## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Vessel Sanitation Program Operations Manual—2000

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces the revision and implementation of the Vessel Sanitation Program Operations Manual—2000.

**EFFECTIVE DATE:** The revised Operations Manual will become effective on November 1, 2000.

**FOR FURTHER INFORMATION CONTACT:** David Forney, Chief, Vessel Sanitation Program, Division of Emergency and Environmental Health Services (EEHS), National Center for Environmental Health (NCEH), Mailstop F–16, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia 30333, telephone (770) 488–7333, e-mail: DForney@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

#### Purpose and Background

The Vessel Sanitation Program (VSP) is a cooperative activity between the cruise ship industry and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services. The purpose and goals of VSP are to achieve and maintain a level of sanitation that will lower the risk for gastrointestinal disease outbreaks and assist the passenger cruise line industry in its effort to provide a healthy environment for passengers and crew.

#### Comments

CDC announced their intention to revise the Vessel Sanitation Operations Manual, August 1989 in the **Federal Register**, Volume 62, Thursday, August 23, 1997, page 44475. A subsequent request to solicit topic-specific information for incorporation into a revised operations manual was published in the **Federal Register** on July 9, 1998 (63 FR 37128). Input and public comments were requested and received from the cruise ship industry, private sanitation consultants, other Federal agencies, and other interested parties and were discussed in detail at a public meeting held in Fort Lauderdale, Florida, on April 14–16, 1999.

Based on comments received, VSP staff redrafted the manual and that revised draft was discussed at a public meeting held in Fort Lauderdale, Florida, on October 5–7, 1999. The current document incorporates the input and comments received from the cruise ship industry, private sanitation consultants, and other interested parties who attended both public meetings, and who submitted comments in writing.

The final draft of the VSP Operations Manual—2000 was also presented to attendees at the VSP annual public meeting held in Ft. Lauderdale, Florida, on March 28, 2000. Major input to this document was also provided by the International Council of Cruise Lines, which represents the 17 largest passenger cruise lines that call on major ports in the United States and abroad.

#### Implementation and Transition for the VSP Operations Manual—2000

The VSP Operations Manual—2000 will become effective on November 1, 2000. At that time, VSP environmental health officers will begin using the new manual and inspection report when they conduct their routine operational inspections.

For a period of one year, or two routine inspections, whichever comes first, VSP staff will document all deficiencies not in compliance with the 2000 manual; however, points will not be deducted for those new and more stringent provisions contained in the 2000 manual that were not in the 1989 manual. During the phase-in period, these deficiencies will only be ''starred'' so corrective actions can be made accordingly. For example, the new cold holding temperature for potentially hazardous foods is 5°C (41°F) and the old temperature is 7.5°C (45°F). Food found to be labeled between these temperatures during the first year, or two routine inspections, will be documented and ''starred'' on the inspection report without points being deducted.

#### Applicability

The VSP Operations Manual—2000 will be applicable to all passenger cruise vessels with international itineraries calling on U.S. ports.

#### Availability

Final copies of the VSP Operations Manual—2000 are available in pdf format on the VSP Web site at *http://www.cdc.gov/nceh/vsp* or by contacting Dorothy Johnson, Program Management Assistant at the Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), Mailstop F–16, 4770 Buford Highway, N.E., Atlanta GA 30341–3274, or by e-mailing her at DJJohnson@cdc.gov. Requests may also be sent to *vsp@cdc.gov.*

Dated: October 3, 2000.

**Thena M. Durham,**

*Director, Executive Secretariat, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 00–25906 Filed 10–6–00; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00N–1521]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's food labeling regulations.

**DATES:** Submit written or electronic comments on the collection of information by December 11, 2000.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Food Labeling Regulations (21 CFR Parts 101, 102, 104, and 105)**

FDA regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to FDA. FDA's food labeling regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the FPLA) (15 U.S.C. 1453, 1454, and 1455) and of sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the act and the FPLA.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.9(g)(9) also provides for the submission to FDA of requests for alternative approaches to nutrition labeling. Finally, § 101.9(j)(18) provides for the submission to FDA of notices from firms claiming the small business exemption from nutrition labeling.

Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(b) provides the reference amount that is used for determining the serving sizes for baking powder, baking soda, and pectin. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show FDA detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g) requires that the label or labeling of a food product disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC. Section 101.12(h) provides for the submission of petitions to FDA to request changes in the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with § 101.9 for any food product for which a nutrient content claim is made. Under some circumstances, § 101.13 also requires the disclosure of other types of information as a condition for the use of a nutrient content claim. For example, under § 101.13(j), if the claim compares the level of a nutrient in the food with the level of the same nutrient in another ''reference'' food, the claim must also disclose the identity of the reference food, the amount of the nutrient in each food, and the percentage or fractional amount by which the amount of the nutrient in the labeled food differs from the amount of the nutrient in the reference food. It also requires that when this comparison is based on an average of served foods, this information must be provided to consumers or regulatory officials upon request. Section 101.13(q)(5) requires that restaurants document and provide to appropriate regulatory officials, upon request, the basis for any nutrient content claims they have made for the foods they sell.

Section 101.14 provides for the disclosure of nutrition information in accordance with § 101.9 and, under some circumstances, certain other information as a condition for making a health claim for a food product. Section 101.15 provides that, if the label of a food product contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in both the foreign language and in English. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives in food products. Section 101.22(i)(4) sets forth reporting and recordkeeping requirements pertaining to certifications for flavors designated as containing no artificial flavor. Section 101.30 specifies the conditions under which a beverage that purports to contain any fruit or vegetable juice must declare the percentage of juice present in the beverage and the manner in which the declaration is to be made.

Section 101.36 requires that nutrition information be provided for dietary supplements offered for sale, unless an exemption in § 101.36(h) applies. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to FDA of requests for alternative approaches to nutrition labeling. Also, § 101.36(h)(2) cross-references the provisions in

§ 101.9(j)(18) for the submission of small business exemption notices.

Section 101.42 requests that food retailers voluntarily provide nutrition information for raw fruits, vegetables, and fish at the point of purchase, and § 101.45 contains guidelines for providing such information. Also, § 101.45(c) provides for the submission of nutrient data bases and proposed nutrition labeling values for raw fruit, vegetables, and fish to FDA for review and approval.

Sections 101.54, 101.56, 101.60, 101.61, and 101.62 specify information that must be disclosed as a condition for making particular nutrient content claims. Section 101.67 cross-references requirements in other regulations for ingredient declaration (§ 101.4) and disclosure of information concerning performance characteristics (§ 101.13(d)). Section 101.69 provides for the submission of a petition requesting that FDA authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that FDA authorize a particular health claim by regulation. Section 101.77(c)(2)(ii)(D) requires the disclosure of the amount of soluble fiber per serving in the nutrition labeling of a food bearing a health claim about the relationship between soluble fiber and a reduced risk of coronary heart disease. Section 101.79(c)(2)(iv) requires the disclosure of the amount of folate per serving in the nutrition labeling of a food bearing a health claim about the relationship between folate and a reduced risk of neural tube defects.

Section 101.100(d) provides that any agreement that forms the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the act be in writing and that a copy of the agreement be made available to FDA upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions.

Section 101.105 specifies requirements for the declaration of the net quantity of contents on the label of a food in packaged form and prescribes conditions under which a food whose label does not accurately reflect the actual quantity of contents may be sold, with appropriate disclosures, to an institution operated by Federal, State, or local government. Section 101.108 provides for the submission to FDA of a written proposal requesting a temporary exemption from certain requirements of §§ 101.9 and 105.66 for the purpose of conducting food labeling experiments with FDA's authorization.

Regulations in part 102 define the information that must be included as part of the statement of identity for particular foods and prescribe related labeling requirements for some of these foods. For example, § 102.22 requires that the name of a protein hydrolysate shall include the identity of the food source from which the protein was derived.

Part 104, which pertains to nutritional quality guidelines for foods, cross-references several labeling provisions in part 101 but contains no separate information collection requirements.

