

“home” country; or (d) a request made to USIA by an interested U.S. Government agency to recommend a waiver to USIA because the applicant’s work is important to the public interest.

The Immigration and Nationality Technical Corrections Act provided an additional basis for waiver of the 2-year requirement. A State Department of Public Health or its equivalent can request the Director of USIA to recommend that INS grant up to 20 waivers a year. Conditions for these requests are that: (a) in the case of an alien who is otherwise contractually obligated to return to a foreign country, the government of that country provides USIA with a written statement that it has no objection to the waiver; (b) the IMG demonstrates that he or she has a bona fide offer of full-time employment and will begin this employment within 90 days of receipt of a waiver, for a period totaling not less than 3 years; (c) the employment is in an area designated by the Secretary of Health and Human Services as having a shortage of health care professionals. Both INS and USIA have published in the Federal Register interim-final regulations, with requests for comments, setting forth procedures and requirements for obtaining State-requested waiver requests. 60 F.R. 26676 (May 18, 1995) and 60 F.R. 16785 (April 3, 1995).

Section 214(k)(1) of the Act (8 U.S.C. 1184) authorizes the Secretary of HHS to designate “geographic area or areas * * * as having a shortage of health care professionals” for purposes of the State-requested waiver. Notice is hereby given that both Health Professional Shortage Areas (“HPSAs”) and Medically Underserved Areas/Medically Underserved Populations (“MUAs/MUPs”), determined under Sections 332 and 330 of the Public Health Service Act, respectively, (42 U.S.C. 254e and 254c) are designated by the Secretary of HHS for purposes of 2-year home residency waiver requests by States under Section 214(k)(1) of the Act. HPSAs can be geographic areas, population groups, and health care facilities meeting regulatory criteria set forth at 42 CFR Part 5. Only physicians specialized in *primary care* (family practice, general internal medicine, pediatrics, and obstetrics and gynecology) are considered for physician shortage areas.

MUAs/MUPs are shortage areas and population groups designated pursuant to criteria set forth at 42 CFR § 51c.102(e) based on weighted values related to primary care physician ratios, infant mortality rates, the percentage of the population age 65 and over, and the percentage of the population below the

poverty level. Whole counties and groups of contiguous counties can be designated.

The Bureau of Primary Health Care, Health Resources Services Administration publishes periodically a list of HPSAs in the Federal Register. The latest list was published on January 21, 1994 (59 F.R. 3412). This office also issues a list of MUAs/MUPs. Persons interested in obtaining this list or other information concerning HPSAs and MUAs/MUPs should contact: Dr. Evan R. Arrindell, Acting Director, Division of Shortage Designation, Bureau of Primary Health Care, 4350 East-West Highway, Room 9-1D-1 Bethesda, Maryland 20814 (phone: (301) 594-0816).

Dated: September 1, 1995.
Donna E. Shalala,
Secretary.
[FR Doc. 95-23199 Filed 9-18-95; 8:45 am]
BILLING CODE 4160-15-M

Food and Drug Administration

[Docket No. 93N-0293]

Guide to Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” that addresses various questions concerning the regulations that FDA issued to implement the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The agency has received a large number of inquiries about how these final rules are being implemented in restaurants and other retail establishments, and it has prepared “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” to respond generally to many of the questions that it has received. Answers to some of the most frequently asked questions are included as an appendix to this notice. This document is intended to facilitate compliance with the new rules.

DATES: Written comments may be submitted at anytime.

ADDRESSES: Copies of the document “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” will be

available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202-512-1800. Please request order No. 017-012-00374-5. Submit written comments on “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION: FDA has received a number of inquiries from industry, consumers, and others concerning how the regulations it has adopted, implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) apply to retail Food establishments, including restaurants. FDA has prepared a document entitled “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” to serve as general guidance on the regulations. This document provides answers to many of the questions that the agency has received. Answers to some of the most frequently asked questions are included as an appendix to this notice.

“Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” is intended only to be guidance to facilitate compliance with the regulations. It does not bind the agency, nor does it create or confer any rights, privileges, or benefits for or on any person. While “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments” represents the best advice of FDA, it does not have the force and effect of law. The interpretations presented herein are obviously subject to the requirements of law both in the statute and in the regulations.

