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

and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3127.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance outlines FDA's current thinking on the use of Bayesian statistical methods in medical device clinical trials. Bayesian statistical methods are currently used in a variety of medical device applications to FDA. This draft guidance includes a general description of Bayesian methods, discussions on design and analysis of Bayesian medical device clinical trials, the benefits and difficulties with the Bayesian approach, and comparisons with standard (frequentist) statistical methods. Finally, the draft guidance presents some ideas on using Bayesian methods in postmarket studies.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on use of Bayesian statistics in medical device clinical trials. 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.

III. Electronic Access

To receive ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1601) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 807 have been approved under 0910–0120; the collections of information in 21 CFR part 812 have been approved under 0910–0078; the collections of information in 21 CFR part 814 have been approved under 0910–0231; and the collections of information in 21 CFR part 822 have been approved under 0910–0449.

V. Comments

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

Dated: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7855 Filed 5–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National institutes of Health

Submission for OMB Review; Comment Request; The Leukocyte Antibodies Prevalence (LAP) Study

Summary: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 1, 2006, pages 5344–5355 and allowed 60 days for public comment. No comments were received in response to this notice. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

Proposed Collection: Title: The Leukocyte Antibodies Prevalence (LAP) Study. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The two current hypotheses for pathogenesis of transfusion-related acute lung injury (TRALI) include the development of acute pulmonary insufficiency from immune and non-immune causes. The immune mediated mechanism postulates that passively transferred anti-leukocyte antibodies from blood donors are responsible for TRALI. The donor antibodies implicated in TRALI include antibodies directed towards HLA class I and class II antigens, and anti-neutrophil antibodies. The LAP Study is a cross-sectional multi-center study to measure the prevalence of HLA and neutrophil antibodies in blood donors with or without a history of blood transfusion or pregnancy, and the development of a repository of blood samples obtained from these donors. Specifically, 7,900 adult blood donors across six blood centers participating in the Retrovirus Epidemiology Donor Study II (REDS–II) will be enrolled in the study. Eligible donors will be asked to complete a short questionnaire on their transfusion history (ever, and date of last transfusion) and, for female donors, questions on pregnancy history (ever, number and outcome of pregnancies, last pregnancy). Each donor will also be asked to provide a sample of blood which will be tested for the presence of HLA class I and Class II antibodies. This data will help us evaluate variations in HLA antibody prevalence based on blood transfusion and pregnancy history and time since the last immunizing event. Further, neutrophil specific antibodies will be measured in those blood donors who have HLA antibodies. Also, donors with neutrophil antibodies will be tested to determine their neutrophil phenotype using routine serologic and DNA methods, since individuals homozygous for certain neutrophil antigens are more