated that addition of these substances was necessary to achieve certain physical properties in the sweetener that are required by virtue of the manufacturing process for sweetened cacao products. The comment maintained that because fruit juice concentrate and rice syrup solids are both nutritive carbohydrate sweeteners, a mixture of these ingredients would also be a nutritive carbohydrate sweetener. The comment urged FDA to proceed with final rulemaking for cacao standards and to defer for later consideration the issue of fruit juice concentrate-based sweeteners that contain maltodextrin or dextrin mixtures.

FDA generally agrees with the comment. FDA stated in the tentative final rule (57 FR 23989 at 23992) that rice syrup solids are nutritive carbohydrate sweeteners. Thus, a mixture of fruit juice concentrate and rice syrup solids would also be a nutritive carbohydrate sweetener and may be suitable for use in cacao products. However, except for the standards for chocolate coatings made with vegetable fat, §§ 163.150, 163.153, and 163.155, which provide for the use of safe and suitable bulking agents and formulation aids, there is no provision

for the use of maltodextrin or dextrin in standardized cacao products.

Although FDA has been persuaded by the preceding comment that nutritive carbohydrate sweeteners do not necessarily consist solely of low molecular weight saccharide components, the agency notes that the other components of such sweeteners (e.g., higher molecular weight saccharides in glucose syrup) are naturally occurring constituents of the food and do not negate or detract from the ability of the food to function as a nutritive carbohydrate sweetener.

FDA advises that the naturally occurring nonsaccharide components of an ingredient that has a long history of use as a nutritive carbohydrate sweetener are not the same as a nonsaccharide component in an ingredient that is a blend of a nutritive carbohydrate sweetener and a nonsaccharide. FDA lacks sufficient information to conclude that a sweetener that is a blend of a nutritive carbohydrate sweetener and an ingredient that is not a nutritive carbohydrate sweetener would still be a nutritive carbohydrate sweetener. Because this rulemaking is concerned with whether to expand the provisions in part 163 to provide for the use of nutritive carbohydrate sweeteners in cacao products, considering whether fruit juice concentrate-based sweeteners containing maltodextrin or dextrins would be suitable for use in cacao products is outside the scope of this rulemaking.

However, as stated in section II.B. *Issues for Future Rulemaking* of the tentative final rule (57 FR 23989 at 23996), FDA recognizes that various forms of new sweetening ingredients will become available with advances in food technology and changes in consumer expectations. FDA advised that should it receive comments (or a petition) that support further broadening the provision for the use of safe and suitable sweeteners in cacao products, this action would be addressed in a future rulemaking. The agency intends to consider the request to use fruit juice concentrate-based sweeteners containing maltodextrin or dextrins to sweeten standardized cacao products in any future rulemaking addressing whether it would be desirable to further broaden the provision for the use of sweeteners in cacao products to provide for "safe and suitable sweeteners" rather than "safe and suitable nutritive carbohydrate sweeteners."

3. Another comment stated that based on their composition and metabolism, polyols should be considered "nutritive carbohydrate sweeteners." However, the comment did not offer any information to support its position. Conversely, the comment maintained that if FDA concludes that polyols are not suitable for use as sweeteners in cacao products, it should characterize the acceptable sweeteners as "safe and suitable saccharides" or "safe and suitable sugars" rather than "nutritive carbohydrate sweeteners" to further emphasize the distinction drawn in the tentative final rule between "saccharides," i.e., sugars, and other sweeteners. The comment argued that continued use of the phrase "nutritive carbohydrate sweeteners" in a way that excludes polyols could result in excluding the appropriate use of polyols in many foods. Finally, the comment urged that FDA "recognize that polyols are not 'sugars' so that a properly limited 'sugar free' claim would be appropriate for polyol-sweetened foods."

FDA disagrees with the comment that polyols, also known as polyhydric alcohols or sugar alcohols, are nutritive carbohydrate sweeteners. As stated in the tentative final rule (57 FR 23989 at 23991) and repeated in this preamble, one of the characteristics that collectively describes the class of sweeteners commonly known as "nutritive carbohydrate sweeteners" is that they are relatively low molecular weight saccharides. Based on the first comment discussed in this section, FDA has modified its definition of "nutritive carbohydrate sweeteners" to reflect that some of the sweeteners commonly recognized as nutritive carbohydrate sweeteners do not consist solely of low molecular weight saccharides but may also contain naturally occurring nonsaccharide constituents. However, it is the saccharide component of such sweeteners that traditionally has resulted in their inclusion in the class of sweeteners known as "nutritive carbohydrate sweeteners."

As noted in the tentative final rule (57 FR 23989 at 23992), polyols such as sorbitol (§ 184.1835 (21 CFR 184.1835)) and xylitol (§ 172.395 (21 CFR 172.395)) are usually used as sweeteners in foods for special dietary use. They also provide other technical functions that may be beneficial in chocolate-containing confections. However, as polyhydric alcohols, these ingredients are not saccharides. Further, the polyol sorbitol is defined in § 184.1835 as a "nutritive sweetener," not as a nutritive carbohydrate sweetener.

Because polyols are not nutritive carbohydrate sweeteners, and this rulemaking is concerned with whether to expand the provisions in part 163 to provide for the use of nutritive carbohydrate sweeteners, whether polyols are safe and suitable for use in cacao products is outside the concerns of this rulemaking. The issue of whether polyols are suitable to sweeten standardized cacao products is a subject for a future rulemaking, e.g., whether it would be appropriate to further broaden the provision for the use of sweeteners in cacao products to read "safe and suitable sweeteners" or "safe and suitable nutritive sweeteners" rather than "safe and suitable nutritive carbohydrate sweeteners," as stated in section II.B. *Issues for Future Rulemaking* of the tentative final rule.

FDA also disagrees with the suggestion that it should redesignate the optional sweeteners in cacao standards as "sugars" or "saccharides." FDA proposed to replace the specified optional saccharine ingredients in the cacao standards with the functional group designation "nutritive carbohydrate sweeteners" to provide greater flexibility in the choice of sweeteners that can be used in cacao products and to reduce the need to amend the cacao products standards as other safe and suitable nutritive carbohydrate sweeteners are developed. The action requested by this comment, however, would limit the choice of sweeteners, not expand it, because many nutritive carbohydrate sweeteners (e.g., fruit juice concentrates) are not exclusively composed of saccharides and thus could not be used.

The agency notes that the phrase "nutritive carbohydrate sweeteners" is used extensively in both the scientific literature and in existing FDA standards of identity to refer to the class of sweeteners in question. The phrase is also consistent with Codex provisions for the use of "suitable carbohydrate sweeteners" in cacao products. Therefore, the agency believes that it would be inappropriate, and potentially confusing, to adopt different terminology.