Interested persons may, submit written comments on “Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail

Establishments" to the Dockets Management Branch (address above). FDA will consider these comments in determining whether revisions to the document are warranted. Two copies of any comments should 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. The document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Appendix—Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments— Sample Questions

The Guide presents answers to a range of questions, including questions about the application of exemptions and other special labeling provisions in restaurants, about the format for nutrition labeling when it is required, and about other issues concerning the nutrition labeling of retail foods. The Guide also responds to questions about the use of nutrient content claims and health claims on restaurant and other retail foods. It explains how to determine whether there is a reasonable basis for a claim, what foods to use as reference foods, and how to determine reference amounts.

Sample Questions

Question: How does FDA define "restaurants"?

Answer: "Restaurants" include conventional full service restaurants and other establishments where food is sold for immediate, on-site consumption (e.g., institutional food service, delicatessens, and catering where there are facilities for immediate consumption on the premises) and establishments where foods are generally consumed immediately where purchased or while walking away (e.g., lunch wagons, cookie counters in a mall, and vending machines including similar foods sold from convenience stores); and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

Question: If a restaurant makes a claim for one item, does it need to provide nutrition information for all the foods it serves?

Answer: No. The exemptions from nutrition labeling set out in §§ 101.9(j)(2)(i) through (iii) apply to individual food items that are served or sold in a restaurant or similar establishment, not to the establishment. A restaurant need only provide nutrition information for those items that bear a claim. The restaurant may voluntarily provide nutrition information for foods that do not bear a claim.

It should be noted that the January 6, 1993, final regulations implementing the NLEA currently apply to all forms of restaurant labeling *except for menus*. Thus, a claim on a menu does not trigger FDA's nutrition labeling or claims requirements. However, States are not prohibited from enforcing these requirements with respect to menus. Furthermore, in the Federal Register of June

15, 1993 (58 FR 33055), FDA published a proposal to remove the exemption for claims on menus. Should the agency publish a final regulation deleting the menu exemption, the requirements discussed herein for non-menu labeling (e.g., signs, posters, placards, brochures, banners, etc.) will apply to all forms of labeling, including menus.

Question: A restaurant serves a food that is commercially manufactured and packaged and labeled. The food is served to consumers in the form it was purchased by the restaurant, e.g., individual serving size packages of condiments are placed in a bowl for consumer use. Would FDA hold the restaurant that serves the food responsible if the label of the food does not meet FDA's requirements, for example, if a package of salad dressing bears a "lowfat" claim but fails to bear nutrition information?

Answer: FDA requires that the label of a food sold in packaged form identify conspicuously the name and place of business of the manufacturer, packer, or distributor (§ 101.5). The firm that is so identified is generally the firm that is responsible for insuring that the food is properly labeled.

Question: Does a restaurant have to use the Nutrition Facts format to provide nutrition information for a food that bears a claim?

Answer: No. FDA is not requiring full nutrition labeling for restaurant foods, nor is it requiring that nutrition information be presented in the Nutrition Facts format. Because restaurant foods tend to be prepared or sold differently from foods from other sources, FDA is providing flexibility for restaurants in how they determine the nutrient content of a food (e.g., using a cookbook, reliable nutrient data base, or other reasonable bases) and in how this information may be presented to consumers. Information on the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition labeling (§ 101.10).

Question: Does nutrition information have to appear on the same labeling that bears the claim?

Answer: No. Nutrition information for restaurant foods may appear on the same or different labeling from that which bears the claim. Nutrition information may be presented in various forms, including those specified in § 101.9 (Nutrition Facts), § 101.45 (e.g., displayed at point of purchase by an appropriate means, such as affixing it to the food, by posting a sign, or by making the information readily available in a brochure, notebook, or leaflet, in close proximity to the foods), and by other reasonable means, such as orally by waiters or waitresses. (The agency notes, however, that to ensure that the information is presented accurately by waitpersons the nutrition information should also be maintained in written form by the restaurant management.)

