Results of these surveys will be used in future program planning initiatives and to redirect resources and efforts, as needed, to improve AHRQ program services. The current clearance will expire September 30, 2004. This is a request for a generic approval from OMB to conduct customer surveys over the next three years.

Method of Collection

The data will be collected using a combination of methodologies appropriate to each survey. These methodologies include:

- Evaluation forms;
- Mail surveys;
- Focus groups;
- Automated and electronic technology (*e.g.,* e-mail, Web-based surveys, instant fax, AHRQ Publications Clearinghouse customer feedback) and,
- Telephone surveys.

ESTIMATED ANNUAL RESPONDENT BURDEN

Type of Survey	No. of respondents	Average burden/response	Total hours of burden
Mail/telephone surveys	51,200	.15	7,680
Automated/Web-based	52,000	D.163	8.476
Focus groups	200	1.0	200
Totals	103,400	NA	16,356

Request for Comments

In accordance with the above cited Paperwork Reduction Act legislation, comments on the AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 16, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–21339 Filed 9–22–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0408]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing the initiation of a Regulatory Site Visit Training Program. This program is intended to give CBER's regulatory review staff, compliance staff, and other relevant staff an opportunity to visit biologics facilities. The visit is intended to provide first hand experience to CBER staff and to give a better understanding of the biologics industry, including its challenges and its operations. The purpose of this notice is to invite biologics companies interested in participating in this program to contact CBER for more information.

DATES: Submit a written or electronic requests for participation in this program by October 25, 2004.

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, you should submit a request to participate in this program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Lonnie Warren-Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, e-mail: *cbertrainingsuggestions@cber.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates biological products including blood and blood products, vaccines, and cellular and gene therapies. CBER is committed to advancing the public health through innovative regulations that help ensure the safety, effectiveness, and timely delivery to patients of biological products. CBER has initiated various training and development programs to promote high performance of its regulatory review staff, compliance staff, and other relevant CBER staff. CBER seeks to continuously enhance and update review efficiency and quality as well as the quality of its regulatory efforts and interactions. CBER is initiating the Regulatory Site Visit Training Program to provide CBER staff the opportunity to visit biologics facilities to observe first-hand the industry's biologic development and manufacturing processes and thereby obtain better understanding of the biologics industry and its operations.

Further, this program is intended to improve CBER's understanding of current practices, regulatory impacts and needs, and improve communication between CBER staff and industry. The first phase of the program will focus on blood, plasma, and fractionation industries including transfusion centers, although other industries may be considered including vaccines, cellular and gene therapy, and tissues.

II. The Regulatory Site Visit Training Program

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the biologics facility, small groups (five or less) of CBER staff may observe operations of biologics manufacturing, packaging, pathology/toxicology laboratory testing, and regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory enforcement function, but are meant to improve mutual understanding and to

provide an avenue for open dialog between the biologics industry and CBER.

B. Site Selection

All travel expenses associated with the site visits will be the responsibility of CBER. Therefore, selection of potential biologics facilities will be based on the coordination of CBER's priorities for staff training and the limited available resources for this program.

Dated: September 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21318 Filed 9–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0371]

Guidance for Industry and Food and Drug Administration Staff: Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan.'' This class II special controls guidance document describes a means by which beta-glucan serological assays used for the detection of invasive fungal infection may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify beta-glucan serological assays into class II (special controls). This guidance document is immediately in effect as the special control for beta-glucan serological assays, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan'' 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: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096, ext. 111.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify beta-glucan serological assays into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). FDA is taking this action in response to a March 22, 2004, petition submitted by the Associates of Cape Cod, Inc., that requested classification of the beta-glucan serological assay under section 513(f)(2) of the act. This guidance document will serve as the special control for the beta-glucan serological assay devices. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs (§ 10.115). The guidance represents the agency's current thinking on beta-glucan serological assays for the detection of invasive fungal infection. 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 ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan'' by fax machine, 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 (1825) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

To receive ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *gwa@cdrh.fda.gov* to receive a hard copy or an electronic copy. Please use the document number (1825) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the 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