With respect to the use of a "sugar free" claim for polyol-sweetened foods, in a final rule on nutrition labeling (58 FR 2079, January 6, 1993), FDA defined "sugars" as "the sum of all mono- and disaccharides (such as glucose, fructose, lactose, and sucrose)." This definition is set forth in 21 CFR 101.9(c)(6)(ii). In the nutrition labeling final rule (58 FR 2079 at 2099), FDA stated that sugar alcohols are not sugars, that they have many chemical and physiological properties that are different from sugars, and that it is these differences that make them useful as sugar substitutes.

In its final rule on nutrient content claims (58 FR 2302, January 6, 1993),

FDA established § 101.60(c)(1) (21 CFR 101.60(c)(1)), which provides for the use of the term "sugar free" on foods that contain less than 0.5 grams (g) of sugars as defined in § 101.9(c)(6)(ii) per serving. Thus, a food containing sugar alcohols may bear a "sugar free" claim as long as it meets the requirements in § 101.60(c)(1) for "sugar free" and in § 101.9(c)(6)(iii) that sugar alcohol content be disclosed.

4. One comment asserted that the standards for cacao products should be amended to permit the use of any safe and suitable sweetener. The comment stated that this change would allow consumers to select products sweetened with a variety of sweeteners without the confusion of using a nonstandardized or fanciful name. The comment further stated that an appropriate name for such products would be, e.g., "chocolate, sweetened with aspartame."

In the tentative final rule (57 FR 23989 at 23996), FDA advised that should it receive substantive comments (or a petition) supporting action to further broaden the provisions for the use of safe and suitable sweeteners in cacao products, it would consider initiating a separate rulemaking. The agency is limiting this rulemaking to considering whether to provide for the use of nutritive carbohydrate sweeteners in cacao products. Thus, the comment is outside the scope of this rulemaking. The agency has noted the comment and filed it with other letters responding to section II.B. *Issues for Future Rulemaking* of the tentative final rule.

FDA has fully considered the comments and concluded that amending the cacao standards to provide for the use of safe and suitable nutritive carbohydrate sweeteners will provide greater flexibility in the choice of sweeteners in cacao products and will minimize the need to amend the standards as other nutritive carbohydrate sweeteners are found to be safe and suitable for use in these foods.

Accordingly, FDA is amending the standards of identity for sweet chocolate in § 163.123(a)(1) and (b)(2), milk chocolate in § 163.130(a)(1) and (b)(2), and, by cross-reference, the standards of identity for buttermilk chocolate (§ 163.135), skim milk chocolate (§ 163.140), mixed dairy product chocolates (§ 163.145), sweet cocoa and vegetable fat coating (§ 163.150), sweet chocolate and vegetable fat coating (§ 163.153), and milk chocolate and vegetable fat coating (§ 163.155), to provide for the use of nutritive carbohydrate sweeteners, as proposed.

III. Milkfat Content, Milk Solids Content, and Nonfat Milk Solids-to-Milkfat Ratio

5. In the June 5, 1992, tentative final rule, FDA tentatively concluded that it is reasonable to reduce the minimum milkfat content requirement for milk chocolate in § 163.130 so that the proportional milkfat content in milk chocolate is not less than that of milk under the standard of identity for that food in § 131.110 (21 CFR 131.110). The agency also proposed to reduce the maximum milkfat content requirements in buttermilk chocolate (§ 163.135) and skim milk chocolate (§ 163.140), and to reflect these changes in the standard for mixed dairy product chocolates (§ 163.145). In addition, FDA proposed to remove the nonfat milk solids-to-milkfat ratio requirement in the standard of identity for milk chocolate (§ 163.130).

The agency did not receive any comments opposed to these proposed actions. Therefore, FDA is amending § 163.130(a)(2) to reduce the minimum milkfat content requirement in milk chocolate from 3.66 percent to 3.39 percent. The agency is also reducing the maximum milkfat content requirement in buttermilk chocolate (§ 163.135) and skim milk chocolate (§ 163.140) from 3.66 percent to 3.39 percent and amending the standard for mixed dairy product chocolates in § 163.145(a)(2) to reflect these changes. In addition, FDA is removing the nonfat milk solids-to-milkfat ratio requirement in the standard of identity for milk chocolate (§ 163.130), as proposed.

IV. Safe and Suitable Ingredients in Coatings Made With Vegetable Fat

6. In the June 5, 1992, tentative final rule, FDA proposed to expand the provisions for the use of safe and suitable ingredients in coatings made with vegetable fat (§§ 163.150, 163.153, and 163.155) to include dairy-derived ingredients, bulking agents, formulation aids, humectants, and texturizers. There were no objections to this proposed action. Therefore, FDA is amending §§ 163.150, 163.153, and 163.155 to provide for the use of safe and suitable dairy-derived ingredients, bulking agents, formulation aids, humectants, and texturizers as proposed. This action will provide manufacturers with increased flexibility and provide consumers with a wider range of product choices.

V. Calculating Milk Solids Content Requirements in Cacao Products

In its discussion of the use of dairy-derived ingredients in coatings made with vegetable fat (57 FR 23989 at 23995), FDA noted that the minimum requirements for total milk solids in the existing standards for milk chocolate (§ 163.130) and, by cross-reference, milk chocolate and vegetable fat (other than cacao fat) coating (§ 163.155) ensure that these products contain the level of dairy flavor that consumers expect in milk chocolate. Conversely, the agency also noted that the sweet chocolate (§ 163.123) and sweet chocolate and vegetable fat (other than cacao fat) coating (§ 163.153) standards contain maximum milk solids content requirements that limit the dairy flavor of these foods and thus distinguish them from milk chocolate and from coatings made with milk chocolate and vegetable fat. Given the distinction that the regulations draw, the agency tentatively concluded that it would be inappropriate to include dairy-derived ingredients, such as whey or lactose, that do not significantly contribute to the dairy character of the food in determining whether a food complies with minimum or maximum milk solids content requirements.

Consequently, FDA proposed to add new language to the standards for sweet chocolate and vegetable fat coating (§ 163.153) and milk chocolate and vegetable fat coating (§ 163.155) (57 FR 23989 at 23996) specifying that compliance with the total milk solids content requirements in §§ 163.123(a)(2) and 163.130(a)(2) is to be calculated using only those diary ingredients referred to in §§ 163.123(b)(4) and 163.130(b)(4).

7. One comment noted that the proposed standards for sweet chocolate (§ 163.123), milk chocolate (§ 163.130), buttermilk chocolate (§ 163.135), skim milk chocolate (§ 163.140), and mixed dairy product chocolates (§ 163.145) do not include the limitation restricting calculation of milk solids content of cacao products to specified optional dairy ingredients. The comment stated that because the proposal provided for lactose to be added to standardized cacao products as a nutritive carbohydrate sweetener, and because lactose is a milk solid, the agency should clarify that the limitation also applies to the calculation of milk solids in §§ 163.123, 163.130, 163.135, 163.140, and 163.145. A second comment agreed that when lactose is added as a nutritive carbohydrate sweetener in cacao products, it should not be counted towards the milk solids content requirements of the standards.

