

and (4) elimination of the Voluntary Cosmetic Experience Program. Except for the "kosher" guidance, all of the targeted provisions have been rendered obsolete or counterproductive by more recent regulations and other changes. The "kosher" guidance is not obsolete, but, as mentioned earlier in this preamble, because it does not have the force and effect of law, it is not necessary for it to be codified in Title 21.

FDA anticipates that the labeling provisions of the proposed rule will not change the availability of health and safety information to consumers. Although some labels may change as a result of revising § 101.2(c) and removing § 101.8, the main effect of the proposal will be to make FDA's regulations less complicated and easier to follow. Removing the kosher labeling guidance in § 101.29 should not affect information used for religious purposes because the agency will still be providing the same guidance but most likely in the form of an FDA Compliance Policy Guide. Any information loss that might result would likely arise from recognition by the affected industry that the policy does not carry the force and effect of law. Nevertheless, such a loss would not affect health or safety.

FDA estimates the economic effects of labeling with a general model described in the November 27, 1991 Federal Register (56 FR 60856). The net benefits of labeling rules are the difference between the benefits to consumers of the information on labels and the cost to producers (and, ultimately, to consumers) of providing that information. The benefits from labeling can be estimated to be the monetary value of the health and safety improvements that can be attributed to better-informed consumers. The costs of labeling regulations include administrative, analytical, printing, inventory, and product reformulation costs. FDA believes that the proposed labeling revisions will not reduce the nutrition and safety information available to consumers. The health and safety benefits from the labeling rules in part 101 therefore will not change.

The primary economic effect of the proposal will be changes in costs. FDA expects compliance costs of labeling to decline, mainly because the proposed rule will reduce administrative costs. The administrative costs include interpreting labeling regulations and determining how they apply to individual products. The more complicated and confusing the regulations, the more costly it is to interpret them. For example, the

existence of type size exemptions in § 101.2(c) that differ from those in § 101.9 forces firms to study both sections before determining how the rules apply to their products. Even if there were no differences in labeling requirements between sections, firms would have to interpret both sections to assure themselves perhaps at considerable cost, that no differences exist.

By streamlining and consolidating labeling rules, the labeling directions in part 101 will be more user friendly, which in turn will substantially reduce compliance costs. Although FDA does not possess enough data to quantify the reduction in costs, the agency is confident that the compliance cost of labeling regulations will indeed fall as a result of the proposal.

Eliminating voluntary cosmetic experience reporting will generate net benefits by reducing costs. FDA receives an average of 125 submissions annually from firms in the industry. The annual cost to FDA of reviewing, evaluating, summarizing, and storing the experience reports is approximately \$12,000. The annual cost to participating firms is approximately \$12,000. Eliminating the program would therefore reduce annual agency and industry costs by approximately \$24,000, without affecting public health. FDA tentatively concludes that because it will reduce the costs but not the benefits of labeling and voluntary reporting regulations, the proposed rule will generate positive net benefits. FDA finds no reason to expect the proposal to impose burdens on small businesses, whose compliance costs could fall.

#### V. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling or other third party disclosure requirements. Thus there is no "information collection" necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is asking for comment on whether this proposed rule to revoke certain regulations that it believes are obsolete imposes any paperwork burden.

#### IV. References

The following reference has been placed on display in the Dockets Management Branch (HFA-305, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum to James Taylor, Center for Food Safety and Applied Nutrition, FDA, from Joan Roenig, the National Institutes of Standards and Technology, April 2, 1996.

#### List of Subjects

##### 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

##### 21 CFR Part 730

Cosmetics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 101 and 730 be amended as follows:

#### PART 101—FOOD LABELING

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

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.2 *Information panel of package form food* is amended by removing paragraphs (c)(1) through (c)(3) and (c)(5)(iii); and by redesignating paragraphs (c)(4) and (c)(5) as paragraphs (c)(1) and (c)(2) respectively.

