DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0490]

Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance document entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2).'' The guidance explains, using a question and answer format, FDA's current thinking on a number of issues related to the regulation of food allergens, including implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA).

DATES: Submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rhonda R. Kane, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371, or e-mail: *rhonda.kane@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The FALCPA (Public Law 108–282) amends the Federal Food, Drug, and Cosmetic Act and requires that the label of a food product that is or contains an ingredient that bears or contains a ''major food allergen'' declare the presence of the allergen as specified by FALCPA. FALCPA defines a ''major food allergen'' as one of eight foods or a food ingredient that contains protein derived from one of those foods. A food ingredient may be exempt from FALCPA's labeling requirements if it does not cause an allergic response that poses a risk to human health or if it does not contain allergenic protein. FALPCA's labeling requirements apply to products labeled on or after January 1, 2006.

II. Discussion

FDA has received numerous questions about the application of FALCPA's requirements to food products. To explain FALCPA's requirements as well as FDA's current thinking on several issues relating to the regulation of food allergens, on October 5, 2005, FDA posted the first edition of a guidance entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004'' on the agency's Web site at *http://www.cfsan.fda.gov/~dms/alrguid.html*. The guidance that is the subject of this notice, ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2)'' is a revision of the guidance posted on October 5, 2005, and responds to additional questions about FALCPA and food allergens. The revised guidance is intended to share with industry FDA's current thinking on the additional questions presented in the guidance.

Given the nature of the revisions to the guidance, FDA is issuing the guidance as a level 1 guidance. Consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, FALPCA's labeling requirements apply to products labeled on or after January 1, 2006. Clarifying FDA's current thinking on the additional issues presented by FALCPA's implementation will help facilitate the food industry's compliance with FALCPA's requirements.

FDA expects to continue to receive a large number of questions regarding the implementation of FALCPA and the regulation of food allergens generally. The agency intends to respond to these inquires under § 10.115 as promptly as possible, using a question and answer format. The agency believes that, at the present time, it is reasonable to maintain all responses to questions concerning food allergens and FALCPA in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

This guidance represents the agency's current thinking on issues related to FALCPA and food allergens generally that are presented in the guidance. The guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/~dms/alrguid2.html*. Other information about food allergens may be obtained at *http://www.cfsan.fda.gov/~dms/wh-alrgy.html*.

Dated: December 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7803 Filed 12–23–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR

56605, as amended November 6, 1995; as last amended at 70 FR 61293—61294). The notice reflects the establishment of the Office of Health Information Technology (RT), and the creation of the following components: Division of Health Information Technology Policy (RT1), the Division of Health Information Technology State and Community Assistance (RT3), and deletes the Office for the Advancement of Telehealth (RV9) in the HIV/AIDS Bureau and creates the Office for the Advancement of Telehealth (RT2) in the Office of Health Information Technology.

Chapter RT—Office of the Associate Administrator

Section RT—00, Mission

To promote the adoption and effective use of health information technology in the safety net community.

Section RT—10, Organization

The Office of Health Information Technology (OHIT) is headed by the Associate Administrator who reports directly to the Administrator, Health Resources and Services Administration, The OHIT includes the following components:

(1) Immediate Office of the Associate Administrator (RT);

(2) Division of Health Information Technology Policy (RT1);

(3) Office for the Advancement of Telehealth (RT2); and

(4) Division of Health Information Technology State and Community Assistance (RT3).

Section RT—20, Functions

Office of the Associate Administrator (RT)

