

553, or by any other law, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act is not required and was not prepared.

D. This rule involves collections of information subject to the Paperwork Reduction Act and cleared by the Office of Management and Budget under control number 0648-0119. The estimated response times for these requirements are 480 hours for management program approval and 8 hours for program amendment and routine program changes. The response estimates shown include the time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing the collection of information. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to penalty for failure to comply with, a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

E. NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the environment. Therefore, an environmental impact statement under the National Environmental Policy Act, 43 U.S.C. 4321 *et seq.* is not required.

F. This rule contains no mandates, under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, for state, local, or tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

G. NOAA has concluded that this regulatory action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment under Executive Order 12612.

#### List of Subjects in 15 CFR Part 921

Administrative practice and procedure, Coastal zone, Grant programs—Natural resources, Reporting and recordkeeping requirements.

Dated: May 11, 1998.

**Nancy Foster,**

*Assistant Administrator for Ocean Services and Coastal Zone Management.*

For the reasons set forth in the Preamble, 15 CFR part 921 is amended as follows:

### PART 921—NATIONAL ESTUARINE RESEARCH RESERVE SYSTEM REGULATIONS

1. The authority citation for part 921 continues to read as follows:

**Authority:** Section 315 of the Coastal Zone Management Act, as amended (16 U.S.C. 1461).

2. Paragraph (f) of § 921.1 is amended by revising the fourth sentence to read as follows:

#### § 921.1 Mission, goals and general provisions.

\* \* \* \* \*

(f) \* \* \* Notwithstanding any financial assistance limits established by this Part, when financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, such assistance may be used to pay 100 percent of all actual costs of activities carried out with this assistance, as long as such funds are available. \* \* \*

\* \* \* \* \*

3. Paragraph (a) of § 921.10 is amended by adding a new sentence, after the third sentence, to read as follows:

#### § 921.10 General.

(a) \* \* \* Notwithstanding the above, when financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, such assistance may be used to pay 100 percent of all actual costs of activities carried out with this assistance, as long as such funds are available. \* \* \*

4. Paragraph (b) of § 921.10 is amended by adding a new sentence, after the last sentence, to read as follows:

#### § 921.10 General.

(b) \* \* \* Notwithstanding the above, when financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, such assistance may be used to pay 100 percent of all actual costs of activities carried out with this assistance, as long as such funds are available.

5. Section 921.20 is amended by revising the last sentence to read as follows:

#### § 921.20 General

\* \* \* In any case, the amount of Federal financial assistance provided to a coastal state with respect to the acquisition of lands and waters, or interests therein, for any one National Estuarine Research Reserve may not exceed an amount equal to 50 percent

of the costs of the lands, waters, and interests therein or \$5,000,000, whichever amount is less, except when the financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, in which case the assistance may be used to pay 100 percent of all actual costs of activities carried out with this assistance, as long as such funds are available.

6. Section 921.31 is amended by revising the fourth sentence to read as follows:

#### § 921.31 Supplemental acquisition and development awards.

\* \* \* Acquisition awards for the acquisition of lands or waters, or interests therein, for any one reserve may not exceed an amount equal to 50 percent of the costs of the lands, waters, and interests therein of \$5,000,000, whichever amount is less, except when the financial assistance is provided from amounts recovered as result of damage to natural resources located in the coastal zone, in which case the assistance may be used to pay 100 percent of all actual costs of activities carried out with this assistance, as long as such funds are available. \* \* \*

[FR Doc. 98-12880 Filed 5-13-98; 8:45 am]

BILLING CODE 3510-08-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. 98N-0274]

#### Food Labeling; Petitions for Nutrient Content and Health Claims, General Provisions

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to define the conditions under which certain petitions for nutrient content and health claims shall be deemed to be denied and to codify the statutory timeframe within which the agency will complete rulemakings on such petitions. FDA is taking this action in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** This regulation is effective May 14, 1998. Submit written comments by June 15, 1998.

**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:** Hilario R. Duncan, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-8281.

**SUPPLEMENTARY INFORMATION:** On November 21, 1997, President Clinton signed into law FDAMA (Pub. L. 105-115). Section 302 of FDAMA amended section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)) so that certain nutrient content claim and health claim petitions are deemed denied if FDA does not act by certain deadlines. In particular, under amended section 403(r)(4)(A)(i) of the act, if FDA fails to make a filing decision on either type of petition within 100 days of receipt of the petition by the agency, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. If the petition is deemed to be denied in this manner without filing, the petition shall not be made available to the public. In addition, if FDA fails to issue a proposed rule within 90 days of filing of either type of petition, that petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. Accordingly, FDA is amending §§ 101.69(m) and 101.70(j) (21 CFR 101.69(m) and 101.70(j)) to include the statutory language, i.e., "Secretary" is replaced with "FDA" in the appropriate places in the regulations. For consistency, FDA also is making a few editorial changes in § 101.69, i.e., replacing "the Commissioner of Food and Drugs" with "FDA" in the appropriate places in the regulation.

