laboratory services. Such issues may include the development, validation, performance, safety, and application of such tests. Nominees must demonstrate personal experience with clinical laboratory tests and services through a past or present history of direct employment with an organization that furnishes clinical diagnostic laboratory tests, or in an academic or research capacity. For purposes of this Panel, consultants or independent contractors are not considered to be representatives of clinical laboratories.

All members will serve on a voluntary basis, without compensation, pursuant to advance written agreement. Members of the Panel will be entitled to receive reimbursement for travel expenses and per diem in lieu of subsistence expenses, in accordance with standard Federal Travel Regulations. A member may serve after the expiration of his/her term until a successor has been sworn in.

The nominees will be evaluated based on expertise and factors needed to maintain a balance of representation on the Panel. These factors include, but are not limited to, geographic area representation, female and minority representation, points of view, and areas of expertise (for example, medical, scientific, financial, technical, or administrative). In addition, all nominees must have at least 5 years of experience with clinical diagnostic laboratory tests or genetic testing.

Nominations will be considered from all geographic locations within the United States or its territories. Any organization or person may nominate one or more qualified individuals for Panel membership. Self-nominations will also be accepted.

Each nomination must state that the nominee has expressed a willingness to serve as a Panel member and must be accompanied by a curriculum vitae and a brief biographical summary of the nominee's experience. All curricula vitae must include the following:

- Title and current position.
- Professional affiliation.
- Home and business address.
- Telephone and fax numbers.
- Email address.
- List of areas of expertise.

In addition, each nomination letter must include the reasons why the nominee should be considered, as well as a written and signed statement that the nominee is willing to serve on the Panel under the conditions described in the notice and further specified in the Charter.

The top nominees will be contacted in regard to their interest and availability. Phone interviews of nominees may also be requested after review of the nominations. The CMS Administrator or designee will make the final decision about who will serve on the Panel. Formal letters of invitation to serve on the Panel will be extended by the CMS Administrator.

To permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

The selected candidates will be invited to serve for a term of up to 3 years, contingent upon the renewal of the Panel by appropriate action prior to its termination. A member may serve after the expiration of that member's term until a successor takes office. Any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term.

III. Copies of the Charter

The Secretary's Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS Web site at *http://www.cms.gov/FACA/XXXXXXX.asp*, or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION** section of this notice.

Dated: October 21, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–25401 Filed 10–24–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: Grant Reviewer Recruitment.

Title: Grant Reviewer Recruitment Form.

OMB No.: NEW.

Description: The Administration for Children and Families' Children's Bureau (CB) is responsible for administering the review of eligible grant applications submitted in response to funding opportunity announcements issued by CB. CB ensures that the objective review process is independent, efficient, effective, economical, and complies with the applicable statutes, regulations, and policies. Applications are reviewed by subject experts knowledgeable in child welfare and related fields. Review findings are advisory to CB; CB is responsible for making award decisions.

This announcement is a request for approval of the proposed information collection system, the Reviewer Recruitment Module (RRM). CB will use a web-based data collection form and database to gather critical reviewer information in drop down menu format for data such as: Degree, occupation, affiliations with organizations and institutions that serve special populations, and demographic information that may be voluntarily provided by a potential reviewer.

These data elements will help CB find and select expert grant reviewers for objective review committees. The web-based system will permit reviewers to access and update their information at will and as needed. The RRM will be accessible by the general public via *https://rrm.grantsolutions.gov/AgencyPortal/cb.aspx.*

Respondents: Generally, our reviewers are current or retired professionals with backgrounds in child welfare and related fields and in some instances current or former foster care parents or clients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Reviewer recruitment module	500	1	.25	125

Estimated Total Annual Burden Hours: 125.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–25526 Filed 10–24–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1630]

Draft Guidance for Industry on Qualification for the Use of Galactomannan in Serum and Bronchoalveolar Lavage Fluid; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Draft Guidance on Qualification of Biomarker—*Galactomannan* in Studies of Treatments of Invasive Aspergillosis.'' This draft guidance provides recommendations on the use of *Galactomannan* detection in serum and/or bronchoalveolar lavage (BAL) fluid as the sole microbiological criterion to classify patients as having probable invasive Aspergillosis (IA) for enrollment in clinical trials. This draft guidance provides the context of use for which this biomarker drug development tool (DDT) is qualified through the Center for Drug Evaluation and Research (CDER) DDT Qualification Program. In the **Federal Register** of January 7, 2014, FDA announced the availability of a guidance for industry entitled ''Qualification Process for Drug Development Tools,'' which described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA's Web site. The qualification recommendations in this draft guidance were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 26, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research (Office of Translational Sciences, Immediate Office), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Draft Guidance on Qualification of Biomarker—*Galactomannan* in studies of treatments of invasive Aspergillosis.'' This draft guidance provides recommendations on the use of *Galactomannan* detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients as having probable IA for enrollment in clinical trials. The draft guidance provides the context of use for which this biomarker DDT is qualified through the CDER DDT Qualification Program. Qualification of this biomarker for this specific context of use represents the conclusion that analytically valid measurements of the biomarker can be relied on to have a specific use and interpretable meaning. Further, the biomarker can be used by drug developers for the qualified context in submission of investigational new drug applications, new drug applications, and biologics licensing applications without the relevant CDER review group reconsidering and reconfirming the suitability of the DDT. Qualification means that the use of this biomarker in the specific context of use is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health. The draft guidance is an attachment to the guidance for industry entitled ''Qualification Process for Drug Development Tools.''

In March 2006, FDA issued the ''Critical Path Opportunities Report and List,'' in which FDA described six key areas along the critical path to improved therapies and listed specific opportunities for advancement within these topic areas. The report noted that a new product development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development.

In 2008, the Mycoses Study Group proposed using *Galactomannan* in serum and BAL fluid as an indicator of IA in lieu of culture in patients with hematologic malignancies and recipients of allogeneic hematopoietic stem cell transplants and who also have radiologic evidence suggestive of invasive fungal infection (Ref. 1). A qualification review team of experts evaluated the data supporting the proposed context of use and rendered a qualification recommendation. The qualification recommendation in the draft guidance includes the following information:

- A use statement;
- conditions for qualified use of the assay;
- patient populations;