##### § 101.8 [Removed]

3. Section 101.8 *Labeling of food with number of servings* is removed.

##### § 101.29 [Removed]

4. Section 101.29 *Labeling kosher and kosher-style foods* is removed.

#### PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

##### Part 730 [Removed]

5. Part 730 is amended by removing it in its entirety.

Dated: May 31, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 96-14887 Filed 6-10-96; 12:17 pm]

BILLING CODE 4160-01-F

**21 CFR Parts 170, 171, 172, 173, 175, 176, 177, 178, 182, and 184**

[Docket 96N-0177]

RIN 0910-AA58

#### Reinvention of Certain Food Additive Regulations

AGENCY: Food and Drug Administration, HHS.

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

**SUMMARY:** The Food and Drug Administration (FDA) is seeking public comment on possible ways to streamline various food additive regulations as the result of a page-by-page review of the agency's regulations. This regulatory review is part of the administration's "Reinventing Government" initiative which seeks to streamline Government and 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:**

Regarding information concerning the regulations: George H. Pauli, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090.

Regarding general information on FDA's "reinventing initiative": Lisa M. Helmanis, Regulations Policy and Management Staff (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

**SUPPLEMENTARY INFORMATION:** On March 4, 1995, President Clinton announced plans for reforming the Federal regulatory system as part of his "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 and to "eliminate or revise those that are outdated or otherwise in need of reform." This notice, which seeks public comment on possible "reinventions", represents FDA's continuing effort to implement the President's plan. In previous issues of the Federal Register, FDA proposed revoking or revising other regulations, and the agency expects to issue future reinvention proposals in upcoming issues.

In this document, FDA is seeking comments on ways in which the following food additive regulations could be updated or revised in order to make them more understandable. The agency is also seeking any other comments regarding parts 170-184 that would assist FDA in fulfilling its mission to protect the interest of consumers. The following is a section-by-section analysis of the regulations that FDA is considering "reinventing."

**I. Section-by-Section Analysis:**

The agency's section-by-section analysis of the regulations listed in parts 170, 171, 172, 173, 175, 176, 177, 178, 182, and 184 (21 CFR parts 170, 171, 172, 173, 175, 176, 177, 178, 182, and 184) has identified candidate regulations to be considered for change, according to the similarity of the regulatory action. The consolidation of multiple listings under one heading would be intended to make the regulations easier to find and use by the regulated industry. Eliminating required analytical methodology would allow more flexibility to use improved methods. Rewriting some sections would be intended to make the regulations easier to understand.

The agency recognizes, however, that apparently simple revisions can inadvertently change the original intent of a regulation. Therefore, care must be taken when revising language to avoid unintended changes. Also, while revising the regulations would not entail reevaluation of the scientific data underlying an approval, it would require agency resources that would otherwise be spent on reviewing petitions and promulgating regulations authorizing uses of other food additives. Additionally, the agency recognizes that while simplification or shortening of the regulations is a useful goal, some users may prefer the detail currently in the regulations. Therefore, before committing further resources to develop proposed changes, FDA is seeking comment on the importance to the regulated community of the various actions under consideration so that the agency can establish appropriate priorities for its reform efforts. The agency is interested in comments both on whether the regulatory actions should be pursued and, for those changes that are needed, any recommendations regarding the specific changes to be made in the regulation and the relative importance of these revisions to interested persons. The agency notes that, due to their technical nature, some of the changes suggested below could be accomplished in a final rule; others may require both a proposed rule and a final rule stage. In some instances, the agency has suggested a reinvention approach.

**II. Consolidate and Delete Regulations**

The following additives have been selected as candidates possible for single listing to minimize redundancy.

**A. Food Additives**

Glycine is listed in §§ 170.50 *Glycine (aminoacetic acid) in food for human*

*consumption*, 172.320 *Amino acids*, and 172.812 *Glycine*. Should these regulations be consolidated and, if so, how?

**B. Food Additives Permitted for Direct Addition to Food for Human Consumption**

Sections 172.836 *Polysorbate 60*, 172.838 *Polysorbate 65*, 172.840 *Polysorbate 80*, and 172.842 *Sorbitan monostearate* could be simplified by deleting references to specific combinations of entries of substances listed within the regulation.

Sections 172.860 *Fatty acids*, 172.862 *Oleic acid derived from tall oil fatty acids*, and 172.863 *Salts of fatty acids* could be combined and simplified under one section. Tests and methods could also be simplified.

