CFSAC:JUNE2012@seamoncorporation.com. Direct other inquiries to *cfsac@hhs.gov*.

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002 to advise, consult with, and make recommendations to the Secretary through the Assistant Secretary for Health, on a broad range of topics including: (1) The current state of knowledge and research on the epidemiology, etiologies, biomarkers, treatment, and risk factors relating to chronic fatigue syndrome (CFS), to identify potential opportunities in these areas; (2) the impact and implications of current and proposed diagnosis and treatment methods for CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical research communities about CFS; and (4) strategies to improve the quality of life for CFS patients.

The agenda for this meeting is being developed and will be posted on the CFSAC Web site, *http://www.hhs.gov/advcomcfs* when finalized. The meeting will be live-video streamed at *www.HHS.gov/Live* and archived through the CFSAC Web site: *www.hhs.gov/advocomcfs*. Listening-only audio via telephone will be available on both days. Call-in information will be posted on the CFSAC Web site.

Public attendance is welcome, but due to limited space advance registration is required. Individuals who plan to attend should register at the following link by June 8, 2012: *http://www.blsmeetings.net/CFSACJune2012*. Members of the media will also need to register. All attendees will be required to show government-issued picture identification for entry into the federal building. Attendees will receive a wrist band that must be worn the entire time. Security requires all non-federal employees to be escorted the entire time they are in the building. Upon leaving the building for any reason all persons will be required to follow the security steps mentioned above and receive a new wrist band.

Members of the public will have the opportunity to provide public comments at the meeting or via telephone. International calls cannot be accommodated. A separate sign-up process for requesting time for public comment must be completed by June 6, 2012 at the following link: *http://www.blsmeetings.net/CFSACPublicComment*. Individuals wishing to provide public comment must also submit an electronic copy of their testimony in advance to: *CFSACJUNE2012@seamoncorporation.com* by Wednesday, June 6, 2012. We require that you email a document (5 pages or less) in MS WORD format that is single-spaced, 12 point font. Note: PDF files, hand-written notes and photographs will not be accepted. Requests for public comment and written testimony will not be accepted through the CFSAC mailbox. Also, the CFSAC mailbox will not respond to questions about specific public comment requests.

All public comment becomes part of the public record, available for viewing and posted on the CFSAC Web site. All testimony and printed material submitted for the meeting are part of the official meeting record and will be uploaded to the CFSAC Web site and made available for public inspection. Testimony and materials submitted should not include sensitive personal information, such as social security number, birthdates, driver's license number, state identification or foreign country equivalent, passport number, financial account number, or credit or debit card number. Sensitive health information, or non-public corporate or trade association information, such as trade secrets or other proprietary information should be excluded from any materials submitted. If you wish to remain anonymous the document must specify this.

We will confirm your time for public comment via email by June 11, 2012. Each speaker will be limited to five minutes per speaker; no exceptions will be made. We will give priority to individuals who have not provided public comment within the previous year.

Persons who wish to distribute printed materials to CFSAC members should submit one copy to Designated Federal Officer at *cfsac@hhs.gov,* prior to Wednesday, June 6, 2012. Submissions are limited to five typewritten pages.

Dated: May 17, 2012.

Nancy C. Lee,

Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 2012–13097 Filed 5–29–12; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: 1309 Head Start Facilities Construction, Purchase and Major Renovations.

OMB No.: 0970–0193.

Description: The Head Start Bureau is proposing to renew, without changes, the information collections activities for the regulations in 45 CFR part 1309. The part contains the administrative requirements applicable to Head Start and Early Head Start grantees, when applying for funding to purchase, renovate or construct Head Start program facilities. The regulations ensure that standard business practices are applied when acquiring real property and that federal interest is preserved in properties acquired with public funds. The regulations further ensure compliance with all other federal statues applicable to the expenditure of federal funds when acquiring real property.

Respondents: Head Start and Early Head Start programs are delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CFR Part 1309	200	1	41	8200

Estimated Total Annual Burden Hours: 8200.

Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title

of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–13029 Filed 5–29–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0432]

Draft Guidance for Industry on Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint To Support Accelerated Approval; 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 ''Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' FDA's accelerated approval regulations permit approval of a new drug to treat a serious disease on the basis of an effect on a surrogate endpoint reasonably likely to predict the clinical benefit of the drug. This draft guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pathologic complete response (pCR) as a surrogate endpoint that could support approval under the accelerated approval regulations. Despite advances in systemic therapy of early-stage breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. This guidance is intended to encourage industry innovation and expedite the development of breakthrough therapies to treat high-risk early-stage breast cancer.

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 July 30, 2012.

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: Tatiana Prowell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5249, Silver Spring, MD 20993–0002, 301–796–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' Under the accelerated approval regulations (21 CFR part 314, subpart H, and 21 CFR part 601, subpart E), FDA may grant marketing approval for a new drug on the basis of adequate and well-controlled trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit (e.g., an effect on survival or irreversible morbidity), provided that the applicant conducts additional trials after approval to verify and describe the predicted clinical benefit. This draft guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pCR as a surrogate endpoint that could support approval under the accelerated approval regulations. The guidance proposes a uniform definition of pCR for regulatory purposes. The guidance also advises on appropriate patient populations for inclusion and on the trial designs intended to verify the predicted clinical benefit associated with pCR to support conversion to full approval.

FDA recognizes that despite advances in adjuvant systemic therapy of breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. Developing highly effective new drugs for these populations is an FDA priority. In providing guidance on the use of pCR as a surrogate endpoint that could support accelerated approval in the neoadjuvant setting, FDA hopes to encourage industry innovation and expedite the development of breakthrough therapies to treat high-risk early-stage breast cancer.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the use of pCR in neoadjuvant treatment of high-risk early-stage breast cancer as an endpoint to support accelerated approval. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information for special protocol assessments have been approved under OMB control number 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the