

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]

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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.

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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