

information provided in these optional fields is not required. For example, the data contained in the "Other Names" and "Other Provider Identifiers" data fields are optional. Further, a primary "Healthcare Provider Taxonomy Code" is required to be furnished when applying for an NPI; however, the reporting of additional "Healthcare Provider Taxonomy Codes" (a total of 15 may be reported) is optional.

The HHS NPPES data dissemination policy is as follows:

1. *NPPES health care provider data that are required to be disclosed under the FOIA will be available as a downloadable file on a Web site.*

Section 552(a)(2)(D) of the FOIA requires agencies to make available by electronic means copies of records which have been released to any person under the FOIA and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records. We believe that the demand for NPPES health care provider data will be such that it will justify our making NPPES health care provider data that are required to be disclosed under the FOIA available for download by the public from an Internet Web site. The location of the downloadable file will be announced on the CMS NPI Web page (<http://www.cms.hhs.gov/NationalProviderStand/>) prior to its availability. Each month, an update file will also be available for download from the same Web site. The update file will not replace the initial file: The update file will contain only (1) data that are required to be disclosed under FOIA for health care providers who obtained NPIs within the prior month, and (2) updates and changes to the data that are required to be disclosed under the FOIA for enumerated health care providers that were made within the prior month. The first update file will be available for downloading 30 days after the availability of the initial file, and a new update file will be available for downloading each month thereafter.

There will be no charge to download the files.

We may decide to discontinue making these files available if we determine that the query-only database described in (2) below is an adequate replacement.

The NPPES data elements that HHS has determined are required to be disclosed under FOIA and will be contained in the downloadable files are listed in the table above.

2. *NPPES health care provider data that HHS has determined are required to be disclosed under FOIA will be*

available in a query-only database on an Internet Web site.

Section 552(a)(2)(D) of the FOIA requires agencies to make available by electronic means copies of records which have been released to any person under the FOIA and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records.

We believe that the demand for NPPES health care provider data will be such that it will justify our making a query-only database containing NPPES health care provider data that are required to be disclosed under the FOIA available to the public on an Internet Web site. Users will be able to run simple queries online, such as queries by NPI and by name of health care provider.

There will be no charge to use the query-only database.

The NPPES data elements that HHS has determined are required to be disclosed under FOIA and will be available from the query-only database are listed in the table above.

3. *Other requests for NPPES health care provider data that HHS has determined are required to be disclosed under the FOIA.*

Requests for FOIA-disclosable data in formats or in media that are not described above, or any other custom requests, will be considered in accordance with the FOIA and CMS FOIA procedures and charges (see http://www.cms.hhs.gov/AboutWebsite/04_FOIA.asp). For example, these could be requests for FOIA-disclosable data for specific health care providers, or for health care providers in certain States or with certain Healthcare Provider Taxonomy Codes, or requests for FOIA-disclosable data on CD, diskette, or paper. These requests must be described in detail and be submitted to the following address: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Freedom of Information Group, Room N2-20-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Requests may be sent by fax to (410) 786-0474. We will not acknowledge, respond to, or honor requests that are made by telephone.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Authority: Sections 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d-1320d-8), as added by section 262 of Pub. L. 104-191, 42 CFR 162, Subpart D. (Catalog of Federal Domestic Assistance Program, No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 30, 2005.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Dated: February 22, 2007.

Michael O. Leavitt
Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0208]

Interim Melamine and Melamine Analogues Safety/Risk Assessment; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled, "Interim Melamine and Melamine Analogues Safety/Risk Assessment." The interim safety/risk assessment describes the risk to human health associated with eating pork, chicken, fish, and eggs from animals that were inadvertently fed animal feed that contained melamine and its analogues (cyanuric acid, ammelide and ammeline). FDA is seeking public comment on the interim safety/risk assessment to assist the agency and the Food Safety and Inspection Service (FSIS) at the U. S. Department of Agriculture (USDA) in the ongoing investigation of contaminated vegetable protein products imported from China that were mislabeled as "wheat gluten" and "rice protein concentrate," and ensuring the safety of the U.S. food supply.

DATES: Comments on the interim safety/risk assessment must be submitted by June 29, 2007.

ADDRESSES: Submit written comments 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>.

