responsibility under the Public Health Service Act.

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

D. Request for Information

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

VIII. Comments

Interested persons may, on or before September 10, 1996, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

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

BILLING CODE 4160–01–F

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21 CFR Parts 101 and 730

[Docket No. 96N–0174]

RIN 0910–AA69

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. Background

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

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

II. The Proposal

A. Food Labeling Regulations

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

1. Section 101.2 Information panel of package form food

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

a. Exemptions for small packages

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

amendments, nutrition information was voluntary unless a nutrient was added to the food or a claim about the nutrient content of the food was made in its labeling. The agency also did not have authority under the Federal Food, Drug, and Cosmetic Act (the act) to require that all ingredients used in standardized foods be declared on the label.

The 1990 amendments amended the act to provide for, among other things, mandatory nutrition labeling of foods and complete ingredient listing on all foods. As a result, FDA amended its nutrition labeling regulations in a number of significant respects, including specifying minimum type sizes and formats for presenting the nutrition information on the label (§ 101.9). The amended nutrition labeling regulations include exemptions from the new minimum type size requirements, depending on the particular format being used and the label space available to bear the information.

Also, in response to the 1990 amendments, FDA revised the definitions and standards of identity for foods in parts 131 to 169 (21 CFR parts 131 to 169) to reflect the requirement that all food ingredients, including the mandatory ingredients of standardized foods, be listed on the label and § 101.6 be revoked (58 FR 2850 and 2888, January 6, 1993).

Because the purpose of § 101.2(c)(1), (c)(2), and (c)(3) was to encourage voluntary declaration of ingredients and nutrition information on food, FDA has tentatively concluded that they are no longer needed. Nutrition labeling is now required on most foods, and the regulations now in effect provide for flexibility in presentation of the information where space is limited. Declaration of all ingredients in standardized foods is also required. Because the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) are obsolete, FDA is proposing to revoke them. If any interested person believes that there is a need to retain any of the exemptions, he or she should submit comments explaining that need in response to this proposal. Comments supporting retention of any of these exemptions should include information on specific products for which other type size exemptions are inadequate.

b. *Nonretail Individual Serving Size Packages*

Section 101.2(c)(5) provides that individual serving size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, are exempt from the type-size requirements of § 101.2(c) under the following conditions:

(i) The package has a total area of 3 square inches or less available to bear labeling;

(ii) There is insufficient area on the package available to print all required information in a type size of one-sixteenth inch in height;

(iii) The label information includes a full list of ingredients in accordance with regulations in part 101 and the policy expressed in § 101.6; and

(iv) The information required by § 101.2 (b) appears on the label in accordance with the provisions of this paragraph, except that the type size is not less than one thirty-second inch in height.

Because declaration of all ingredients in standardized foods is now required, and § 101.6 has been revoked, reference to § 101.6 is no longer meaningful. Therefore, FDA is proposing to delete that reference from § 101.2(c)(5). Specifically, FDA is proposing to revoke paragraph § 101.2(c)(5)(iii) and redesignate paragraph (5)(iv) as (5)(iii).

2. Section 101.8 Labeling of foods with number of servings

Section 101.8(a) requires that any package of food that bears a representation as to the number of servings contained in such package bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving. However, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example, in cups or tablespoons rather than in avoirdupois ounces) when such differing term is common to cookery and describes a constant quantity. This paragraph also requires that the statement not be misleading in any particular. It goes on to state that where nutrition labeling information is required in accordance with the provisions of § 101.9, the statement of the net quantity of each serving shall be consistent with the requirements for serving size expression set forth in that section (e.g., 10 1-cup (240 milliliters) servings). The provision also states that a statement of the number of units in a package is not in itself a statement of the number of servings.

Paragraph (b) of this regulation (§ 101.8(b)) provides that, if there exists a voluntary product standard issued by the Department of Commerce under the procedures found in 15 CFR part 10, that quantitatively defines the meaning of the term ''serving'' with respect to a particular food, then any label representation as to the number of servings in such packaged food shall correspond with such quantitative definition. It also states that, ''Copies of published standards are available upon request from the National Bureau of Standards, Department of Commerce, Washington, DC 20234.''

The agency has tentatively concluded, based on two factors, that this regulation is obsolete. The first factor is that the description of how serving size information should appear on food labels in § 101.8(a) has been obviated by the recent extensive changes in FDA's regulations governing mandatory nutrition labeling of foods that the agency adopted in response to the 1990 amendments. Section 101.9 requires that quantitative nutrition information be declared in relation to a serving of the food as defined in paragraph (b)(1) of that section. Section 101.9(b)(1) defines a ''serving'' or ''serving size'' for the purpose of these regulations as the amount of food, expressed in a common household measure that is appropriate for the food, customarily consumed per eating occasion by persons 4 years of age and older. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. Section 101.9(b) also provides specific guidance as to how the serving or serving size is to be determined for various food products. Section § 101.12 specifies the reference amount customarily consumed per eating occasion for 139 food product categories and requires the declaration of the serving in terms of metric units and familiar household measures. Among other things, the serving size regulation provides criteria for determining the serving size based on the reference amount for the food category, thereby ensuring that reasonable and uniform serving sizes will be used in product labeling. Such uniformity in food labeling enhances consumers' ability to make nutrition comparisons among foods. With § 101.8(a), however, there is not the same specificity for determining appropriate serving sizes. Consequently, there is far less assurance under § 101.8(a) than under § 101.9 that uniform serving sizes will appear on similar products. Therefore, FDA is proposing to revoke § 101.8(a).