Question: When making a claim for a food, does a restaurateur have to have the food that bears the claim analyzed by a lab to determine its nutrient content?

Answer: No. A restaurant food may bear a nutrient content claim or health claim if the

restaurateur has a "reasonable basis" for believing that the food meets the definition for the claim. If a restaurateur labels a food "low fat," for example, he or she must have a reasonable basis for believing that the food complies with FDA's definition for "low fat," i.e., that it contains no more than 3 g of fat per reference amount customarily consumed or, in the case of meals and main dishes, no more than 3 g of fat per 100 g.

Question: Will FDA require prior approval for labeling that bears a claim?

Answer: No. FDA does not have the authority to require prior approval of restaurant labeling that bears a nutrient content claim, health claim, or other nutrition information.

Question: Will restaurants be required to have claim bearing foods "certified" by a third party or an independent dietary professional?

Answer: No. FDA has provided broad flexibility in establishing the "reasonable basis" criterion for restaurant foods. Thus, while some restaurateurs may choose to work with a third party to modify recipes or revise labeling, there is no requirement to do so. Restaurants should be able to make their own determinations once they are familiar with the claims requirements.

Question: Many food service items are partially or wholly processed when they are purchased for use in a restaurant or similar establishment. Thus, it is difficult for the restaurant to keep track of the sodium content of foods. It may also be difficult for a restaurant to monitor the use of sodium in the cooking process and to develop recipes for "low sodium" foods that taste good. How will these problems be addressed in implementing the new requirements?

Answer: FDA does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants. However, the agency is requiring that a restaurant have a reasonable basis for believing that a food meets the nutrient requirements for a claim, and that it be able to provide reasonable assurance that the preparation of the food adheres to the basis for the claim. If a restaurateur has no knowledge of, or control over, the sodium content of a food, or some other aspect of its nutrient content, he/she should not attempt to make a sodium content or other claim about the nutrient levels in that food.

Question: What is a "reference amount"? Do restaurants need to alter their serving size to be equal to the reference amount?

Answer: The reference amount or reference amount customarily consumed (RACC) is the amount of a food item customarily consumed per eating occasion as determined by FDA for the purpose of establishing realistic and consistent serving sizes for use in food labeling. Reference amounts for 139 different food categories are set out in 21 CFR 101.12. (Reference amounts for meat and poultry products are listed in 9 CFR 317.312.)

Restaurants do not need to alter the size of the portions they serve to be the same as the reference amount, nor does the serving size used in the labeling for a particular food need to be the same as the reference amount. However, in order to make certain nutrient content claims or health claims, an

individual food must meet the definition for the claim based on the amount of the subject nutrient in an amount of the food equal to its reference amount, e.g., a "low fat" food may contain up to 3 grams of fat per reference amount. When a food's reference amount is small (i.e., 30 g or less or 2 tablespoons or less), the food (e.g., a sauce or condiment) must also meet the requirements for the claim based on its nutrient content per 50 grams.

Question: Must a restaurant develop recipes for, analyze, and market, a reference food for every food that bears a relative claim?

Answer: No. The reference food may be the restaurant's regular product, or that of another restaurant, that has been offered for sale to the public on a regular basis for a substantial period of time. Nutrient values for a reference food may also be derived from such sources as a valid data base, an average of top national or regional brands, or a market basket norm (§ 101.13(j)(1)(ii)).

Dated: September 14, 1995

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-23242 Filed 9-18-95; 8:45 am]

BILLING CODE 4160-01-F

Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 60 FR 30092, June 7, 1995) is amended to reflect the reorganization of the Office of the Director, National Institute of Allergy and Infectious Diseases (OD/NIAID). The reorganization consists of the following: (1) Retitle the Office of Financial Management (HNM12) to the Office of Financial Management and Technology Transfer (HNM12) and revise the functional statement; and (2) retitle the Office of Policy Analysis and Technology Transfer (HNM16) to the Office of Policy Analysis (HNM16) and revise the functional statement. This reorganization will enable the NIAID to better fulfill its mission by restructuring the OD/NIAID to better integrate related program areas and streamline operations.