The agency agrees with the comments that limiting the dairy ingredients used in calculating the total milk solids content of standardized cacao products

to those that are specified in §§ 163.123(b)(4) and 163.130(b)(4) will ensure that these products contain the level of dairy flavor that consumers expect from each product. Although this position was implied in the preamble of the tentative final rule (57 FR 23989 at 23995), it was only explicitly set out in proposed §§ 163.153 and 163.155. As stated in the tentative final rule, FDA tentatively concluded that it would be inappropriate to include dairy-derived ingredients that do not contribute to the dairy character of the food in determining whether a food complies with the milk solids content requirement. Because FDA is amending the cacao products standards to provide for the use of nutritive carbohydrate sweeteners, including lactose, it is necessary to include the limitation restricting calculation of milk solids content to specified dairy ingredients in these standards.

Therefore, FDA is adding new language to §§ 163.153(a) and 163.155(a) to limit the calculation of the total milk solids content requirements to those dairy ingredients listed in §§ 163.123(b)(4) and 163.130(b)(4), as proposed. FDA is also amending §§ 163.123, 163.130, 163.135, 163.140, and 163.145 to expressly limit the ingredients that are to be included in determining whether a product satisfies the total milk solids content requirements to those ingredients that are specified as optional dairy ingredients in the respective standards.

FDA notes that several of the standards in part 131 (21 CFR part 131) for milk and cream products that are optional dairy ingredients in standardized cacao products (e.g., sweetened condensed milk (§ 131.120), sweetened condensed skimmed milk (§ 131.122), and nonfat dry milk (§ 131.125)) provide for the use of nutritive carbohydrate sweeteners, including lactose. Furthermore, several standards in part 131 (e.g., skim milk (§ 131.143) and lowfat milk (§ 131.135)) provide for the addition of optional dairy or dairy-derived ingredients, including lactose and whey, to increase the nonfat solids content of the food. These standards provide that the ratio of protein to total nonfat solids in the food, and the protein efficiency ratio of all proteins present, shall not be decreased as a result of adding such ingredients. Therefore, the amount of the dairy-derived ingredients that can be added to increase the total solids content of the dairy products in part 131 is limited.

However, according to § 131.120(a), sweetened condensed milk must contain a sufficient quantity of nutritive carbohydrate sweetener to prevent spoilage. Products typically contain 40 to 45 percent by weight nutritive carbohydrate sweetener. Thus, a dairy product such as sweetened condensed milk sweetened with lactose could contain a significant amount of a dairy-derived ingredient (i.e., the added lactose) that would not significantly contribute to the dairy character of the product or to the dairy character of any food in which the lactose sweetened condensed milk was used as an ingredient.

FDA stated (57 FR 23989 at 23995) that dairy-derived ingredients, such as lactose and whey, that do not contribute to the dairy character of a food should not be included in determining whether a food meets the milk solids content requirements of the standards. While the discussion in the tentative final rule addressed the direct addition of dairy-derived ingredients to cacao products, to be consistent with its treatment of dairy-derived ingredients in coatings made with vegetable fat, FDA concludes that the dairy ingredients used to determine whether a food complies with the milk solids content requirements must also significantly contribute to the dairy character of the food, regardless of their source.

Thus, for example, the limitation on calculating milk solids content that it proposed to include in §§ 163.153 and 163.155 (i.e., to limit the calculation of total milk solids content to those dairy ingredients that contribute significant dairy character) will apply not only when lactose is directly added as a nutritive carbohydrate sweetener, but also when it (or any other milk solid or dairy-derived ingredient) is added as a component of any of the specified dairy ingredients used in the food. As stated in the tentative final rule, and supported by comments to the tentative final rule, lactose should not be used in determining whether a food complies with the milk solids content requirements for cacao products. FDA knows of no reason to include a dairy-derived ingredient, such as lactose, in determining whether a cacao product meets the minimum or maximum milk solids content requirements when it is used, for example, to sweeten an optional dairy ingredient, while excluding lactose when it is used as a nutritive carbohydrate sweetener in the cacao product.

Therefore, FDA is adding language to the above limitations in §§ 163.123, 163.130, 163.135, 163.140, 163.145, 163.153, and 163.155 to specify that the amount of the milk solid component beyond that amount that is a normal component of the specified dairy ingredient (e.g., lactose added to sweetened condensed milk) is to be excluded from the calculation of minimum and maximum milk solids content requirements in standardized cacao products. FDA believes that this action is a logical outgrowth of, and fully consistent with, the limitations on determining compliance with the minimum and maximum milk solids requirements proposed in the tentative final rule. FDA also believes that this action will ensure that cacao products contain the level of dairy flavor that consumers expect from each product.

VI. Percent Fat in Chocolate Liquor

In the January 25, 1989, proposed rule (54 FR 3615), FDA proposed to retain the existing cacao fat content requirements for chocolate liquor in § 163.111. The agency also proposed to remove the method of calculating chocolate liquor content based on the weight of nonfat cacao solids in finished sweet chocolate and milk chocolate (§§ 163.123(a)(2) and 163.130(a)(2)).

8. A comment to the proposed rule stated that current research in breeding has produced cacao nibs containing up to 60 percent cacao fat. The comment requested that FDA increase the upper limit for cacao fat content in the standard for chocolate liquor (§ 163.111) from "not more than 58 percent" to "not more than 60 percent" to reflect the changes in cacao fat content of cacao nibs which have resulted from breeding programs. The comment also stated that an increase in cacao fat content in chocolate liquor should not be accompanied by a decrease in nonfat cacao solids in the finished cacao product.

In the tentative final rule, FDA proposed (57 FR 23989 at 23993) to increase the maximum cacao fat content requirement in chocolate liquor (§ 163.111) from 58 percent to 60 percent to reflect an increased fat content in cacao beans. The agency also proposed to retain the calculation to determine chocolate liquor content in the current standards for sweet chocolate (§ 163.123(a)) and milk chocolate (§ 163.130(a) to ensure that the nonfat cacao solids content of these products is not diminished when higher levels of cacao fat are used.

The agency did not receive any comments opposed to these proposed actions. Therefore, FDA is amending the standard for chocolate liquor in § 163.111 by increasing the maximum cacao fat content requirement from "not more than 58 percent" to "not more than 60 percent," and is retaining the calculation to determine chocolate liquor content in the standards for sweet

chocolate (§ 163.123(a)) and milk chocolate (§ 163.130(a)) as proposed.

VII. Chocolate Coatings Made with Vegetable Fat

9. FDA proposed to revise §§ 163.150, 163.153, and 163.155 by removing the phrase "other than cacao fat" from the names of coatings made with vegetable fat (57 FR 23989 at 23994).