Provides leadership to HRSA's grantees for the development and nationwide implementation of health information technology infrastructure to improve the quality, safety and efficiency of health care and the ability of consumers to manage their care. Serves as the focal point for HRSA on the development, application, and use of health information technology; and as a catalyst for the wider adoption of advanced technologies in the provision of health care services and education. In conjunction with the Office of the National Health Information Technology Coordinator, ensures that HRSA's health information technology policy and programs are coordinated with those of other relevant executive branch agencies. Promotes and implements health care information technology standards for the medically underserved, ensuring that key issues affecting the public and private adoption of health information technology are addressed, including privacy and security issues. Specific functional responsibilities include: (1) Develops a nationwide health information technology and telehealth strategy for HRSA that focuses on the health care safety net and the needs of the uninsured, underserved, and special needs populations; (2) Develops HRSA's Health Information Technology (HIT) and telehealth policy, including leadership for all of HRSA's HIT projects; (3) Ensures successful dissemination of appropriate information technology advances, such as electronic medical records systems or provider networks, in the community health centers and other HRSA programs; (4) Works collaboratively with foundations, national organizations, private sector providers, as well as Departmental agencies and other Federal departments in order to promote the adoption of health information technology by HRSA's grantees; (5) Ensures the health information technology policy and programs of HRSA are coordinated with those of other HHS components; (6) Serves as the Administrator's principal advisor on the impact of health information technology initiatives in the community, especially for the uninsured, underserved, and special needs populations; and (7) Coordinates outreach and consultation with public and private parties of interest (within the extent of the law), including consumers, providers, payers, and administrators focusing on the needs of the uninsured, underserved, and special needs populations.

Division of Health Information Technology Policy (RT1)

Serves as the focal point for developing policy to promote the coordination and advancement of health information technology to HRSA's programs, including user networks, telemedicine and the use of electronic medical record systems. Specific responsibilities include: (1) Develops a nationwide health information technology and telehealth strategy for HRSA that focuses on the health care safety net and the needs of the uninsured, underserved, and special needs populations; (2) Develops HRSA's Health Information Technology (HIT) and telehealth policy; (3) Ensures successful dissemination of appropriate information technology advances, such as electronic medical records systems or provider networks, to HRSA programs; (4) Works collaboratively with States, foundations, national organizations, private sector providers, as well as Departmental agencies and other Federal departments in order to promote the adoption of health information technology by HRSA's grantees; (5) Ensures the health information technology policy and programs of HRSA are coordinated with those of other HHS components; (6) Assesses the impact of health information technology initiatives in the community, especially for the uninsured, underserved, and special needs populations; (7) Coordinates outreach and consultation with public and private parties of interest (within the extent of the law), including consumers, providers, payers, and administrators focusing on the needs of the uninsured, underserved, and special needs populations; and (8) Develops and translates policy to promote the coordination and advancement of health information technology to HRSA's programs.

Office for the Advancement of Telehealth (RT2)

Serves as the operational focal point for coordinating and advancing the use of telehealth technologies across all of HRSA's programs including, but not limited to, the provision of healthcare at a distance (telemedicine); distance-based leaning to improve the knowledge of agency grantees, and others; and improved information dissemination to both consumers and providers about the latest developments in telemedicine. The Office for the Advancement of Telehealth carries out the following functions, specifically: (1) Develops and coordinates telehealth network and telehealth resource centers grant programs; (2) Provides professional assistance and support in developing telehealth initiatives; (3) Administers grant programs to promulgate and evaluate the use of appropriate telehealth technologies among HRSA grantees and others; (4) Disseminates the latest information and research findings related to the use of telehealth technologies in agency programs and underserved areas, including findings on ''best practices;'' and (5) Provides guidance on telehealth policy through the Associate Administrator for Health Information Technology to the Office of the National Health Information Technology Coordinator and the other components of the Department, with other Federal and State agencies, and with the private sector to promote and overcome barriers to cost-effective telehealth programs.

Division of Health Information Technology State and Community Assistance (RT3)

Serves as the operational focal point for coordinating and advancing the adoption of health information technology across all of HRSA's programs, including, but not limited to, user networks, clinical management systems, and the use of electronic medical record systems. Ensures information dissemination to HRSA grantees and other consumers and providers about the latest developments in health care information technology, and the impact of health information technology on other activities designed to improve the health status of the Nation. The Division of Health Information Technology State and Community Assistance carries out the following functions: (1) Develops and coordinates health information technology (HIT) programs and policies; (2) Provides professional assistance and support in developing HIT initiatives among HRSA grantees; (3) Administers grant programs to promote and evaluate the use of appropriate HIT among grantees and others; (4) Advises HRSA grantees on strategies to maximize the potential of new and existing HIT technologies for meeting quality and technical assistance objectives; (5) Disseminates the latest information and research findings related to the use of HIT technologies in the agency programs and underserved areas, including findings on ''best practices;'' and (6) Provides guidance on HIT policy for safety net providers through the Associate Administrator for Health Information Technology to the Office of the National Health Information Technology Coordinator and the other components of the Department, with other Federal and State agencies and with the private sector to promote and overcome barriers to effective HIT programs.

