Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–06311 Filed 4–1–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19VJ; Docket No. CDC–2019–0013]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled The Childcare Survey of Activity and Wellness (C-SAW) Pilot Study. The pilot study will determine the current practices and policies of early care and education (ECE) providers in four states around nutrition, physical activity, and wellness and will inform the development of a potential national surveillance system.

DATES: CDC must receive written comments on or before June 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0013 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

The Childcare Survey of Activity and Wellness (C–SAW) Pilot Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) works to promote optimal nutrition, physical activity, and wellness in early care and education (ECE) facilities for children 0–5 years of age. Consistent with this mission, and with clear evidence that ECE facilities can impact the habits and preferences of young children, this survey is necessary to better understand ECE center practices related to nutrition, physical activity, and wellness. These critical data are used to effectively inform state and national programs.

Data collected from this pilot survey will be used to understand the current practices of ECE centers in a representative sample in four states. This initial C–SAW will establish baseline measures of the prevalence of specific practices related to nutrition, physical activity, and wellness in a standard way across states. This baseline will also allow CDC and state partners to better understand ECE center needs and provide opportunities for collaboration and areas for improvement at the state and national levels. Second, the survey will be used to inform the development of a potential national surveillance system enabling states and CDC to track changes over time and obtain data to guide the planning, implementation, and evaluation of national and state obesity prevention efforts.

A sample of approximately 1,266 ECE centers across four states will be selected to participate in this one-time data collection effort. However, it is estimated that approximately 10% of the original sample will be out of business or otherwise ineligible yielding an actual sample of 1,140 ECEs to be recruited. Each center will receive a recruitment letter introducing the survey, explaining its objectives and the importance of their participation, and instructions for completing the survey. It is anticipated that most responses will be submitted through the web. However, paper surveys will be available upon request. Approximately two weeks after the initial recruitment letter is mailed, all sampled centers will receive a reminder postcard. Approximately four weeks after the initial recruitment letter is mailed, nonrespondents will be sent another letter along with a hardcopy of the questionnaire. It is also anticipated that the response rate will be approximately 55% based on a review of recent surveys of child care centers conducted by the Federal government. Thus, we anticipate the number of completed surveys to be 627. CDC requests approval for an estimated 409 Burden Hours. Participation in this study is completely voluntary and there are no costs to the respondent other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
ECE Director or Administrator	Recruitment Letter	1,140	1	5/60	95
ECE Director or Administrator	Web/Mail Survey	627	1	30/60	314
Total					409

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0803]

Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Technical Electronic Product Radiation Safety Standards Committee (Committee) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until December 24, 2020.

DATES: Authority for the Technical Electronic Product Radiation Safety Standards Committee would have expired on December 24, 2018, unless the Commissioner formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993–0002, 301–796–6875, *Patricio.Garcia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Committee. The Committee is a non-discretionary Federal advisory committee established to provide advice and consultation to the Commissioner. The Commissioner of Food and Drugs is charged with the administration of the Radiation Control for Health and Safety Act of 1968. This act creates the Committee and requires the Commissioner to consult with the Committee before prescribing standards for radiation emissions from electronic products. This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products and may recommend electronic product radiation safety standards to the Commissioner for consideration.

The Committee shall consist of a core of 15 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the Committee by appropriate action prior to its expiration. The core of voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/default.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: March 27, 2019.

Lowell J. Schiller,

Commissioner of Food and Drugs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–2754]

Determination That ONFI (Clobazam) Tablets, 5 Milligrams, Was 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 or Agency) has determined that ONFI (clobazam) tablets, 5 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to the drug product, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

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