Under amended section 403(r)(4)(A)(i) of the act, FDA also must publish a final rule within 540 days of receipt of the petition, or FDA is required to provide the relevant House and Senate legislative committees with the reasons for failing to do so. Accordingly, FDA is amending §§ 101.69(m) and 101.70(j) to state that rulemakings on health and certain nutrient content claim petitions shall be completed within 540 days of receipt of those petitions. The agency notes that § 101.70(j) provides that a

final rule in response to a health claim petition will be published by FDA within 270 days of the date of publication of the proposal but that, for cause, the agency may extend the period for agency action no more than twice with each extension being for no more than 90 days. In view of amended section 403(r)(4)(A)(i) of the act, the agency advises that, to ensure final action shall be within 540 days of the date of receipt of the petition, the agency may be limited to only one such extension for cause, and such extension may be limited to fewer than 90 days.

Additionally, the agency is taking this opportunity to correct and clarify some inconsistent references in § 101.69 to FDA and to the Commissioner of Food and Drugs so that all references are to the FDA.

The agency has determined under 21 CFR 25.30(k) 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.

FDA has examined the economic implications of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency finds that this final rule is not a significant rule as defined by Executive Order 12866. No analysis is required for this rule under the Regulatory Flexibility Act (5 U.S.C. 601-612) because, as discussed in this document, FDA is issuing it without publishing a general notice of proposed rulemaking.

Finally, in accordance with the Small Business Regulatory Enforcement Fairness Act, the administrator of the

Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this final rule is not a major rule for the purpose of congressional review.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Because the amendments set forth in this document incorporate the language of section 302 of FDAMA into §§ 101.69 and 101.70, FDA finds, for good cause, that notice and public procedure are unnecessary and, therefore, are not required under 5 U.S.C. 553. Nonetheless, under 21 CFR 10.40(e), FDA is providing an opportunity for comment on whether the regulations set forth in this document should be modified or revoked. Interested persons may, on or before June 15, 1998, submit to the Dockets Management Branch (address above) written comments regarding this final rule. 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.

#### List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

#### PART 101—FOOD LABELING

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

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.69 is amended in paragraph (c) by removing "FDA's Center for Food Safety and Applied Nutrition" and adding in its place "the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition"; in paragraph (d) by removing "the Food and Drug Administration" and adding in its place

“FDA”; and in paragraphs (l), (m)(4), (n)(3) and (n)(4), and (o)(3) and (o)(4) by removing “the Commissioner of Food and Drugs”, wherever it appears, and adding in its place “FDA”; by revising paragraph (m)(3); and by adding paragraphs (m)(4)(iii) and (m)(5) to read as follows:

**§ 101.69 Petitions for nutrient content claims.**

\* \* \* \* \*

(m) \* \* \*

(3) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the FDA and the petitioner. A petition that has been denied, or has been deemed to be denied without filing, shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (g) of this section.

\* \* \* \* \*

(4) \* \* \*

(iii) If FDA does not act within 90 days of the filing date, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(5) If FDA issues a proposal, the rulemaking shall be completed within 540 days of the date of receipt of the petition.

\* \* \* \* \*

3. Section 101.70 is amended by revising paragraph (j)(2), by adding paragraph (j)(3)(iii), and by revising paragraph (j)(4)(ii) to read as follows:

**§ 101.70 Petitions for health claims.**

\* \* \* \* \*

(j) \* \* \*

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in “B. Summary

of Scientific Data” if the information in “A. Preliminary Requirements” is inadequate in explaining how the substance conforms to the requirements of § 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. A petition that has been denied, or has been deemed to be denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) \* \* \*

(iii) If FDA does not act within 90 days of the filing date, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(4) \* \* \*

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the **Federal Register**. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published, which date shall be within 540 days of the date of receipt of the petition.

Dated: May 6, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98-12832 Filed 5-13-98; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF LABOR**

**Mine Safety and Health Administration**

**30 CFR Part 100**

RIN 1219-AB03

**Civil Penalties; Correction**

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects the RIN number to the final rule for criteria and procedures for proposed assessment of civil penalties published in the **Federal Register** on April 22, 1998.

**EFFECTIVE DATE:** May 14, 1998.

**FOR FURTHER INFORMATION CONTACT:** Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, (703) 235-1910.

**SUPPLEMENTARY INFORMATION:** On April 22, 1998, (63 FR 20032) MSHA published a final rule on criteria and procedures for proposed assessment of civil penalties. This document corrects an error that appears on the front page of the notice. The RIN number 1219-AA49 is corrected to read 1219-AB03.

**Patricia W. Silvey,**

*Director, Office of Standards, Regulations, and Variances.*

[FR Doc. 98-12759 Filed 5-13-98; 8:45 am]

BILLING CODE 4510-43-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 9**

[FRL-6013-2]

**OMB Approval Numbers Under the Paperwork Reduction Act**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA), this technical amendment amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for the Urban Bus Rebuild Requirements.

**EFFECTIVE DATE:** This final rule is effective June 15, 1998.

**FOR FURTHER INFORMATION CONTACT:** William Rutledge, Engine Programs and Compliance Division (Mail Code 6403-J), U.S. Environmental Protection Agency, Washington, DC 20460. Telephone: (202) 564-9297.