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

on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 10, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–21317 Filed 9–22–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden 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 through the use of automated collection techniques or other forms of information technology.

Proposed Project: Medicaid Mental Health Services Program and Analytic Reports—New

The Substance Abuse and Mental Health Services Administration (SAMHSA) will conduct a survey of state Medicaid directors to learn about the relationships between state mental health authorities and state Medicaid agencies in each state and the District of Columbia. In addition, SAMHSA will ask about the administration of Medicaid mental health services, the development of Medicaid mental health policy, mental health services statistics generated by Medicaid programs, and the characteristics of mental health-related data maintained by Medicaid agencies and used by mental health and other state agencies.

The survey will contact state Medicaid directors in all fifty states (and the District of Columbia) and will gather information on the following five survey domains: Organizational structure; Medicaid mental health services policy infrastructure; Medicaid mental health services, rates, and funding; Medicaid mental health providers; and, Data.

The survey will identify and describe, at the state level, how Medicaid mental health policy is developed; whether Medicaid mental health services and providers are treated differently from other Medicaid services and providers, and if so, how; and the availability of data and reports on Medicaid mental health service use and/or expenditures.

This information collection supports the New Freedom Initiative, one of SAMHSA's current priorities. As part of this effort, the President launched the New Freedom Commission on Mental Health to address the problems in the current mental health system. The Commission noted that fragmentation of responsibility for mental health services is a serious problem at the state level. Two of the Commission's 19 recommendations for the improvement of the mental health system were aimed at this problem. One was directed to states (create a comprehensive state mental health plan) and the other to the federal government (align relevant federal programs to improve access and accountability for mental health services). This survey is aimed at providing information that can help in carrying out these recommendations by further illuminating the relationships between state Medicaid and mental health agencies in the development and implementation of mental health policy.

Telephone interviews will be conducted with state Medicaid directors. Each interview will last one hour. Because of the open-ended nature of many of the survey questions and the general reluctance of state Medicaid directors to complete detailed paper or electronic surveys, we propose to conduct all the interviews by telephone, unless interviewees prefer to respond to a paper or electronic version.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Number of respondents	Responses per respondent	Hours per response	Total hour burden
51	1	1	51