FDA also proposed a number of changes to the standards for coatings made with vegetable fat to provide manufacturers with increased flexibility in choice of ingredients and to provide consumers with a broader range of product choices than had been provided by the standards. Specifically, FDA proposed to amend the standard for "sweet cocoa and vegetable fat (other than cacao fat) coating" in § 163.150 to provide for the optional use of chocolate liquor (57 FR 23989 at 23994). FDA stated that this action would allow manufacturers to supplement or replace part of the cocoa in coatings made with sweet cocoa and vegetable fat with chocolate liquor while maintaining the minimum required nonfat cacao solids content requirement for the food. The agency pointed out that this action would also allow consumers to choose from a wider range of products that provide the expected level of chocolate flavor (57 FR 23989 at 23994).

Further, FDA proposed (57 FR 23989 at 23995) to expand the coverage of § 163.155 (milk chocolate and vegetable fat (other than cacao fat) coating) to provide for products that contain less than 3.3 percent by weight of milkfat and are labeled "skim milk chocolate and vegetable fat coating." FDA stated (57 FR 23989 at 23995) that this action would provide a means whereby manufacturers could produce milk chocolate-like coatings with vegetable fats that are not compatible with milkfat, while coatings labeled "milk chocolate and vegetable fat coating" would continue to contain levels of milkfat and milk solids equal to those in milk chocolate.

FDA did not receive any comments opposed to these proposed actions. Therefore, FDA is revising the heading of § 163.150 as *Sweet cocoa and vegetable fat coating*, § 163.153 as *Sweet chocolate and vegetable fat coating*, and § 163.155 as *Milk chocolate and vegetable fat coating*, as proposed. FDA is amending the description in § 163.150(a)(1) to provide for the optional use of chocolate liquor. FDA is also amending the standard for milk chocolate and vegetable fat coating in § 163.155 to provide for products that contain less than 3.3 percent by weight of milkfat and are labeled "skim milk chocolate and vegetable fat coating," as proposed.

VIII. Other Matters

10. Two comments commended FDA for proposing to provide for the use of functional ingredients such as polydextrose in coatings made with vegetable fat. The comments requested that FDA, in promulgating its final rule, also provide for the use of polydextrose in the cacao product standards in §§ 163.110 (cacao nibs), 163.111 (chocolate liquor), 163.112 (breakfast cocoa), 163.123 (sweet chocolate), 163.130 (milk chocolate), 163.140 (skim milk chocolate), and 163.145 (mixed dairy product chocolates). The comments maintained that because polydextrose § 172.841 (21 CFR 172.841) is approved for use in hard and soft candy, and because these categories include the above mentioned foods, the agency should state its approval of the use of polydextrose in the additional cacao products in §§ 163.110, 163.111, 163.112, 163.123, 163.130, 163.140, and 163.145.

The agency disagrees with the comments. FDA notes that the provisions in § 172.841 for the use of polydextrose as a bulking agent, formulation aid, humectant, or texturizer in certain foods (e.g., confections and hard and soft candies) is limited to those foods where such use is not precluded by identity standards established under section 401 of the act. The current standards for cacao products in part 163 do not provide for the use of polydextrose. In its discussion in the tentative final rule, however, the agency noted that providing for the use of ingredients, such as polydextrose, that perform a specific technical effect would be consistent with the history and intent of the standards for coatings made with vegetable fat in §§ 163.150, 163.153, and 163.155, that is to provide for the use of vegetable fat in lieu of additional cacao fat to achieve desired melting characteristics.

FDA notes that the standards for coatings made with vegetable fat provide for products with similar levels of chocolate flavor but with modified characteristics (e.g., melting point) compared to other cacao products. FDA did not propose to provide for the use of bulking agents, formulation aids, humectants, or texturizers in the additional cacao product standards in §§ 163.110, 163.111, 163.112, 163.123, 163.130, 163.140, and 163.145, nor has the agency received any information indicating that such action would be appropriate for these foods. Therefore, providing for the use of bulking agents, formulation aids, humectants, or texturizers in the additional cacao product standards in §§ 163.110, 163.111, 163.112, 163.123, 163.130, 163.140, and 163.145 is outside the scope of this final rule, and FDA is denying the request.

11. One comment stated that it assumed that the omission of the word "ground" in § 163.112(a)(1) to describe the cacao nibs used to make breakfast cocoa was unintentional. The comment stated that the grinding process not only reduces particle size but also reduces bacterial load from the heat that is generated. The comment also stated that the elimination of the requirement that cacao nibs be ground before part of the cacao fat is removed would in fact establish a new process for the manufacture of cacao powders for human consumption.

FDA acknowledges the inadvertent omission of the word "ground" and has made the appropriate editorial changes in § 163.112 to provide that breakfast cocoa, and by cross-reference, cocoa (§ 163.113) and lowfat cocoa (§ 163.114), are prepared by removing part of the fat from ground cacao nibs.

IX. Ingredient Labeling

12. In the **Federal Register** of January 25, 1989 (54 FR 3615), FDA proposed to require label declaration of all optional ingredients used in cacao products. Subsequently, in response to a statutory change enacted by the 1990 amendments, FDA issued a proposal (hereinafter referred to as the ingredient labeling proposal) (see the **Federal Register** of June 21, 1991 (56 FR 28592)), to require label declaration of all ingredients used in standardized foods, including cacao products. In this document, FDA proposed to revise, or to add a new paragraph to, §§ 163.110, 163.111, 163.112, 163.113, 163.114, 163.117, 163.123, 163.130, 163.135, 163.140, 163.145, 163.150, 163.153, and 163.155, to reflect the new ingredient labeling requirements.

FDA stated in the tentative final rule (57 FR 23989 at 23998) that the ingredient labeling proposal supersedes this rulemaking with respect to ingredient labeling. FDA also stated that any comments concerning label declaration of ingredients in cacao products received in response to the ingredient labeling proposal would be considered within the context of that rulemaking.

The June 21, 1991, ingredient labeling proposal was based on the existing cacao standards. FDA published the final rule on ingredient labeling on January 6, 1993 (58 FR 2850). FDA has included in the codified material set

forth in this document language for label declaration of all ingredients used in cacao products, as proposed in the ingredient labeling proposal and finalized on January 6, 1993, except that the agency has made minor editorial changes (e.g., in response to paragraph redesignation). Thus, the new labeling provisions are set forth in §§ 163.110(d), 163.111(d), 163.112(d), 163.113(a), 163.114(a), 163.117(a), 163.123(d), 163.130(d), 163.135(a), 163.140(a), 163.145(a), 163.150(a), 163.153(a), and 163.155(a).

X. Economic Impact

The agency previously conducted an economic assessment of the potential effects of this rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). FDA concluded (57 FR 23989 at 24000) that this action would allow manufacturers to take advantage of new ingredients and technologies and to develop a greater variety of cacao products with a wider range of physical characteristics. The agency found that amending the cacao products standards as proposed would increase flexibility and allow for innovation. FDA also concluded that consumers will benefit from increased product choices and from potentially lower costs.

Because firms will not have to change existing labels, and because no marginal costs are expected to be incurred, the agency found that this rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act, FDA also determined that this final rule will not have a significant adverse impact on a substantial number of small businesses. Finally, FDA concluded that increased flexibility would reduce the costs associated with updating the standards to keep current with technology.

