comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: The Fiscal Soundness Reporting Requirements; Use: The Centers for Medicare and Medicaid Services (CMS) is assigned responsibility for overseeing the on-going financial performance for all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors and Program of All-Inclusive Care for the Elderly (PACE) organizations. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. The revised fiscal soundness reporting form combines MAO, PDP, 1876 Cost Plans, Demonstration Plans and PACE organizations. Entities contracting in these programs currently submit all documentation being requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a net loss, a negative net worth or both must file three quarterly statements. Currently there are approximately 44 MAOs filing quarterly financial statements. The PDPs must also file three unaudited quarterly financial statements. The PACE organizations are required to file 3 quarterly financial statements for the first three years in the program. Additionally, PACE organizations with a net loss, a negative net worth or both must file statements as well.

The information collection request is being revised to include one additional data element for PACE organizations only, Total Subordinated Liabilities. The addition of the new data element will actually reduce the time to analyze the financial standing of PACE organizations because we will no longer have to contact the PACE organizations to establish whether or not the organization's total liabilities calculation includes subordinated debt. *Form Number:* CMS–906 (OCN: 0938–0469); *Frequency:* Annually, Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 648; *Total Annual Responses:* 1,281; *Total Annual Hours:* 428. (For policy questions regarding this collection contact Joe Esposito at 410–786–1129. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *November 5, 2012:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–R–284 (OCN 0938–0345), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 29, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–21671 Filed 8–31–12; 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

Title: Child Care and Development Fund Plan for States/Territories for FFY 2014–2015 (ACF–118).

OMB No.: 0970–0114.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for States and Territories is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101–508, Pub. L. 104–193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF–118, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the States' and Territories' child care programs. The ACF–118 is currently approved through April 30, 2014, making it available to States and Territories needing to submit Plan Amendments through the end of the FY 2013 Plan Period. However, on July 1, 2013, States and Territories will be required to submit their FY 2014–2015 Plans for approval by September 30, 2013. Consistent with the statute and regulations, ACF requests revision of the ACF–118 with minor corrections and modifications. The Tribal Plan (ACF–118a) will be addressed under a separate notice.

Respondents: State and Territory CCDF Lead Agencies (56).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–118	56	0.50	162.5	4,550

Estimated Total Annual Burden Hours: 4,550.

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 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. 2012–21695 Filed 8–31–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–0458]

Determination That ALOXI (Palonosetron Hydrochloride) Capsules, 0.5 Milligram (Base), Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ALOXI (palonosetron hydrochloride (HCl)) Capsules, 0.5 milligram (mg) (base), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for palonosetron HCl capsules, 0.5 mg (base), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 301–796–3543.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), is the subject of NDA 22–233, held by Helsinn Healthcare, and initially approved on August 22, 2008. ALOXI is indicated for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Helsinn Healthcare has never marketed ALOXI (palonosetron HCl) Capsules, 0.5 mg (base). In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc. submitted a citizen petition dated May 7, 2012 (Docket No. FDA–2012–P–0458), under 21 CFR 10.30, requesting that the Agency determine whether ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.