Section 172.866 *Synthetic glycerin produced by the hydrogenolysis of carbohydrates* could be combined with § 182.1320 to eliminate the apparent redundancy.

**C. Secondary Direct Food Additives Permitted in Food for Human Consumption**

Sections 173.160 *Candida guilliermondii* and 173.165 *Candida lipolytica* could be combined and simplified under one section.

**D. Indirect Food Additives: Adhesives and Components of Coatings**

Sections 175.360 *Vinylidene chloride copolymer coatings for nylon film* and 175.365 *Vinylidene chloride copolymer coatings for polycarbonate film* could be combined and simplified under one section.

**E. Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers**

Section 178.2010 *Antioxidants and/or stabilizers for polymers* contains a listing of antioxidants. Thus the information in § 178.2550 *4-Hydroxymethyl-2,6-di-tert-butylphenol* could be added to the listing in § 178.2010.

Sections 178.3530 *Isoparaffinic petroleum hydrocarbons, synthetic* and 178.3650 *Odorless light petroleum hydrocarbons* are related substances which could be combined under one section.

Section 178.3600 *Methyl glucoside-coconut oil ester* could be deleted and the substance listed as a processing aid under 21 CFR 172.816 and 178.3520.

Sections 178.3610 *Methylstyrene-vinyltoluene resin, hydrogenated* and 178.3930 *Terpene resins* could be deleted and the substances listed as components for use in olefin polymers under § 177.1520.

Sections 178.3700 *Petrolatum*, 178.3710 *Petroleum wax* and 178.3720 *Petroleum wax synthetic* could be simplified and combined under one section.

Section 178.3860 *Release agents* contains a listing of release agents. Thus, the information in 21 CFR 178.3290 could be added to the listing in § 178.3860.

*F. Direct Food Substances Affirmed as Generally Recognized as Safe*

Sections 184.1271 *L-Cysteine* and 184.1272 *L-Cysteine monohydrochloride* could be simplified under one section.

III. Proposed Deletion of Descriptions of Analytical Methods

Lengthy descriptions of the analytical methods may not be necessary. Each reference to a method could state that copies are available from the Center for Food Safety and Applied Nutrition (CFSAN) and could also specify that equivalent methods are acceptable. Thus, the descriptions of methods could be deleted from the following regulations:

*A. Indirect Food Additives: Paper and Paperboard Components*

Section 176.170 *Components of Paper and Paperboard in Contact with Aqueous and Fatty Foods*.

*B. Indirect Food Additives: Polymers*

Section 177.1010 *Acrylic and modified acrylic plastics, semirigid and rigid*.

Section 177.1050 *Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer*.

Section 177.1315 *Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers*.

Section 177.1330 *Ionomeric resins*.

Section 177.1500 *Nylon resins*.

Section 177.1520 *Olefin polymers*.

Section 177.1640 *Polystyrene and rubber-modified polystyrene*.

Section 177.1950 *Vinyl chloride-ethylene copolymers*.

Section 177.1970 *Vinyl chloride-lauryl vinyl ether copolymers*.

Section 177.1980 *Vinyl chloride-propylene copolymers*.

*C. Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*

Section 178.1010 *Sanitizing solutions*.

Section 178.3620 *Mineral oil*.

Section 178.3770 *Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids*.

Section 178.3910 *Surface lubricants used in the manufacture of metallic articles*.

IV. Methodology

The methodology in the following regulations could be simplified.

*A. Food Additives Permitted for Direct Addition to Food for Human Consumption*

The method and descriptions in § 172.133 *Dimethyl dicarbonate* could be simplified.

The analytical specification in § 172.250 *Petroleum naphtha* could be simplified.

In § 172.695 *Xanthan gum*, the tests as specified in paragraph (d) could be eliminated.

In § 172.820 *Polyethylene glycol (mean molecular weight 200–9,500)*, the analytical method referenced for determining ethylene glycol and diethylene glycol could be simplified.

Section 172.859 *Sucrose fatty acid esters* could be rewritten to clarify preparation and methods.

In § 172.864 *Synthetic fatty alcohols* paragraphs (a) and (c) could be revised, and refer to analytical methods that are available from CFSAN.