FDA has not received any new information or comments that would alter its previous determinations that: (1) There is no substantive economic issue in this rulemaking, and (2) this is not a major rule. Therefore, FDA finds that this final rule is not a major rule as defined by Executive Order 12291. FDA also finds that this final rule will not have a significant adverse impact on a substantial number of small businesses.

XI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (see the **Federal Register** of January 25, 1989 (54 FR 3615 at 3618)). No new information or comments have been received that would affect the agency's previous determination that there is no significant effect on the human environment and that an environmental impact statement is not required.

List of Subjects in 21 CFR Part 163

Cacao products, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 163 is revised as follows:

PART 163—CACAO PRODUCTS

Subpart A—General Provisions

Sec.
163.5 Methods of analysis.

Subpart B—Requirements for Specific Standardized Cacao Products

163.110 Cacao nibs.
163.111 Chocolate liquor.
163.112 Breakfast cocoa.
163.113 Cocoa.
163.114 Lowfat cocoa.
163.117 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.
163.123 Sweet chocolate.
163.130 Milk chocolate.
163.135 Buttermilk chocolate.
163.140 Skim milk chocolate.
163.145 Mixed dairy product chocolates.
163.150 Sweet cocoa and vegetable fat coating.
163.153 Sweet chocolate and vegetable fat coating.
163.155 Milk chocolate and vegetable fat coating.

Authority: Secs. 201, 301, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 341, 343, 348, 371, 376).

Subpart A—General Provisions

§ 163.5 Methods of analysis.

Shell and cacao fat content in cacao products shall be determined by the following methods of analysis prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 2200 Wilson Blvd., suite 400, Arlington, VA 22201–3301, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700 Washington, DC.

(a) Shell content—12th ed. (1975), methods 13.010–13.014, under the heading "Shell in Cacao Nibs—Official Final Action," pp. 208–210.

(b) Fat content—15th ed. (1990), method 963.15, under the heading "Fat in Cacao Products—Soxhlet Extraction Method—Final Action, 1973," pp. 770–771.

Subpart B—Requirements for Specific Standardized Cacao Products

§ 163.110 Cacao nibs.

(a) *Description.* (1) Cacao nibs is the food prepared by removing the shell from cured, cleaned, dried, and cracked cacao beans. The cacao shell content is not more than 1.75 percent by weight, calculated on an alkali free basis, as determined by the method prescribed in § 163.5(a).

(2) The cacao nibs, or the cacao beans from which they are prepared, may be processed by heating with one or more of the optional alkali ingredients specified in paragraph (b)(1) of this section.

(3) The cacao nibs, or the cacao beans from which they are prepared, as appropriate, may be further processed with one or more of the optional neutralizing agents specified in paragraph (b)(2) of this section.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, added as such, or in aqueous solution. For each 100 parts by weight of cacao nibs, used as such, or before shelling from the cacao beans, the total quantity of alkali ingredients used is not greater in neutralizing value (calculated from the respective combined weights of the alkali ingredients used) than the neutralizing value of 3 parts by weight of anhydrous potassium carbonate.

(2) Neutralizing agents. Phosphoric acid, citric acid, and *L*-tartaric acid, added as such, or in aqueous solution. For each 100 parts by weight of cacao nibs, used as such, or before shelling from the cacao beans, the total quantity of phosphoric acid used is not greater than 0.5 part by weight, expressed as P_2O_5. The total amount, singly or in combination, of citric acid and *L*-tartaric acid is not greater than 1.0 part by weight.

(c) *Nomenclature.* The name of the food is "cacao nibs", "cocoa nibs", or "cracked cocoa".

(1) When the cacao nibs, or the cacao beans from which they are prepared, are processed with alkali ingredients specified in paragraph (b)(1) of this section, the name of the food shall be accompanied by the statement "Processed with alkali" or "Processed with ————", the blank being filled in with the common or usual name of the

specific alkali ingredient used in the food.

(2) When the cacao nibs, or the cacao beans from which they are prepared, are processed with neutralizing agents specified in paragraph (b)(2) of this section, the name of the food shall be accompanied by the statement "Processed with neutralizing agent" or "Processed with ————", the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in paragraphs (c)(1) and (c)(2) of this section shall precede or follow the name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.111 Chocolate liquor.

(a) *Description.* (1) Chocolate liquor is the solid or semiplastic food prepared by finely grinding cacao nibs. The fat content of the food may be adjusted by adding one or more of the optional ingredients specified in paragraph (b)(1) of this section to the cacao nibs. Chocolate liquor contains not less than 50 percent nor more than 60 percent by weight of cacao fat as determined by the method prescribed in § 163.5(b).

(2) Optional alkali ingredients specified in paragraph (b)(2) of this section may be used as such in the preparation of chocolate liquor under the conditions and limitations specified in § 163.110(b)(1).

(3) Optional neutralizing agents specified in paragraph (b)(3) of this section may be used as such in the preparation of the chocolate liquor under the conditions and limitations specified in § 163.110(b)(2).

(4) Chocolate liquor may be spiced, flavored, or seasoned with one or more of the ingredients listed in paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cacao fat and cocoas (breakfast cocoa, cocoa, or lowfat cocoa);

(2) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, added as such, or in aqueous solution;

(3) Neutralizing agents. Phosphoric acid, citric acid, and *L*-tartaric acid, added as such, or in aqueous solution;

(4) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(5) Butter or milkfat; or

(6) Salt.

(c) *Nomenclature.* The name of the food is "chocolate liquor", "chocolate", "unsweetened chocolate", "bitter chocolate", "baking chocolate", "cooking chocolate", "chocolate coating", or "unsweetened chocolate coating".

(1) When any optional alkali ingredient specified in paragraph (b)(2) of this section is used, including those used in the preparation of the cacao nibs and cocoas from which the chocolate liquor was prepared, the name of the food shall be accompanied by the statement "Processed with alkali" or "Processed with ————", the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When any optional neutralizing agent specified in paragraph (b)(3) of this section is used, including those used in the preparation of the cacao nibs and cocoas from which the chocolate liquor was prepared, the name of the food shall be accompanied by the statement "Processed with neutralizing agent" or "Processed with ————", the blank being filled in with the common or usual name of the specific neutralizing ingredient used in the food.

(3) When one or more spices, flavorings, or seasonings specified in paragraphs (b)(4) and (b)(5) of this section are used in the chocolate liquor, the label shall bear an appropriate statement, e.g., "Spice added", "Flavored with ————", "Seasoned with ————", or "With ———— added", the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing optional ingredients used, shall precede or follow the name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.112 Breakfast cocoa.

(a) *Description.* (1) Breakfast cocoa is the food prepared by pulverizing the material remaining after part of the cacao fat has been removed from ground cacao nibs. Breakfast cocoa contains not less than 22 percent by weight of cacao fat as determined by the method prescribed in § 163.5(b).

