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

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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 20, 2002.

Margaret M. Dotzel

Associate Commissioner for Policy.

[FR Doc. 02–23105 Filed 9–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0333]

Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Juice HACCP Hazards and Controls Guidance'' (first edition) (the draft guidance). The draft guidance supports and complements the FDA regulation that requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles and, if necessary, to develop and implement HACCP systems for its operations. The draft guidance represents FDA's views on potential hazards in juice products and how to control them, and it is designed to assist juice processors in the development of HACCP plans.

DATES: Submit written or electronic comments concerning the draft guidance and collection of information by November 12, 2002, to ensure adequate consideration in the preparation of the final guidance document. Comments on the draft guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (see **FOR FURTHER INFORMATION CONTACT**). Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments concerning the draft guidance 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2022, FAX 301–436–2651, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the first edition of the draft guidance entitled ''Guidance for Industry: Juice HACCP Hazards and Controls Guidance.''

Under the HACCP regulations in part 120 (21 CFR part 120), juice processors are required to evaluate their operations using HACCP principles and, if necessary, to develop and implement HACCP systems for their operations. Under § 120.9, juice products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) if a processor or importer fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations. The primary purpose of the draft guidance is: (1) To help processors and importers of juice products identify the likelihood that a food safety hazard may occur in their product, and (2) to guide them in the preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur.

II. Significance of the Guidance

The draft guidance is a level 1 guidance issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance represents the agency's current thinking on the potential hazards that are associated with various juice products and processing operations, and how the occurrence of these hazards can be avoided with HACCP controls when they are reasonably likely to occur, as required under part 120. 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 requirements of the applicable statute and regulations.

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the draft guidance has been submitted to OMB for review and was approved under OMB control number 0910–0466.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to 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 draft guidance 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. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at http://www.cfsan.fda.gov/~dms/guidance.html.

Dated: August 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23106 Filed 9–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

The President's New Freedom Commission on Mental Health; Notice of Meeting

Pursuant to Executive Order 13263, notice is hereby given of a meeting of the President's New Freedom Commission on Mental Health in October 2002.

The meeting will be open and will consider how to accomplish the Commission's mandate to conduct a comprehensive study of the United States mental health service delivery system and to make recommendations on improving the delivery of public and private mental health services for adults and children. The Commission meeting will focus on issues relating to the Interim Report, which the Commission is required to send to the President by the end of October.