Part 105 contains special labeling requirements for hypoallergenic foods, infant foods, and certain foods represented as useful in reducing or maintaining body weight.

The disclosure and other information collection requirements in the above regulations are placed primarily upon manufacturers, packers, and distributors of food products. Because of the existence of exemptions and exceptions, not all of the requirements apply to all food producers or to all of their products. Some of the regulations affect food retailers, such as supermarkets and restaurants.

The purpose of the food labeling requirements is to allow consumers to be knowledgeable about the foods they purchase. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables a consumer to comparison shop. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to FDA provide the basis for the agency to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable FDA to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the act or the FPLA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Sections and Parts | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Capital, Operating, and Maintenance Costs |
|---|---|---|---|---|---|---|
| 101.3, 101.22 and 102 and 104 | 17,000 | 1.03 | 17,500 | 0.5 | 8,750 | 0 |
| 101.4, 101.22, 101.100 and 102, 104, and 105 | 17,000 | 1.03 | 17,500 | 1 | 17,500 | 0 |
| 101.5 | 17,000 | 1.03 | 17,500 | 0.25 | 4,375 | 0 |
| 101.9, 101.13(n), 101.14(d)(3), 101.62, and 104 | 17,000 | 1.03 | 17,500 | 4 | 70,000 | $1,000,000 |
| 101.9(g)(9) and 101.36(f)(2) | 12 | 1 | 12 | 4 | 48 | 0 |
| 101.9(j)(18) and 101.36(h)(2) | 10,000 | 1 | 10,000 | 8 | 80,000 | 0 |
| 101.10 | 265,000 | 1.5 | 397,500 | 0.25 | 99,375 | 0 |
| 101.12(b) | 29 | 2.3 | 66 | 1 | 66 | $39,600 |
| 101.12(e) | 25 | 1 | 25 | 1 | 25 | 0 |

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

| 21 CFR Sections and Parts | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Capital, Operating, and Maintenance Costs |
|---|---|---|---|---|---|---|
| 101.12.(g) | 5,000 | 1 | 5,000 | 1 | 5,000 | 0 |
| 101.12(h) | 5 | 1 | 5 | 80 | 400 | $400,000 |
| 101.13(d)(i) and 101.67 | 200 | 1 | 200 | 1 | 200 | 0 |
| 101.13(j)(2), 101.13(k), 101.54, 101.56, 101.60, 101.61, and 101.62 | 2,500 | 1 | 2,500 | 1 | 2,500 | 0 |
| 101.13(q)(5) | 265,000 | 1.5 | 397,500 | 0.75 | 298,125 | 0 |
| 101.14(d)(2) | 265,000 | 1.5 | 397,500 | 0.75 | 298,125 | 0 |
| 101.15 | 160 | 10 | 1,600 | 8 | 12,800 | 0 |
| 101.22(i)(4) | 25 | 1 | 25 | 1 | 25 | 0 |
| 101.30 and 102.33 | 1,500 | 3.3 | 5,000 | 1 | 5,000 | 0 |
| 101.36 | 300 | 40 | 12,000 | 4 | 48,000 | $15,000,000 |
| 101.42 and 101.45 | 72,270 | 1 | 72,270 | 0.5 | 36,135 | 0 |
| 101.45(c) | 5 | 4 | 20 | 4 | 80 | 0 |
| 101.69 | 3 | 1 | 3 | 25 | 75 | 0 |
| 101.70 | 3 | 1 | 3 | 80 | 240 | $400,000 |
| 101.77(c)(2)(ii)(D) | 1,000 | 1 | 1,000 | 0.25 | 250 | 0 |
| 101.79(c)(2)(iv) | 100 | 1 | 100 | 0.25 | 25 | 0 |
| 101.100(d) | 1,000 | 1 | 1,000 | 1 | 1,000 | 0 |
| 101.105 and 101.100(h) | 17,000 | 1.03 | 17,500 | 0.5 | 8,750 | 0 |
| 101.108 | 0 | 0 | 0 | 40 | 0 | 0 |
| Total | | | | | 985,000 | $16,800,000 |