Section 172.886 *Petroleum wax* could be simplified and refer to the analytical procedures that are available from CFSAN.

*B. Secondary Direct Food Additives Permitted in Food for Human Consumption*

Section 173.350 *Combustion product gas* could be simplified and could state that analytical procedures were available from CFSAN.

V. General provisions applicable to indirect additives

The statement on good manufacturing practice and the general list of acceptable components in articles that contact food, as referenced in § 174.5, are applicable to indirect food additives in general. Therefore, similar statements could be deleted in the following individual regulations:

*A. Indirect Food Additives: Adhesives and Components of Coatings*

Section 175.105 *Adhesives*.

Section 175.125 *Pressure-sensitive adhesives*.

Section 175.230 *Hot-melt strippable food coatings*.

Section 175.300 *Resinous and polymeric coatings*.

Section 175.320 *Resinous and polymeric coatings for polyolefin films*.

Section 175.350 *Vinyl acetate/crotonic acid copolymer*.

Section 175.390 *Zinc-silicon dioxide matrix coatings*.

*B. Indirect Food Additives: Paper and Paperboard Components*

Section 176.130 *Anti-offset substances*.

Section 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods*.

Section 176.200 *Defoaming agents used in coatings*.

Section 176.210 *Defoaming agents used in the manufacture of paper and paperboard*.

Section 176.300 *Slimicides*.

*C. Indirect Food Additives: Polymers*

Section 177.1010 *Acrylic and modified acrylic plastics, semirigid and rigid*.

Section 177.1030 *Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer*.

Section 177.1040 *Acrylonitrile/styrene copolymer*.

Section 177.1200 *Cellophane*.

Section 177.1210 *Closures with sealing gaskets for food containers*.

Section 177.1240 *1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer*.

Section 177.1310 *Ethylene-acrylic acid copolymers*.

Section 177.1320 *Ethylene-ethyl acrylate copolymers*.

Section 177.1350 *Ethylene-vinyl acetate copolymers*.

Section 177.1400 *Hydroxyethyl cellulose film, water-insoluble*.

Section 177.1520 *Olefin polymers*.

Section 177.1550 *Perfluorocarbon resins*.

Section 177.1630 *Polyethylene phthalate polymers*.

Section 177.1635 *Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene)*.

Section 177.1640 *Polystyrene and rubber-modified polystyrene*.

Section 177.1650 *Polysulfide polymer-polyepoxy resins*.

Section 177.1660 *Poly(tetramethylene terephthalate)*.

Section 177.1970 *Vinyl chloride-lauryl vinyl ether copolymers*.

Section 177.1980 *Vinyl chloride-propylene copolymers*.

Section 177.1990 *Vinylidene chloride/methyl acrylate copolymers*.

Section 177.2000 *Vinylidene chloride/methyl acrylate/methyl methacrylate polymers*.

Section 177.2400 *Perfluorocarbon cured elastomers*.

Section 177.2460 *Poly(2,6-dimethyl-1,4-phenylene) oxide resins*.

Section 177.2470 *Polyoxymethylene copolymer*.

Section 177.2480 *Polyoxymethylene homopolymer*.

Section 177.2550 *Reverse osmosis membranes*.

Section 177.2600 *Rubber articles intended for repeated use*.

Section 177.2800 *Textiles and textile fibers*.

**D. Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers**

Section 178.1005 *Hydrogen peroxide solution*.

Section 178.3120 *Animal glue*.

Section 178.3570 *Lubricants with incidental food contact*.

Section 178.3850 *Reinforced wax*.

**VI. Regulations Reinvented for Clarity**

The agency has noted that some of its food additive regulations could be rewritten to provide clearer guidance.

**A. Food Additives Permitted for Direct Addition to Food for Human Consumption**

The labeling directions in § 172.725 *Gibberellic acid and its potassium salt* could be rewritten for clarity.

Section 172.177 *Sodium nitrite used in processing smoked chub* could be revised to achieve greater consistency with 21 CFR 172.175.