Section RT—30, Delegations of Authority

All delegations and redelegations of authorities to officers and employees of HRSA that were in effect immediately prior to the effective date of this action will be continued in effect in them or their successors, pending further redelegation, provided they are consistent with this action.

This document is effective upon date of signature.

Dated: December 14, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. E5–7800 Filed 12–23–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–030–1320–EL, NDM91535]

West Mine Area, Freedom Mine Coal Lease Application, North Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability (NOA) of record of decision.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Environmental Impact Statement (EIS) for the West Mine Area, Freedom Mine Coal Lease Application. The EIS analyzed the potential impacts of leasing and mining federal coal on lands in Mercer County, North Dakota. BLM's decision was to approve the implementation of Alternative C, which analyzed the impacts of offering for competitive lease sale approximately 5,334 acres containing approximately 89 million tons of recoverable lignite coal. Alternative C incorporates a preservation component for Native American cultural resources by bypassing approximately 237 acres and an estimated 4 million tons of federal coal which would have been leased under Alternative A (the Proposed Action Alternative). Alternative C also allows for the recovery of federal coal which would be bypassed if not leased under Alternative B (the No Action Alternative).

The BLM received 26 written comments on the draft EIS. These comments and BLM's responses to them were included in the final EIS. All of the comments and the transcript of the formal hearing are on file in the Dickinson, ND and Billings, MT Offices of the BLM. BLM also received 13 written comments on the final EIS. All of the comments received during the process were considered in the preparation of the EIS and/or the Record of Decision.

BLM Notices of Availability for the draft EIS and for the final EIS were published in the **Federal Register** on April 30, 2004 (Volume 69, Number 84), and August 26, 2005 (Volume 70, Number 165).

DATES: The ROD was signed by the Field Manager (NDFO) on November 1, 2005, and by the Montana State Director on November 3, 2005. Parties in interest have the right to appeal that decision pursuant to 43 CFR part 4, within 30 days from the date of publication of this NOA in the **Federal Register**. The ROD contains instructions on taking appeals to the Interior Board of Land Appeals.

FOR FURTHER INFORMATION CONTACT: Allen J. Ollila, phone: (701) 227–7735. Copies of the ROD may be obtained from the following BLM offices: North Dakota Field Office, 2933 3rd Avenue West, Dickinson, North Dakota 58601, (701) 227–7700; and Montana State Office, 5001 Southgate Drive, Billings, Montana 59107, (406) 896–5006.

Lonny R. Bagley,

North Dakota Field Office Manager.

[FR Doc. E5–7835 Filed 12–23–05; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

National Park Service

[AZ–110–05–1610–DP–083A–241E]

Notice of Availability for the Draft Resource Management Plan and Draft Environmental Impact Statement for the Arizona Strip, the Vermilion Cliffs National Monument, and the Grand Canyon-Parashant National Monument, and a Draft General Management Plan and Draft Environmental Impact Statement for the Grand Canyon-Parashant National Monument

AGENCIES: Bureau of Land Management, Department of the Interior. National Park Service, Department of the Interior.

ACTION: Issuance of a Notice of Availability for the Draft Resource Management Plan and Draft EIS for the Arizona Strip, the Vermilion Cliffs National Monument, and the Grand Canyon-Parashant National Monument, and a Draft General Management Plan and Draft EIS for the Grand Canyon-Parashant National Monument, all located in Mohave and Coconino counties, Arizona.

SUMMARY: In accordance with the Bureau of Land Management (BLM) planning regulations, Title 43 Code of Federal Regulations (CFR) 1610.2(f)(3), the National Environmental Policy Act (NEPA) Regulations, Title 40 CFR 1502.9(a), and the National Park Service (NPS) Director's Order 2 (Park Planning), the BLM and NPS hereby gives notice that the Draft Resource Management Plan/Draft EIS for the Arizona Strip Field Office, the Vermilion Cliffs National Monument, and the BLM portion of the Grand Canyon-Parashant National Monument, and a Draft General Management Plan/Draft EIS for the NPS portion of the Grand Canyon-Parashant National Monument (Draft Plan/DEIS) is available for public review and