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]

BILLING CODE 4120–03–P

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 action plan will be 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/

list.html on or before the date of the public meeting. The preliminary agenda for the public meeting also will be made available on or before the date of the public meeting under the docket number found in brackets in the heading of this document at the Dockets Management Branch (see **ADDRESSES**).

III. Comments

Interested persons may present data, information, or views orally or in writing on issues pending at the public meeting. Those desiring to make oral presentations should notify the contact person (see *Contact*) by September 26, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, their names, addresses, phone numbers, fax numbers, and e-mail addresses. Oral presentations are scheduled for the afternoon session starting at 1:30 p.m. Oral presentations may be limited to 5 minutes, but may be expanded based on the number of people wishing to comment.

You may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) for 30 days following the public meeting on the FDA's acrylamide draft action plan. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Reference

The following reference has been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Tareke, E.; Rydberg, P.; Karlsson, P.; Eriksson, S.; and Tornquist, M.; *Journal of Agricultural and Food Chemistry*, 2002, vol. 50, pp. 4998 to 5006.

Dated: September 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23193 Filed 9–9–02; 2:37 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0324]

Draft ''Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the U.S. Department of Agriculture (USDA), is announcing the availability of a draft document entitled ''Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals'' dated September 2002. The draft guidance document is intended to provide guidance to sponsors, manufacturers, licensees, and applicants of products derived from bioengineered plants or plant materials. The draft guidance document provides recommendations on the use of bioengineered plants or plant materials to produce biological products, including intermediates, protein drugs, medical devices, new animal drugs, and veterinary biologics.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by January 10, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document also may be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER-FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (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: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA, in collaboration with USDA, is announcing the availability of a draft document entitled ''Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals'' dated September 2002. The draft guidance document provides recommendations on the use of bioengineered plants or plant materials to produce biological products, including intermediates, protein drugs, medical devices, new animal drugs, and veterinary biologics. The draft guidance document does not address nonprotein drugs, botanicals, or allergenic products for human use. The draft guidance document outlines important scientific questions and information that should be addressed during the preparation of an investigational new drug application, investigational device exemption, biologics license application, new drug application, investigational new animal drug file, new animal drug application, premarket approval, or 510(k), to FDA or a U.S. veterinary biological product license application to USDA.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking on this topic. It 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by January 10, 2003. Two copies of any written comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number