B. Review Criteria

Applications will be evaluated by program and grants management staff for responsiveness. Applications will be reviewed and ranked. Funding will start with the highest ranked application and additional awards will be made based on an application's standing within the review rankings. All questions of a technical or scientific nature should be directed to the CFSAN program staff, and all questions of an administrative or financial nature should be directed to the grants management staff. (See the **FOR FURTHER INFORMATION CONTACT** section of this document for addresses.)

All applications will be reviewed and scored on the following criteria:

1. Soundness of the scientific rationale for the proposed study and appropriateness of the study design and its ability to address all of the objectives of the RFA;

2. Availability and adequacy of laboratory facilities, equipment, and support services, e.g., bio-statistics computational support, databases, etc.;

3. Research experience, training, and competence of the principal investigator and support staff; and

4. Whether the proposed study is within the budget guidelines and proposed costs have been adequately justified and fully documented.

VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura Stephanos (see **ADDRESSES**). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. The application receipt date is June 10, 2002. No supplemental or addendum material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled: ''Response to RFA FDA CFSAN–02–3.''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) NOTE: Do not send applications to the Center for Scientific Research, National Institutes of Health (NIH). Any application that is sent to NIH, and is then forwarded to FDA and not received in time for orderly processing will be deemed not responsive and returned to the applicant. Applications must be submitted via mail or hand delivery as stated previously. FDA is unable to receive applications electronically. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or PHS 5161–1 (Rev. 7/00). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address.

The face page of the application should reflect the request for applications number, RFA–FDA–CFSAN–02–3. Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph,etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: April 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8777 Filed 4–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99D–4575 and 99D–4576]

Guidance for Industry: Food Contact Substance Notification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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 Recommendations'' and ''Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations.'' These guidance documents are intended to provide guidance for industry regarding the preparation of food contact notifications (FCNs) and petitions for food contact substances (FCSs). FDA is providing these guidance documents as part of its implementation of the FCN process established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments on these guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance documents to the Office of Food Additive Safety (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on these guidance documents 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. You also may request a copy of the guidance documents by electronic mail at OPAPMN@CFSAN.FDA.GOV, or by telephone to the Office of Food Additive Safety at 202–418–3087 (voice) or FAX

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.