Section HN-B, Organization and Functions is amended as follows:

(1) Under the heading *Office of Financial Management (HNM12)*, delete the title and functional statement in their entirety and substitute the following:

Office of Financial Management and Technology Transfer (HNM12). (1) Is the

principal organization that provides advice to the NIAID Director, Deputy Director, and senior staff on all financial management and technology transfer issues affecting the NIAID; (2) has functional responsibilities in financial management and technology transfer, and (3) is intricately involved in (a) program planning, (b) budget preparation and execution, (c) developing position papers for the NIAID Director and other senior staff, (d) managing NIAID's extensive technology transfer program, and (e) accelerating the transfer of NIAID technology to the private sector.

(2) Under the heading *Office of Policy Analysis and Technology Transfer (HNM16)*, delete the title and functional statement in their entirety and substitute the following:

Office of Policy Analysis (HNM16). (1) Serves as principal advisor to the Institute Director, Deputy Director, and Division Directors regarding the planning, evaluation, and program, policy, and legislative analytical needs of the Institute; (2) provides support and serves as liaison to program managers in coordinating, integrating, and articulating long-range program goals and strategies; (3) is responsible for the development and coordination of the Institute's annual Planning and Reporting process; (4) maintains a continuing liaison with program planning, evaluation, and legislation counterparts in other ICDs in the OD/NIH; (5) advises Institute Task Forces to assure that the charge and work of the Task Forces are directed toward the projected planning and evaluation needs of the Institute; (6) conducts the intra-institute program assignments of all research, training, career and fellowship grant applications; (7) analyzes, interprets, and classifies the scientific content of research grants, contracts, and intramural research projects, and manages the scientific information data and coding of the Multi-Axis Coding System (MACS); (8) directs and coordinates all program evaluation activities, assessing the impact and focus of programs which are of major concern to the Institute; (9) advises on material for all stages related to Congressional budget presentations; (10) designs, develops and maintains the computer-based scientific and fiscal data collection, storage, and retrieval system for the Institute's contracts, grants, intramural research projects, fellowships and training awards; (11) directs and coordinates the legislative liaison, legislative tracking and analysis for the Institute; (12) manages the Executive Secretariat (controlled correspondence) functions for the

Institute; and (13) serves as the focus for communications for trans-NIH concerns.

Dated: August 9, 1995.

Harold Varmus,

Director, NIH.

[FR Doc. 95-23135 Filed 9-18-95; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-060-1990-01]

Notice of Availability for the Round Mountain Mill and Tailings Facility Draft Environmental Impact Statement and Notice of Comment Period and Public Meetings

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of availability for the Round Mountain Mill and Tailings Facility Draft Environmental Impact Statement (EIS), for the Smoky Valley Common Operation, Nye County, Nevada; and notice of comment period and public meetings.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act, 40 CFR 1500-1508, and 43 CFR 3809, notice is given that the Bureau of Land Management (BLM) has prepared, with the assistance of a third-party consultant, a Draft EIS on the proposed Round Mountain Mill and Tailings Facility, and has made copies available for public and agency review.

DATES: Written comments on the Draft EIS must be submitted or postmarked to the BLM no later than November 22, 1995. Oral and/or written comments may also be presented at two public meetings, to be held:

October 17, 1995; 7 p.m.; Donald Simpson

Community Center, Hadley, Nevada

October 18, 1995; 7 p.m.; Airport Plaza Hotel,

1981 Terminal Way, Reno, Nevada

ADDRESSES: Written comments on the Draft EIS should be addressed to: Bureau of Land Management, Battle Mountain District, Post Office Box 1420, Battle Mountain, Nevada 89820, Attn.: Christopher J. Stubbs, Round Mountain EIS Project Manager. A limited number of copies of the Draft EIS may be obtained at the same address. In addition, the Draft EIS and supporting documentation are available for review at the following locations: BLM, Battle Mountain District Office, Battle Mountain, Nevada; BLM, Nevada State Office, Reno, Nevada; and the Getchell Library, University of Nevada, Reno, Nevada.