

and economic self-sufficiency for children and families. The Office provides leadership direction and technical guidance, with ACF Regional Offices, to the States, Tribes and Territories on the TANF program, the Native Employment Works program, and the Aid to the Aged, Blind and Disabled program in Guam, Puerto Rico and the Virgin Island. The Office refocuses efforts to increase economic independence and productivity for families. It provides direction and guidance in the collection and dissemination of performance and other valuable data for these programs. The office provides technical assistance to States, Territories, Indian Tribes, native American organizations, localities and community groups, and assesses State, Territorial and Tribal performance in administering these programs; reviews State and Tribal planning for administrative and operational improvement; and recommends actions to improve effectiveness.

In addition, the Office of Family Assistance advises the Secretary, through the Assistant Secretary for Children and Families, on matters relating to child care. The Child Care Bureau serves as the principal advisor to the Director, OFA, on issues regarding child care programs. It has primary responsibility for the operation of child care programs authorized under the Child Care Development Block Grant (CCDBG) Act and section 418 of the Social Security Act. It develops legislative, regulatory and budgetary proposals; presents operational planning objectives and initiatives related to child care to the Director, OFA; and oversees the progress of approved activities. It provides leadership and coordination for child care within ACF. It provides leadership and linkages with other agencies on child care issues including agencies within DHHS, relevant agencies across the Federal, State, local governments and Tribal governments, and non-governmental organizations at the Federal, State and local levels.

B. Under Paragraph KH.10 Organization, include the following new component:

—Child Care Bureau (KHJ).

C. Amend Paragraph KH.20 Functions, as follows:

(1) Establish a new component Child Care Bureau (KHJ).

(2) Transfer from the Administration on Children, Youth and Families, Chapter KB, the Child Care Bureau (KBG), along with its respective organization components into the Child Care Bureau (KHJ). The statement of

organization, functions, and delegations of authority for the Child Care Bureau (KHJ) and its respective subcomponents will remain intact, until either superseded or amended.

III. Amend Chapter K, Administration for Children and Families, as follows:

A. Under Section K.10 Organization, add the following new component:

—Office of Head Start (KU).

B. Amend Section K.20 Functions, as follows:

(1) Establish a new Chapter (KU).

(2) Transfer from the Administration on Children, Youth and Families, Chapter (KB), the Head Start Bureau (KBC) along with its respective functional statement and responsibilities to the Office of Head Start, Chapter (KU). The statement of organization, functions, and delegations of authority for the Office of Head Start (KU) and its respective subcomponents will remain intact, until either superseded or amended.

IV. *Continuation of Policy:* Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components effected by this Notice within the Administration for Children and Families heretofore issued and in effect on the date of this reorganization are continued in full force and effect.

V. *Delegations of Authority:* All delegations and delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

VI. *Funds, Personnel and Equipment:* Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

Dated: May 16, 2006.

Michael O. Leavitt,
Secretary.

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BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Testing for Malarial Infections in Blood Donors; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: Testing for Malarial Infections in Blood Donors. The purpose of the public workshop is to gather and review current information on scientific developments that might support donor testing for malarial infections as a part of predonation screening, or alternatively, followup testing in deferred at-malaria-risk-donors to permit a reduced deferral period.

Date and Time: The public workshop will be held on July 12, 2006, from 7:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Natcher Conference Center, National Institutes of Health, 45 Center Dr., rm. E1/E2, Bethesda, MD 20892.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: rhonda.dawson@fda.hhs.gov.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by June 23, 2006. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:15 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop will feature presentations by national and international experts from government, academic institutions, and industry. Topics to be discussed include: (1) The impact of transfusion-transmitted malaria on the United States' blood supply, (2) current donor deferral policies in the United States and in Europe, (3) available and emerging technologies that could be used to test blood donors for malarial infections, and (4) the potential effects of donor testing for malarial infection on the safety and availability of the blood supply.

Transcripts: Transcripts of the public workshop 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 public workshop at a cost of 10 cents

per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: May 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-7854 Filed 5-22-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0056]

Draft Compliance Policy Guide; Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled "Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces." The draft CPG establishes regulatory action guidance for FDA personnel for 3-MCPD in acid-hydrolyzed protein (acid-HP) and Asian-style sauces.

DATES: Submit written or electronic comments regarding the draft CPG by July 24, 2006.

ADDRESSES: Submit written requests for single copies of the draft CPG entitled "Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces" to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

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:

Judith L. Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park,

MD 20740, 301-436-1071, FAX: 301-436-2972.

SUPPLEMENTARY INFORMATION:

I. Background

The draft CPG is intended to provide clear policy and regulatory guidance for FDA's field and headquarters staff with regard to 3-MCPD in acid-HP and Asian-style sauces. In particular, the draft CPG sets forth guidance levels for 3-MCPD in acid-HP and Asian-style sauces. FDA would use these levels to help determine whether acid-HP and Asian-style sauces are unsafe. The levels adopted in the draft CPG are not binding on FDA, the regulated industry, or the courts. In any given case, FDA may decide to initiate an enforcement action against acid-HP and Asian-style sauces with concentrations below these levels or decide not to initiate an enforcement action against acid-HP and Asian-style sauces with concentrations that meet or exceed the levels. The draft CPG also contains information that may be useful to the regulated industry and to the public.

FDA has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft CPG is being issued as a Level 1 draft guidance consistent with GGPs. This draft CPG represents the agency's current thinking on 3-MCPD in acid-HP and Asian-style sauces. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

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

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG at <http://www.fda.gov/ora> under "Compliance References."

Dated: May 12, 2006.

David Horowitz,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. E6-7796 Filed 5-22-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0191]

Draft Guidance for Industry and Food and Drug Administration Staff; Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials." This draft guidance provides FDA's recommendations on the use of Bayesian statistical methods in the design and analysis of medical device clinical trials. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by August 21, 2006.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Greg Campbell, Center for Devices and Radiological Health (HFZ-542), Food