(2) Optional alkali ingredients specified in paragraph (b)(1) of this section may be used as such in the preparation of breakfast cocoa under the conditions and limitations specified in § 163.110(b)(1).

(3) Optional neutralizing agents specified in paragraph (b)(2) of this section may be used as such in the preparation of the breakfast cocoa under the conditions and limitations specified in § 163.110(b)(2).

(4) Breakfast cocoa may be spiced, flavored, or seasoned with one or more of the ingredients listed in paragraphs (b)(3) and (b)(4) of this section.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, used as such, or in aqueous solution;

(2) Neutralizing agents. Phosphoric acid, citric acid and L-tartaric acid, used as such, or in aqueous solution;

(3) Spices, natural and artificial flavorings, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter; or

(4) Salt.

(c) *Nomenclature.* The name of the food is "breakfast cocoa", or "high fat cocoa".

(1) When any optional alkali ingredient specified in paragraph (b)(1) of this section is used, including those used in the preparation of the cacao nibs from which the breakfast cocoa was prepared, the name of the food shall be accompanied by the statement "Processed with alkali", or "Processed with ————", the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When any optional neutralizing agent specified in paragraph (b)(2) of this section is used, including those used in the preparation of the cacao nibs from which the breakfast cocoa was prepared, the name of the food shall be accompanied by the statement "Processed with neutralizing agent" o.

"Processed with ————————", the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(3) of this section are used in the breakfast cocoa, the label shall bear an appropriate statement, e.g., "Spice added", "Flavored with ————————", or "With ———————— added", the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing optional ingredients used shall precede or follow the name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.113 Cocoa.

(a) *Description.* Cocoa is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for breakfast cocoa in § 163.112, except that the cacao fat content is less than 22 percent, but not less than 10 percent by weight, as determined by the method prescribed in § 163.5(b).

(b) *Nomenclature.* The name of the food is "cocoa" or "medium fat cocoa".

§ 163.114 Lowfat cocoa.

(a) *Description.* Lowfat cocoa is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for breakfast cocoa in § 163.112, except that the cacao fat content is less than 10 percent by weight, as determined by the method prescribed in § 163.5(b).

(b) *Nomenclature.* The name of the food is "lowfat cocoa".

§ 163.117 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

(a) *Description.* Cocoa with dioctyl sodium sulfosuccinate for manufacturing is the food additive complying with the provisions prescribed in § 172.520 of this chapter. It conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, for breakfast cocoa in § 163.112, or for cocoa in § 163.113, or for lowfat cocoa in § 163.114, except that the food additive contains dioctyl sodium sulfosuccinate (complying with the requirements of § 172.810 of this chapter, including the limit of not more than 0.4 percent by weight of the finished food additive).

(b) *Nomenclature.* The name of the food additive is "cocoa with dioctyl sodium sulfosuccinate for manufacturing" to which is added any modifier of the word "cocoa" required by the definition and standard of identity to which the food additive otherwise conforms. When the food additive is used in a fabricated food, the phrase "for manufacturing" may be omitted from any declaration of ingredients required under § 101.4 of this chapter.

§ 163.123 Sweet chocolate.

(a) *Description.* (1) Sweet chocolate is the solid or semiplastic food prepared by intimately mixing and grinding chocolate liquor with one or more optional nutritive carbohydrate sweeteners, and may contain one or more of the other optional ingredients specified in paragraph (b) of this section.

(2) Sweet chocolate contains not less than 15 percent by weight of chocolate liquor complying with the requirements of § 163.111, as calculated by subtracting from the weight of the chocolate liquor used the weight of the cacao fat therein and the weights therein of any alkali, neutralizing, and seasoning ingredients, and multiplying the remainder by 2.2, dividing the result by the weight of the finished sweet chocolate, and multiplying the quotient by 100. The finished sweet chocolate contains less than 12 percent by weight of total milk solids based on those dairy ingredients specified in paragraph (b)(4) of this section, exclusive of any added sweetener or other dairy derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(3) Semisweet chocolate or bittersweet chocolate is sweet chocolate that contains not less than 35 percent by weight of chocolate liquor complying with the requirements of § 163.111 and calculated in the same manner as set forth in paragraph (a)(2) of this section.

(4) Cacao fat is determined by the method prescribed in § 163.5(b).

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cacao fat;

(2) Nutritive carbohydrate sweeteners;

(3) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(4) Dairy ingredients:

(i) Cream, milkfat, butter;

(ii) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk;

(iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk;

(iv) Concentrated buttermilk, dried buttermilk; and

(v) Malted milk; or

(5) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1.0 percent by weight.

(c) *Nomenclature.* The name of the food is "sweet chocolate", "sweet chocolate coating", "semisweet chocolate", "semisweet chocolate coating", "bittersweet chocolate", or "bittersweet chocolate coating", as appropriate.

(1) When optional alkalizing ingredients are used in the preparation of the chocolate liquor or the cacao nibs from which the chocolate was prepared, the label shall bear the statement "Processed with alkali", or "Processed with ————————", the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When optional neutralizing agents are used in the preparation of the chocolate liquor or the cacao nibs from which the chocolate was prepared, the label shall bear the statement "Processed with neutralizing agents", or "Processed with ————————", the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(3) of this section are used in the breakfast cocoa, the label shall bear an appropriate statement, e.g., "Spice added", "Flavored with ————————", or "With ———————— added", the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing optional ingredients used shall precede or follow such name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.130 Milk chocolate.

(a) *Description.* (1) Milk chocolate is the solid or semiplastic food prepared by intimately mixing and grinding chocolate liquor with one or more of the optional dairy ingredients and one or more optional nutritive carbohydrate sweeteners, and may contain one or more of the other optional ingredients specified in paragraph (b) of this section.

(2) Milk chocolate contains not less than 10 percent by weight of chocolate liquor complying with the requirements of § 163.111 as calculated by subtracting from the weight of the chocolate liquor used the weight of cacao fat therein and the weights of alkali, neutralizing and seasoning ingredients, multiplying the remainder by 2.2, dividing the result by the weight of the finished milk chocolate, and multiplying the quotient by 100. The finished milk chocolate contains not less than 3.39 percent by weight of milkfat and not less than 12 percent by weight of total milk solids based on those dairy ingredients specified in paragraph (b)(4) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cacao fat;

(2) Nutritive carbohydrate sweeteners;

(3) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(4) Dairy ingredients:

(i) Cream, milkfat, butter;

(ii) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk; and

(iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk; or

(5) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1.0 percent by weight.

(c) *Nomenclature.* The name of the food is "milk chocolate" or "milk chocolate coating".

(1) When optional alkali ingredients are used in the preparation of the chocolate liquor or the cacao nibs from which the milk chocolate was prepared, the label shall bear the statement "Processed with alkali", or "Processed with ————————", the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When optional neutralizing agents are used in the preparation of the chocolate liquor or the cacao nibs from which the milk chocolate was prepared, the label shall bear the statement "Processed with neutralizing agents", or "Processed with ————————", the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(3) of this section are used in the breakfast cocoa, the label shall bear an appropriate statement, e.g., "Spice added", "Flavored with ————————", or "With ———————— added", the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing optional ingredients used shall precede or follow such name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.135 Buttermilk chocolate.

