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[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

Jeffrey M. Zirger,

*Lead, Information Collection Review Office,
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Centers for Disease Control and Prevention.*

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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.

[FR Doc. 2019-06360 Filed 4-1-19; 8:45 am]

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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