FOR FURTHER INFORMATION CONTACT: P. Michael Bolger, Chief, Risk Assessment Staff, Center for Food Safety and Applied Nutrition (HFS-308), 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1941, FAX 301-436-2632, or e-mail: Mike.Bolger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The interim safety/risk assessment was prepared by FDA in collaboration with FSIS and in consultation with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Homeland Security. The purpose of the safety/risk assessment is to assist FDA and FSIS in the ongoing investigation of contaminated vegetable protein products imported from China that were mislabeled as "wheat gluten" and "rice protein concentrate," and ensuring the safety of the U.S. food supply. The interim safety/risk assessment concludes that, based on currently available data and information, the consumption of even large amounts of pork, chicken, fish, and/or eggs from animals that had been inadvertently fed animal feed contaminated with melamine and its analogues is very unlikely to pose a human health risk. This safety/risk assessment was developed rapidly due to the extremely time-sensitive need to understand the nature of the potential risk. However, we are seeking public comment on this interim safety/risk assessment, and in addition it will undergo expert peer review.

II. Safety/Risk Assessment

A human health safety/risk assessment is a scientifically-based methodology used to estimate risk to human health from exposure to specific compounds such as contaminant(s) in food. The interim melamine and its analogues safety/risk assessment addresses:

- (1) The chemical characteristics of melamine and its analogues;
- (2) The toxicological profile of melamine and its analogues, including the observed results from controlled animal studies conducted with melamine; and
- (3) The likelihood that consumption of pork, chicken, fish and eggs from animals fed feed contaminated with melamine and its analogues poses a health risk to humans.

FDA used the following methodology to develop the safety/risk assessment.

The safety/risk assessment was based on the currently available scientific data and information. FDA estimated human exposure to melamine and its analogues based on the estimated levels in specific foods and the estimated consumption of those foods. The agency compared the exposure estimate to a "Tolerable Daily Intake" level, which was derived using available toxicity data on the level of melamine that did not cause adverse renal effects in a laboratory-animal (13-week rat) bioassay study. FDA adjusted this level, "the No Observed Adverse Effect Level" for uncertainty in the data by dividing by a safety/uncertainty factor of 100 to account for differences in sensitivity within and across species.

Recognizing the time-sensitive need for the safety/risk assessment, FDA invites comments concerning:

- (1) The assessment approach used;
- (2) The assumptions made;
- (3) The data used; and
- (4) The transparency and clarity of the report.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

The interim safety/risk assessment is available electronically at <http://www.cfsan.fda.gov/~dms/melamra.html>.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07-2679 Filed 5-25-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given

that the following committee will convene its fifty-sixth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 10, 2007, 1 p.m.–5:45 p.m., June 11, 2007, 8:45 a.m.–5 p.m., June 12, 2007, 8:50 a.m.–10:45 a.m.

Place: Fort Collins Hilton, 425 Prospect Road, Fort Collins, CO 80526, *Phone:* 970-482-2626.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Sunday afternoon, June 10, at 1 p.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley. Jim Wescott, Senior Demographer with Colorado State will give an overview of Rural Colorado. Following this presentation will be two panels on health and human services issues. The first will be an health panel. The speakers will be Mark Wallace, President of Northern Colorado Health Alliance, and Dr. Jack Westfall, Associate Dean for Rural Health at the Colorado University School of Medicine. The second will be a human services panel. The speakers will be Patricia Brewster-Willeke, a Public Health Nurse, and Kindra Mulch, Administrator of Kit Carson County Health and Human Services. Following the panel discussions will be an overview of Monday's site visits by Lou Ann Wilroy with the Colorado State Office of Rural Health. The Sunday meeting will close at 5:45 p.m.

Monday morning, June 11, at 8:30 a.m., the Committee will break into Subcommittee format for the site visits. At 8:45 a.m., both Subcommittees will depart for site visits. The Health Subcommittee will depart to East Morgan County Hospital in Brush, Colorado. The Human Services Subcommittee will depart to the Area Agency on Aging in Fort Morgan, Colorado. Transportation to these sites will not be provided. Both Subcommittees will return to Fort Collins Hilton and resume meeting in Subcommittee format at 4 p.m. The Monday meeting will close at 5 p.m.

The final session will be convened Tuesday morning, June 12, at 8:50 a.m. A Committee member, Mayor Larry Otis, will present a case study titled Employee Health Care in Rural Mississippi. Following this presentation will be a review of the site visits, discussion on the letter to the Secretary, and discussion of the upcoming September meeting. The meeting will be adjourned at 10:45 a.m.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.