(a) *Description.* Buttermilk chocolate is the food that conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130, except that:

(1) The optional dairy ingredients are limited to sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, and any combination of these; and

(2) The finished buttermilk chocolate contains less than 3.39 percent by weight of milkfat and not less than 12 percent by weight of sweet cream buttermilk solids based on those dairy ingredients specified in paragraph (a)(1) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Nomenclature.* The name of the food is "buttermilk chocolate", "buttermilk chocolate coating", "sweet buttermilk chocolate", "sweet buttermilk chocolate coating", "sweet cream buttermilk chocolate", or "sweet cream buttermilk chocolate coating".

§ 163.140 Skim milk chocolate.

(a) *Description.* Skim milk chocolate is the food that conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130, except that:

(1) The optional dairy ingredients are limited to skim milk, evaporated skim milk, concentrated skim milk, sweetened condensed skim milk, nonfat dry milk, and any combination of these; and

(2) The finished skim milk chocolate contains less than 3.39 percent by weight of milkfat and not less than 12 percent by weight of skim milk solids based on those dairy ingredients specified in paragraph (a)(1) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Nomenclature.* The name of the food is "skim milk chocolate", "skim milk chocolate coating", "sweet skim milk chocolate", or "sweet skim milk chocolate coating".

§ 163.145 Mixed dairy product chocolates.

(a) *Description.* Mixed dairy product chocolates are the foods that conform to the standard of identity, and are subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130, except that:

(1) The optional dairy ingredients for each of the foods are mixtures of two or more of the following:

(i) Any dairy ingredients specified in § 163.130;

(ii) Any dairy ingredients specified in § 163.135;

(iii) Any dairy ingredients specified in § 163.140; or

(iv) Malted milk; and

(2) The finished mixed dairy product chocolates shall contain not less than 12

percent by weight of total milk solids derived from those dairy products referred to in paragraph (a)(1) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy product, and may contain less than 3.39 percent by weight of milkfat. The quantity of each component used in any such mixture is such that no component contributes less than one third of the weight of the total milk solids contributed by that component which is used in the largest proportion.

(b) *Nomenclature.* The name of the food is "chocolate", or "chocolate coating", preceded by the designation of the type of milk ingredients used as prescribed in paragraph (a) of this section in order of predominance by weight, e.g., "milk and skim milk chocolate".

§ 163.150 Sweet cocoa and vegetable fat coating.

(a) *Description.* Sweet cocoa and vegetable fat coating is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for sweet chocolate in § 163.123, except that:

(1) In the preparation of the product, cocoa or a mixture of cocoa and chocolate liquor is used in such quantity that the finished food contains not less than 6.8 percent by weight of nonfat cacao solids, calculated on a moisture-free basis;

(2) One or more optional ingredients specified in paragraph (b) of this section are used; and

(3) The requirement in § 163.123(a)(2) limiting the total milk solids content to less than 12 percent by weight does not apply.

(b) *Optional ingredients.* (1) Breakfast cocoa, cocoa, lowfat cocoa;

(2) Chocolate liquor;

(3) Safe and suitable vegetable derived fats, oils, and stearins other than cacao fat. The fats, oils, and stearins may be hydrogenated;

(4) Safe and suitable dairy-derived ingredients; and

(5) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is "sweet cocoa and vegetable fat coating". Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., "sweet cocoa and _____ oil coating", the blank being filled in with the common or usual name of the specific vegetable fat used.

§ 163.153 Sweet chocolate and vegetable fat coating.

(a) *Description.* Sweet chocolate and vegetable fat coating is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for sweet chocolate in § 163.123, except that one or more optional ingredients specified in paragraph (b) of this section are used. Compliance with the requirement in § 163.123(a)(2) limiting the total milk solids content to less than 12 percent by weight shall be calculated by including only those dairy ingredients referred to in § 163.123(b)(4), exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* (1) Safe and suitable vegetable derived fats, oils, and stearins other than cacao fat. The fats, oils, and stearins may be hydrogenated;

(2) Safe and suitable dairy-derived ingredients; and

(3) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is "sweet chocolate and vegetable fat coating". Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., "sweet chocolate and _____ oil coating", the blank being filled in with the common or usual name of the specific vegetable fat used.

§ 163.155 Milk chocolate and vegetable fat coating.

(a) *Description.* Milk chocolate and vegetable fat coating is the food that conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130 or skim milk chocolate in § 163.140, except that one or more optional ingredients specified in paragraph (b) of this section are used. Compliance with the requirement in § 163.130(a)(2) that the product contains not less than 12 percent by weight of nonfat milk solids shall be calculated using only those dairy ingredients referred to in § 163.130(b)(4), exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* (1) Safe and suitable vegetable derived oils, fats, and stearins other than cacao fat. The oils, fats, and stearins may be hydrogenated;

(2) Safe and suitable dairy-derived ingredients; and

(3) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is "milk chocolate and vegetable fat coating" or "skim milk chocolate and vegetable fat coating", as appropriate. Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., "milk chocolate and _____ oil coating", the blank being filled in with the common or usual name of the specific vegetable fat used

Dated: May 6, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–11963 Filed 5–20–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 874

[Docket No. 91M–0401]

Medical Devices; Reclassification and Codification of Microsurgical Argon Laser for Rhinology and Laryngology

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to HGM Medical Laser Systems, Inc., reclassifying the microsurgical argon laser for use in rhinology and laryngology from class III (premarket approval) to class II (special controls). The order is being codified in the Code of Federal Regulations as specified herein.

DATES: The reclassification was effective on July 16, 1991. The codification becomes effective June 21, 1993.

FOR FURTHER INFORMATION CONTACT: Harry Sauberman, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1230.

SUPPLEMENTARY INFORMATION: On August 18, 1989, FDA filed the reclassification petition submitted by HGM Medical Laser Systems, Inc., requesting reclassification of the microsurgical argon laser from class III to class II. FDA consulted with the Ear, Nose, and Throat Devices Panel (the Panel). The Panel, during an open public meeting on November 14, 1989, recommended that FDA reclassify the microsurgical argon laser for use in rhinology and laryngology for the purpose of coagulating and vaporizing soft and fibrous, but not osseous, tissues from class III to class II. In addition, the Panel

recommended that FDA assign a low priority for the development of a performance standard for such uses of the argon laser device. The Panel also recommended that specific labeling for the device include a warning to use a laser plume evacuator when performing laser surgery. FDA considered the Panel's recommendations and tentatively agreed that the generic type of device, the argon laser device for use in rhinology and laryngology, be reclassified from class III to class II, and that the promulgation of a performance standard for the device be low priority. Consequently, in the **Federal Register** of January 24, 1991 (56 FR 2728), FDA issued the Panel's recommendation for public comment.