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

| 21 CFR Sections and Parts | No. of Recordkeepers | Annual Frequency per Recordkeepers | Total Annual Records | Hours per Record | Total Hours | Total Capital, Operating, and Maintenance Costs |
|---|---|---|---|---|---|---|
| 101.12(e) | 25 | 1 | 25 | 1 | 25 | 0 |
| 101.13(q)(5) | 265,000 | 1.5 | 397,500 | 0.75 | 298,125 | 0 |
| 101.14(d)(2) | 265,000 | 1.5 | 397,500 | 0.75 | 298,125 | 0 |
| 101.22(i)(4) | 25 | 1 | 25 | 1 | 25 | 0 |
| 101.100(d)(2) | 1,000 | 1 | 1,000 | 1 | 1,000 | 0 |
| 101.105(t) | 100 | 1 | 100 | 1 | 100 | 0 |
| Total | | | | | 597,400 | 0 |

These estimates are based on the document entitled ''Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations,'' which is the agency's most recent comprehensive review of food labeling costs that published in the **Federal Register** of January 6, 1993 (58 FR 2927); agency communications with industry; and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to

the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: October 2, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

***Proposed Project:*** **The Health Education Assistance Loan (HEAL)**

***Program:*** **Regulatory Requirements—(OMB No. 0915–0108)—Revision**

This clearance request is for revision of approval for the notification, reporting and recordkeeping requirements in the HEAL program to insure that the lenders, holders and schools participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under this OMB number, some of the burden associated with the regulations is cleared under the OMB numbers for the HEAL forms used to report required information (listed below). The table listed at the end of this notice contains the estimate of burden for the remaining regulations.

Annual Response Burden for the following regulations is cleared by OMB when the reporting forms are cleared:

**OMB Approval No. 0915–0034, Lender's Application, Borrower Status, Loan Transfer, Contract for Loan Insurance**

*Reporting*

42 CFR 60.31(a), Lender annual application.

42 CFR 60.38(a), Loan Reassignment.

*Notification*

42 CFR 60.12(c)(1), Borrower deferment.

**OMB Approval No. 0915–0036, Lender's Application for Insurance Claim**

*Reporting*

42 CFR 60.35(a)(2), Lender skip-tracing activities.

42 CFR 60.40(a), Lender documentation to litigate a default.

42 CFR 60.40(c)(i), (ii), and (iii), Lender default claim.

42 CFR 60.40(c)(2), Lender death claim.

42 CFR 60.40(c)(3), Lender disability claim.

42 CFR 60.40(c)(4), Lender report of student bankruptcy.

**OMB Approval No. 0915–0043, Repayment Schedule, Call Report**

*Notification*

42 CFR 60.11(e), Establishment of repayment terms-borrower.

42 CFR 60.11(f)(5), Borrower notice of supplemental repayment agreement.

42 CFR 60.34(b)(1), Establishment of repayment terms-lender.

**OMB Approval No. 0915–0204, Physicians Certification of Permanent and Total Disability**

*Reporting*

42 CFR 60.39(b)(2), Holder request to Secretary to determine borrower disability.

**OMB Approval No. 0915–227, Refinancing Application/Promissory Note**

42 CFR 60.33(e), Executed application and note to borrower.

The estimate of burden for the regulatory requirements of this clearance are as follows:

REPORTING REQUIREMENTS

| Number of respondents | Number of transactions per respondent | Total transactions | Time per response (hours) | Total burden hours |
|---|---|---|---|---|
| 22 Lenders | 7 | 161 | 0.7 | 116 |
| 200 Schools | 7 | 139 | 0.2 | 23 |
| Total Reporting | ..... | ..... | ..... | 139 |

NOTIFICATION REQUIREMENTS

| Number of respondents | Number of transactions per respondent | Total transactions | Time per response (hours) | Total burden hours |
|---|---|---|---|---|
| 22 Lenders | 11,271 | 247,958 | 0.2 | 46,293 |
| 200 Schools | 30 | 5,956 | 0.3 | 1,988 |