

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Vaccine Advisory Committee, Subcommittee on Future Vaccines, Subcommittee on Immunization Coverage, and Subcommittee on Vaccine Safety and Communication Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following Federal advisory committee meetings.

Name: National Vaccine Advisory Committee (NVAC).

Times and Dates: 9 a.m.–3 p.m., October 8, 2002. 8:30 a.m.–3 p.m., October 9, 2002.

Place: Hubert H. Humphrey Building, Room 705A, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each day either between 8 a.m. and 8:30 a.m. or 12:30 p.m. and 1 p.m. Entrance to the meeting at other times during the day cannot be assured.

Purpose: This committee advises and makes recommendations to the Director of the National Vaccine Program on matters related to the Program responsibilities.

Matters To Be Discussed: Agenda items will include: A report from the National Vaccine Program Office (NVPO) and the Interagency Vaccine Workgroup; a report from the Assistant Secretary for Health; discussion on a proposal for a workshop on traveler's vaccines; an update on the Influenza Pandemic Preparedness Plan; an update on vaccine supply; a discussion of compensation for vaccine administration; Center for Medicare and Medical Services Ruling; a discussion of international vaccine development and introduction; an update on immunization registries; a discussion of racial and ethnic disparities in adult immunization rates; Polio Laboratory Containment and ramifications of recent synthesis of poliovirus; Vaccine Safety and Communication Subcommittee report; Immunization Coverage Subcommittee report; Future Vaccines Subcommittee report; Increasing Public Participation in Dialogue and Deliberation About Vaccines—Report from Wingspread; discussions on Smallpox Vaccine Development and DHHS Smallpox Vaccine Policy; Institute of Medicine (IOM) Report—Vaccine Financing, also an update on the IOM Safety Review Committee; reports from Advisory Committee Immunization Practices/NVAC Smallpox Working Group—Update, Advisory Commission on Childhood Vaccines/Division

of Vaccine Injury Compensation, Vaccine Related Biological Products Advisory Committee/Food and Drug Administration, Advisory Committee on Immunization Practices/National Immunization Program/National Center for Infectious Diseases.

Name: Subcommittee on Future Vaccines.
Time and Date: 3:15 p.m.–5 p.m., October 8, 2002.

Place: Hubert H. Humphrey Building, Room 405A, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee develops policy options and guides national activities that lead to accelerated development, licensure, and the best use of new vaccines in the simplest possible immunization schedules.

Matters To Be Discussed: Agenda items will be; a discussion on Planning for a meeting on Pneumococcal Vaccinations for Adults; a report on the CMV meeting; a discussion of potential future topics, Cell-culture based influenza vaccine, Implications of vectored vaccines.

Name: Subcommittee on Immunization Coverage.

Time and Date: 3:15 p.m.–5 p.m., October 8, 2002.

Place: Hubert H. Humphrey Building, Room 705A, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee will identify and propose solutions that provide a multifaceted and holistic approach to reducing barriers that result in low immunization coverage for children.

Matters To Be Discussed: Agenda items will include discussions on the updates on Publication of Adult and Pediatric Standards; IOM Study on Financing Vaccines; Influenza Immunization Study/READII; Registry for missed immunizations; Areas of Unmet Needs.

Name: Subcommittee on Vaccine Safety and Communication.

Time and Date: 3:15 p.m.–5 p.m. October 8, 2002.

Place: Hubert H. Humphrey Building, Room 425A, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee reviews issues relevant to vaccine safety and adverse reactions to vaccines.

Matters To Be Discussed: Influenza communications programs; a progress report from the IOM Vaccine Safety Review; and a progress report about changes in the Vaccine Injury Compensation Program; a report about Thimerosal class action suits.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gloria Sagar, Committee Management Specialist, NVPO, CDC, 4700 Buford Highway M/S K-77, Chamblee, Georgia 30341, telephone 770/488-2040.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices

pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 6, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02-23152 Filed 9-11-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-484]

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

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations 42 CFR 410.38 and 42 CFR 424.5.

Form No.: 0938-0534 (CMS-484).