The second factor is that FDA is aware of no need to continue the reference in § 101.8(b) to ''voluntary product standards issued by the

National Bureau of Standards of the Department of Commerce (DOC)'' that quantitatively define the meaning of the term ''serving.'' (The agency notes that the National Bureau of Standards is now known as the National Institute of Standards and Technology (NIST)). NIST has advised (Ref. 1) FDA that it no longer issues voluntary product standards, and it has been withdrawing its voluntary serving size standards for FDA-regulated food products for some time. NIST stated that its only standard for an FDA-regulated commodity is one for carbonated soft drink bottles and that standard is about to be withdrawn. Therefore, FDA is proposing to revoke § 101.8(b).

3. Section 101.29 Labeling of kosher and kosher-style foods

Section 101.29 is a statement of informal agency policy regarding the use of the terms ''kosher'' and ''kosher style'' in the labeling of food products. This policy was excerpted from agency correspondence and codified in part 101 (formerly codified as § 3.302, see 22 FR 9593 at page 9594, November 30, 1957) because the agency believed that it was of general interest to the public. Because it was not established through rulemaking procedures, this provision serves only as guidance and does not have the force and effect of law. If these terms are used in a manner that would render the product misbranded, the agency could take action against such products under section 403(a) of the act (21 U.S.C. 343(a)). Although § 101.29 could be removed without notice and comment rulemaking, FDA is proposing to remove it in this document to ensure that its decision is as informed as possible. The agency also solicits comments on whether it should prepare a Compliance Policy Guide that reflects the policy that has been codified in § 101.29. Compliance Policy Guides are used by FDA as informal guidance in evaluating products and accompanying label statements and in recommending regulatory actions for efficient enforcement of the act.

B. Cosmetic Regulations (Part 730—21 CFR 730)

Parts 710, 720, and 730 (21 CFR parts 710, 720, and 730) of FDA's regulations provide for the Voluntary Cosmetic Reporting Program (VCRP) for the voluntary submission of information relating to cosmetic products. Part 730 of this program provides for the voluntary filing of cosmetic product experience reports (VCPE) by the cosmetics industry. In the Federal Register of October 17, 1973 (38 FR 28914), FDA, in response to a petition from the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), issued regulations for the voluntary filing of cosmetic product experiences. The petitioner believed that the VCPE would serve: ''(1) To provide reliable baseline information against which to assess or evaluate products or their ingredients, and (2) prompt information where specific public health questions may be presented.'' The regulation was implemented in 1974 as the Voluntary Cosmetic Experience Program. FDA recodified these regulations in 1974 (39 FR 10054, 10062, March 15, 1974) and modified them in 1981 (46 FR 38073, July 24, 1981) and 1986 (51 FR 25687, July 16, 1986).

During the 23 years the CVRP has been in place, companies have submitted information about adverse reactions that consumers have reported to them. FDA has performed a statistical assessment of the data to calculate the ''baseline'' adverse reactions (expected number of reactions per million units distributed) that occur for the different cosmetic product categories identified in the program.

While the VCPE has provided useful information regarding relative adverse reaction baseline rates, it has suffered from some serious limitations. Industry participation in this portion of the program has historically been very limited and selective, the reports lack sufficient details to be useful, and annual reports are sent in long after the occurrence of an adverse reaction. This limited participation has persisted even though the program has been modified several times over the years to make it easier for companies to participate. In this regard, the VCPE provides a false impression about the ability of the voluntary program to ensure the safety of cosmetics. Thus, the VCPE program no longer provides any new information about cosmetic adverse reactions, and it no longer serves the important purpose of helping to find harmful cosmetics and to remove them from the marketplace.

With current budgetary constraints on FDA, it is difficult to justify the continuation of a program that does not contribute directly to increasing the safety of cosmetics or protecting the public health. Adding data to the information that FDA has obtained over 20 years about baseline adverse reaction rates will be unlikely to have any value. Thus, FDA is proposing to revoke part 730. FDA intends to perform a thorough evaluation of information received over the years and will prepare an in-depth report that will be useful to both the cosmetic industry and the public in understanding adverse reaction trends for different product categories and the baseline rates of adverse reactions. Companies will be able to use this in-depth report for assessing their own individual products without having to report their information to FDA.

The agency is interested in comments on whether the VCPE should be eliminated in its entirety, reduced in scope, or some other alternative. For example, one alternative would be to revoke part 730 but maintain the availability of reporting forms or other means of access (e.g., electronic). These forms could be used for the prompt reporting of any unusually severe adverse reactions or for reporting an unusually high number of adverse reactions of moderate severity. In addition to comments on the issues discussed in this proposal, FDA requests comments on any other related matters that would assist FDA in fulfilling its mission to protect the interests of consumers.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) and (a)(8), respectively, that the actions to revoke or revise several food labeling regulations in part 101, and to eliminate or modify part 730 of the cosmetic regulations, are of a type that do not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

FDA has examined the economic impact of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that the proposed rule does not constitute a major rule as defined by Executive Order 12866. FDA also finds that the proposed rule will not have a significant impact on small businesses.

The proposed rule will remove or revise several provisions in part 101 and all of part 730. The proposed removals include: (1) Certain type-size exemptions, (2) the labeling of foods with number of servings other than as specified in the 1990 amendments, (3) guidance on use of the term ''kosher'',

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 Brance (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

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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.