FDA received one comment on the Panel's recommendation to reclassify the argon laser device. The comment expressed concern about some uses of the device, including use in the surrounding tissue of the nasal passages and larynx, and suggested that clinical studies be conducted to evaluate the efficacy of the device in these areas. However, the comment did not disagree with the Panel's recommendation to reclassify the device to class II.

After reviewing the data in the petition and presented before the Panel, and after considering the Panel's recommendation and the comment's suggestions, FDA, based on the information set forth, issued an order to the petitioner on July 16, 1991, reclassifying the microsurgical argon laser for use in rhinology and laryngology from class III to class II. In addition, FDA changed the generic description of the device from microsurgical argon laser to argon laser for otology, rhinology, and laryngology. As required by 21 CFR 860.134(b)(6) and (b)(7), FDA is announcing the reclassification of this generic type of device. In addition, FDA is codifying the reclassification of this device by revising § 874.4490.

Under the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act), devices were to be classified in class I (general controls) if there was information showing that the general controls of the act were sufficient to provide reasonable assurance of safety and effectiveness; devices were to be classified in class II (performance standards) if there was insufficient information showing that general controls themselves would provide such assurance, but there was sufficient information to establish a performance standard that would provide such assurance; devices were to be classified in class III (premarket approval) if there was insufficient information to support placing a device in class I or class II and the device was life-sustaining or life-supporting or was for a use of substantial importance in preventing impairment of human health. As a minimum, all devices in any class were to be subject to the regulatory requirements of general controls.

The Safe Medical Devices Act of 1990 (the SMDA) amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls themselves will provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, including the promulgation of a performance standard. Thus, the definition of a class II device was changed from "performance standards" to "special controls."

It is the agency's position that the SMDA does not require the agency to obtain new reclassification recommendations from a panel which had recommended reclassification under the previous definition of class II. The Panel recommended the microsurgical argon laser for use in rhinology and laryngology be reclassified from class III (premarket approval) to class II (performance standards). Under the SMDA, FDA may establish a performance standard, as well as establish other special controls, including postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, FDA's final determination was made under the standard set forth in the SMDA.

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis, as specified in Executive Order 12291, nor an analysis under the Regulatory Flexibility Act (Pub. L. 96–354). This reclassification will not have a significant economic impact on a substantial number of small entities. All manufacturers of microsurgical argon lasers for use in rhinology and laryngology will no longer be required to comply with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e) and, therefore, will not be subject to the costs of such compliance.

Costs that manufacturers may incur from reclassification into class II are those associated with complying with special controls, once they are imposed. The magnitude of the economic savings attributable to this reclassification depends on the number of premarket approval studies that would have been required of the manufacturers had reclassification not occurred. These savings may not be reliably calculated to permit an accurate quantification of the economic savings.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 874.4490 is revised to read as follows:

§ 874.4490 Argon laser for otology, rhinology, and laryngology.

(a) *Identification.* The argon laser device for use in otology, rhinology, and laryngology is an electro-optical device which produces coherent, electromagnetic radiation with principal wavelength peaks of 488 and 514 nanometers. In otology, the device is used for the purpose of coagulating and vaporizing soft and fibrous tissues, including osseous tissue. In rhinology and laryngology, the device is used to coagulate and vaporize soft and fibrous tissues, but not including osseous tissues.

(b) *Classification.* Class II.

Dated: April 2, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–12077 Filed 5–20–93; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 890

[Docket No. 91N–0232]

Physical Medicine Devices; Revocation of the Classification of Mechanical Automobile Hand and Foot Driving Control

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the physical medicine device classification regulations by removing the mechanical automobile hand and foot driving control classification regulation. The agency no longer believes these products are medical devices. Also, any safety concerns about these products are more appropriately addressed by the National Highway Traffic Safety Administration (NHTSA).

EFFECTIVE DATE: May 21, 1993.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4874.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 23, 1983 (48 FR 53032 at 53048), FDA published a final rule classifying the mechanical automobile hand and foot driving control as a class II medical device. Later, in the **Federal Register** of March 2, 1992 (57 FR 7339), FDA published a proposed rule to amend the physical medicine devices regulations by removing the mechanical automobile hand and foot driving control classification regulation. The agency issued the proposal because it no longer believed that these products were medical devices and that the primary risks presented by the product were motor vehicle safety concerns, more appropriately regulated by NHTSA.

In response to a letter from FDA, NHTSA stated in a letter dated February 19, 1991, that the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1392) authorizes NHTSA to: (1) Set performance requirements for motor vehicle equipment; (2) investigate allegations that motor vehicle equipment, such as mechanical hand and foot driving controls, contain defects related to motor vehicle safety; and (3) take appropriate action.

Interested persons were invited to submit comments. One comment was received. This comment, from the U.S. Small Business Administration, stated that FDA had failed to adequately address the effect of the proposed action on small businesses. The agency has determined that this rule will decrease, rather than increase, any burden on manufacturers of this equipment, while maintaining adequate safety regulation as provided by NHTSA's authorities (see Economic Impact of this document). Accordingly, FDA is issuing this final rule to remove the mechanical automobile hand and foot driving control classification regulation. Persons who have additional questions concerning issues related to NHTSA may contact Mary Versailles at 202–366–2992.

Environmental Impact

The agency has determined under 21 CFR 25.24 (a)(8) and (a)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Impact

FDA has carefully examined the economic impact of this final rule. The Commissioner of Food and Drugs certifies that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (Pub. L. 96–395). This final rule will have the effect of relieving manufacturers of this equipment from the requirement of complying with FDA's medical device regulations. Therefore, this final rule will relieve an existing burden on the industry. There will be no immediate economic effect from the regulation of these products by NHTSA as NHTSA has not yet set any performance requirements for these products. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been analyzed, and it has been determined that the final rule is not a major rule as defined in section 1(b) of the Executive Order.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360l, 371).

§ 890.3450 [Removed]

2. Section 890.3450 *Mechanical automobile hand and foot driving control* is removed from subpart D.

Dated: April 15, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–12076 Filed 5–20–93; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8417]

RIN 1545–AQ53

Limitation on Passive Activity Losses and Credits—Technical Amendments to Regulations; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final and temporary regulations (T.D. 8417), which were published in the **Federal Register** for Friday, May 15, 1992 (57 FR 20747). The final and temporary regulations related to the limitation on passive activity losses and credits.

EFFECTIVE DATE: May 15, 1992.

FOR FURTHER INFORMATION CONTACT: Donna J. Welch, (202) 622–3080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these correcting amendments adopted as final regulations changes to the regulations under section 469 of the Internal Revenue Code, as amended. The regulations also revised the temporary regulations to reflect where portions have been adopted as final.

Need for Correction

As published, T.D. 8417 contained errors which may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR 1.446–1 through 1.483–2T

Accounting, Income taxes, Reporting and recordkeeping requirements.

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments: