202–418–3131. All requests should identify the guidance documents by the titles listed in the **SUMMARY** section. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Background

The FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish the FCN process as the primary method for authorizing new uses of food additives that are FCSs. An FCS is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' FDA expects most new uses of FCSs that previously would have been regulated by issuance of a listing regulation in response to a food additive petition or would have been exempted from the requirement of a regulation under the threshold of regulation process will be the subject of FCNs. FDA is announcing the availability of two final guidance documents entitled: ''Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendation'' (Docket No. 99D–4575) and ''Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations'' (Docket No. 99D–4576). These documents are intended to provide guidance for industry regarding the preparation of FCNs. FDA is providing these final guidance documents as part of its implementation of the FCN process established by FDAMA.

II. Significance of Guidance

These two final guidance documents represent the agency's current thinking on the data and information that should be submitted in an FCN. These guidance documents do not create or confer any rights for or on any person and do 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. These two guidance documents are level 1 guidance under the agency's good guidance practices (GGPs) regulation (21 CFR 10.115).

Because they are level 1 guidance under the agency's GGPs, FDA announced the availability of these two guidance documents entitled: ''Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations'' and ''Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations'' in draft form for comment in a notice published in the **Federal Register** of November 12, 1999 (64 FR 61648). The comment period for these two draft guidance documents closed on February 14, 2000. FDA received two comments on the draft guidance documents which it has addressed in the final guidance documents being made available by this notice. Thus, in accordance with its GGPs, FDA is now reissuing these two guidance documents in final form. The final guidance documents have different titles than the draft guidance documents made available in the November 12, 1999, notice.

III. Comments

Interested persons may, at any time, submit written comments regarding the guidance documents to the Dockets Management Branch (see **ADDRESSES** section for address). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket numbers found in brackets in the heading of this document. The guidance documents and received comments may be examined in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

The guidance also may be accessed on the Internet site for the Center for Food Safety and Applied Nutrition (CFSAN) listing all CFSAN guidances at http://www.cfsan.fda.gov/~dms/guidance.html.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8745 Filed 4–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0081]

Draft ''Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HbsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations,'' dated April 2002. The draft guidance document when finalized is intended to provide recommendations to manufacturers of assays for the detection of HBsAg that are intended to be used to test blood, blood components, and Source Plasma. Topics include recommendations on minimum sensitivity specifications for HbsAg assays used to test blood, blood components, and Source Plasma donations.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by July 10, 2002. 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 may also 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: Joseph L. Okrasinski, 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 is announcing the availability of a draft document entitled ''Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations,'' dated April 2002. Under 21 CFR 610.44, manufacturers of HBsAg assays used to test donations must verify acceptable sensitivity and specificity of such kits by testing the kit-lots using an FDA reference panel. This draft guidance document is intended to provide recommendations to manufacturers of assays for the detection of HBsAg that are intended to be used to test blood, blood components, and Source Plasma donations. The current limit of detection specification for HBsAg assays used to test blood donations corresponds to 1.0 nanogram (ng) HBsAg/milliliter (mL), and was established in 1996. The draft guidance contains the recommendation that all HBsAg detection assays that are used to test blood, blood components, and Source Plasma donations have a lower limit of detection specification of 0.50 ng HBsAg/mL or less.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on the minimum sensitivity for the HBsAg assays used to test blood and Source Plasma donations. 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

This draft 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 (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by July 10, 2002. 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.

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: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8747 Filed 4–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group, Biomedical Research and Research Training Review Subcommittee B.

Date: June 13, 2002.

Time: 8 AM to 6 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Select—Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Arthur L. Zachary, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13H, Bethesda, MD 20892, (301) 594–2886, *zacharya@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: April 2, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–8724 Filed 4–10–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group Biomedical Research and Research Training Review Subcommittee A

Date: June 12, 2002

Time: 8 AM to 6 PM

Agenda: To review and evaluate grant applications

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814

Contact Person: Carole H. Latker, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13, Bethesda, MD 20892, (301) 594–2848, *latkerc@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)