**B. Secondary Direct Food Additives Permitted in Food for Human Consumption**

Section 173.357 *Materials used as fixing agents in the immobilization of enzyme preparations* could be revised to give a clearer statement of components that may be safely used.

Section 173.395 *Trifluoromethane sulfonic acid* could be revised for clarity.

**C. Indirect Food Additives: General**

Section 174.5 *General provisions applicable to indirect food additives* could be revised to achieve greater clarity in paragraph (d)(l) and in the restrictions placed on GRAS substances authorized for use in this part.

**D. Indirect Food Additives: Polymers**

In § 177.1560 *Polyarylsulfone resins*, the agency could add a definition for "normal baking temperature."

In § 177.2490 *Polyphenylene sulfide resins*, the agency could add a definition for "normal baking and frying temperature."

**E. Direct Food Substances Affirmed as Generally Recognized as Safe**

In §§ 184.1257 *Clove and its derivatives* and 184.1259 *Cocoa butter substitute primarily from palm oil*, the description of the additives could be simplified.

Section 184.1287 *Enzyme-modified fats* does not contain general

requirements for enzyme preparations. FDA could reinvent this section to be consistent with the agency's general enzyme provisions.

In § 184.1333 *Gum ghatti*, the agency could eliminate the specifications under paragraph (b) and incorporate by reference the specifications in the Food Chemicals Codex.

In § 184.1408 *Licorice and licorice derivatives* could be revised to achieve greater clarity and the regulation could state that methods of analysis are available from CFSAN.

The description of the additives in § 184.1685 *Rennet (animal-derived) and chymosin preparation (fermentation-derived)* could be simplified.

**VII. Request for Comments**

Interested persons may, on or before, September 10, 1996, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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: June 6, 1996.

William B. Schultz,

Deputy Commissioner for Policy

[FR Doc. 96-14889 Filed 6-7-96; 3:02 pm]

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 26**

[PS-22-96]

RIN 1545-AU26

**Generation-Skipping Transfer Tax**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed regulations relating to the final generation-skipping transfer (GST) tax regulations under chapter 13 of the Internal Revenue Code (Code). This document proposes a change to the final regulations and is necessary to provide guidance to taxpayers so that they may comply with chapter 13 of the Code.

**DATES:** Written comments and requests for a public hearing must be received by September 10, 1996.

**ADDRESSES:** Send submissions to: CC:DOM:CORP:R (PS-22-96), room

5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (PS-22-96), Courier's Desk, Internal Revenue Service, 1111 Constitution NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulation, James F. Hogan, (202) 622-3090 (not a toll-free number); concerning submissions, Christina Vasquez, (202) 622-7180, (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

On December 24, 1992, the IRS published a notice of proposed rulemaking in the Federal Register (57 FR 61356) containing proposed regulations under sections 2611, 2612, 2613, 2632, 2641, 2642, 2652, 2653, 2654, and 2663. On December 27, 1995, the IRS published final regulations in the Federal Register (60 FR 66898) under sections 2611, 2612, 2613, 2632, 2641, 2642, 2652, 2653, 2654, and 2663. This proposed regulation will delete § 26.2652-1(a)(4) and two related examples.

**Explanation of Provision**

Section 2652(a)(1) provides generally, that the term *transferor* means—(A) in the case of any property subject to the tax imposed by chapter 11, the decedent, and (B) in the case of any property subject to the tax imposed by chapter 12, the donor. An individual is treated as transferring any property with respect to which the individual is the transferor. Under § 26.2652-1(a)(2), a transfer is subject to Federal gift tax if a gift tax is imposed under section 2501(a) and is subject to Federal estate tax if the value of the property is includable in the decedent's gross estate determined under section 2031 or section 2103. Under § 26.2652-1(a)(4), the exercise of a power of appointment that is not a general power of appointment is also treated as a transfer subject to Federal estate or gift tax by the holder of the power if the power is exercised in a manner that may postpone or suspend the vesting, absolute ownership, or power of alienation of an interest in property for a period, measured from the date of the creation of the trust, extending beyond any specified life in being at the date of creation of the trust plus a period of 21 years plus, if necessary, a reasonable period of gestation.

The purpose of the rule in § 26.2652-1(a)(4) was to apply the GST tax when