Use: This form is used to determine if oxygen is reasonable and necessary pursuant to Medicare Statute; Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information

including estimate length of need (# of months), diagnosis codes (ICD-9) etc.

Frequency: As needed.

Affected Public: Business of other for-profit.

Number of Respondents: 175,000.

Total Annual Responses: 500,000.

Total Annual Hours: 50,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 4, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02-23246 Filed 9-11-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0393]

Assessing Acrylamide in the U.S. Food Supply; Public Meeting; Draft Action Plan on Acrylamide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Assessing Acrylamide in the U.S. Food Supply." The purpose of the public meeting is to update the public on FDA's activities related to acrylamide in food, to present FDA's draft action plan on acrylamide, and to obtain and solicit comments on the action plan.

Date and Time: The public meeting will be held on September 30, 2002, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at the Center for Food Safety and Applied Nutrition, Food and Drug Administration, Harvey W. Wiley

Building Auditorium, 5100 Paint Branch Pkwy, College Park, MD.

Contact: Louis J. Carson, Food Safety Staff (HFS-32), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 301-436-2130, FAX: 301-436-2605, e-mail: Louis.Carson@cfsan.fda.gov.

Addresses: Submit written comments concerning the agency's draft action plan on acrylamide to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 by October 30, 2002. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. The draft action plan will be available on the Internet at <http://www.cfsan.fda.gov/list.html>.

Registration and Request for Oral Presentations: Send registration information (including name, title, firm name, address, telephone number, and fax number) to the contact person by September 26, 2002. Additionally, specify if you wish to make an oral presentation.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please notify the contact person at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

On April 24, 2002, researchers at the Swedish National Food Administration and Stockholm University reported finding the chemical acrylamide in a variety of fried and oven baked foods. The initial Swedish research indicates that acrylamide formation is particularly associated with traditional high temperature cooking processes for certain carbohydrate-rich foods (Ref. 1). Since the Swedish report, similar findings have been reported by Norway, the United Kingdom, and Switzerland. The discovery of acrylamide in foods is a concern because acrylamide is a potential human carcinogen and genotoxicant.

FDA is currently conducting a broad survey of the occurrence of acrylamide in foods. Analytical test methodology was developed for a broad range of food types by FDA to measure acrylamide levels. This methodology is available on the Internet at <http://www.cfsan.fda.gov/dms/acrylami.html>.

Preliminary FDA food analyses for acrylamide suggest that U.S. food levels are consistent with Swedish and European published findings.

Acrylamide is a potential cancer causing chemical that appears to be formed in many foods during the cooking process. It is not known if there is a link between acrylamide in food and cancer in humans. Further research into a number of factors will assist us in evaluating adequately the potential human risk of acrylamide. These factors include: Which foods contain acrylamide, range of levels in these foods, dietary exposure, the bioavailability of acrylamide from food, the potential of acrylamide to cause cancer when consumed in food, acrylamide's potential to cause germ cell mutations, and biomarkers of acrylamide exposure.

Therefore, FDA has drafted an action plan to develop the information to assess effectively the risks associated with acrylamide in food and to make appropriate risk management choices. Until more is known, FDA is not recommending that consumers change their diet or cooking methods because of concerns about acrylamide. Consumers are advised to eat a balanced diet, choosing a variety of foods that are low in fat, and rich in high fiber grains, fruits, and vegetables.

II. Components of FDA's Draft Action Plan on Acrylamide

The components of FDA's draft action plan on acrylamide include:

- Assess the dietary exposure of U.S. consumers to acrylamide by measuring acrylamide levels in various foods,
- Develop screening methods and validate confirmatory methods of analysis,
- Assess the potential risks associated with acrylamide in foods by extensive evaluation of the available information and by expanding research into acrylamide toxicology,
- Identify mechanisms responsible for the formation of acrylamide in foods and identify means to reduce acrylamide exposure,
- Inform and educate consumers of the potential risks throughout the assessment process and as knowledge is gained, and
- Develop and foster public/private partnerships to gather scientific and technological information and data for assessing the human risk.

This public meeting is intended to present FDA's draft action plan on acrylamide and to obtain and solicit public comment on the plan. The draft action plan will be made public on the Internet at <http://www.cfsan.fda.gov/>