

form will take approximately one hour which results in 20 burden hours each.

The total estimated and time-related burden is 40 hours.

There are no costs to respondents 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 hrs.)
Nursing Home Administrator .....	Evaluation of Nursing Home Workplace Violence Prevention Program: Abstraction Form.	20	1	1
Nursing Home Administrator .....	Committee Chair Interview .....	20	1	1

**Leroy A. Richardson,**  
 Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* National Center on Early Head Start Child Care Partnerships (NCEHS-CCP) Evaluation.

*OMB No.:* New Collection.

*Description:* The Administration for Children and Families (ACF) in the Department of Health and Human Services (HHS) has awarded 275 Early Head Start expansion and Early Head Start-child care partnership grants (EHS-CCP) in 50 states; Washington, DC; Puerto Rico; and the Northern Mariana Islands. These grants will allow new or existing Early Head Start programs to partner with local child care centers and family child care providers to expand high-quality early learning opportunities for infants and toddlers from low-income families.

NCEHS-CCP will support the effective implementation of new EHS-

CCP grants by disseminating information through training and technical assistance (T/TA) and resources and materials. NCEHS-CCP is primarily targeted to T/TA providers working directly with the EHS-CCP grantees (including Office of Head Start (OHS) and Office of Child Care (OCC) National Centers, regional training and technical assistance (T/TA) specialists, and implementation planners and fiscal consultants). State and federal agencies (including OHS and OCC federal staff, Child Care and Development Fund (CCDF) administrators, Head Start State and National Collaboration directors), as well as EHS-CCP grantees will also find helpful information on partnerships through NCEHS-CCP's resources.

The NCEHS-CCP at ZERO TO THREE is proposing to conduct a descriptive study of NCEHS-CCP that will provide information that will document the activities and progress of NCEHS-CCP toward its goals and objectives. Findings from the evaluation will be translated into action steps to inform continuous quality improvement of NCEHS-CCP.

The proposed data collection activities for the descriptive study of NCEHS-CCP will include the following components:

- *Stakeholder survey.* Web-based surveys will be conducted in the spring of 2016 and 2018 with key stakeholders (including OHS and OCC federal and national center staff, regional T/TA specialists, CCDF administrators, Head Start state and national collaboration

office directors, and implementation planners and fiscal consultants). The stakeholder survey will collect information about the types of support they received from NCEHS-CCP in the past year, their satisfaction with the support, how the T/TA informed their work with EHS CCP grantees, and how support could be improved.

- *Stakeholder telephone interviews.* Semi-structured telephone interviews will be conducted in spring of 2017 and 2019 with a purposively selected subgroup of stakeholders that complete the stakeholder survey. The interviews will explore in more detail the types of T/TA support participants received from NCEHS-CCP, how that support has informed their work with EHS-CCP grantees, their satisfaction with the support, successes and challenges, and suggestions for improvement.

This 60-Day Federal Register Notice covers the data collection activities for NCEHS-CCP and requests clearance for (1) the stakeholder survey, and (2) the stakeholder telephone interviews.

*Respondents:* Respondents include OHS and OCC federal and national center staff, regional T/TA specialists, CCDF administrators, Head Start state and national collaboration office directors, and implementation planners and fiscal consultants.

*Annual Burden Estimates:* The following instruments are proposed for public comment under this 60-Day **Federal Register** Notice.

Instrument	Total number of respondents	Annual number of responses per respondent	Number of responses per respondent	Average burden hours per response	Annual burden hours
Stakeholder survey .....	350	1	2	.5	175
Stakeholder telephone interviews .....	150	1	1	1.0	75

*Estimated annual burden total:* 250.

In compliance with the requirements of Section 3506(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: OPRE Reports Clearance Officer.  
Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-3534]

#### **Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of public docket.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is developing a list of bulk drug substances (active ingredients) that can be used to compound drug products in accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (503A bulks list). The Agency previously solicited nominations for the list, but some of the nominated substances were not supported by sufficient information for FDA to evaluate them. FDA is establishing a public docket where these substances can be renominated with sufficient supporting information or to receive

nominations of bulk drug substances that were not previously nominated for consideration for inclusion on the 503A bulks list. Interested parties can also submit comments on nominated substances via this docket.

**DATES:** Nominations and comments may be submitted to this docket at any time.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-N-3534 for "Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket." Received comments will be placed in

the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Philantha Bowen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5175, Silver Spring, MD 20993-0002, 301-796-2466.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions under which a compounded drug