ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Aim 1 participants—YMSM; General public, adults.	Aim 1 Participant Follow-up Survey	134	4	30/60	268
Aim 2 participants—YMSM; General public, adults.	Aim 2 Participant Eligibility Screener	20	1	5/60	2
Aim 2 participants—YMSM; General public, adults.	Aim 2 Participant Locator Form	10	1	5/60	1
Aim 2 participants—YMSM; General public, adults.	Aim 2 Participant Interview Guide ...	10	1	1.0	10
Aim 3 participants—providers; General public, adults.	Aim 3 Participant Eligibility Screener	14	1	5/60	2
Aim 3 participants—providers; General public, adults.	Aim 3 Participant Locator Form	7	1	5/60	1
Aim 3 participants—providers; General public, adults.	Aim 3 Participant Interview Guide ...	7	1	1.0	7
Aim 3 participant—clinic staff respondent, 1 per clinic site; General public, adults.	Aim 3 Clinic Assessment	4	2	30/60	4
Total	.....	.....	.....	.....	441

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–17921 Filed 8–18–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–1319; Docket No. CDC–2023–0073]

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 continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level. This surveillance collects the fluoridation status of, and population served by the nation's 52,000 community water systems (CWS) which serve the 50 States and the District of Columbia.

DATES: CDC must receive written comments on or before October 20, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0073 by either of the following methods:

- *Federal eRulemaking Portal: www.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 H21–8, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (*www.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 H21–8, Atlanta, Georgia 30329; Telephone: 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;

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; and

5. Assess information collection costs.

Proposed Project

National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level (OMB Control No. 0920–1319, Exp. 2/29/2024)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Community water fluoridation is the process of adjusting the fluoride concentration of a community water system (CWS) to the level beneficial for prevention of dental caries as recommended by the U.S. Public Health Service (PHS). Community water fluoridation is a major factor contributing to the large decline in caries in the U.S. in the past 75 years and is recognized as one of 10 great public health achievements of the twentieth century. Community water fluoridation reduces dental caries by 25% and is a safe and the cost-effective way to deliver fluoride to people of all ages, regardless of education and income level. It is especially important for populations with limited access to preventive dental measures.

CDC is authorized to collect the information under the U.S. Public Health Service Act. This data collection aligns with CDC's strategy to use public health surveillance to inform programs and policies to improve the oral health of the nation by reducing disparities and expanding access to effective prevention programs. CDC uses the Water Fluoridation Reporting System (WFRS) to collect water fluoridation coverage and quality throughout the U.S. This data allows CDC and States to monitor the performance and efficiency of their water fluoridation programs, which will improve and extend program delivery. Respondents to the information collection are State fluoridation managers or other State government officials designated by the State dental director or drinking water administrator. State participation in the data collection is voluntary.

CDC requests OMB approval for an estimated 2,824 annual burden hours. There is no cost to respondents other than their time to participate.

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)
State Official	Fluoridation status and population	50	1	38	1,900
State Official	Fluoride testing data	33	1	28	924
Total					2,824

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–17925 Filed 8–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3240]

List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is evaluating substances that have been nominated for inclusion on a list of bulk drug substances (active pharmaceutical ingredients) for which there is a clinical need (the 503B Bulks List). Drug products that outsourcing facilities compound using bulk drug substances on the 503B Bulks List can qualify for certain exemptions from the Federal Food, Drug, and Cosmetic Act (FD&C Act) provided certain conditions are met. This notice identifies two bulk drug substances that FDA has considered and is not including on the list at this time: ephedrine sulfate and hydroxychloroquine sulfate. Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of future notices.

DATES: The announcement of the notice is published in the **Federal Register** on August 21, 2023.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Tracy Rupp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that must be satisfied for drug products compounded in an outsourcing facility to be exempt from section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)), section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and section 582 of the FD&C Act (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).[1]

Compounded drug products that meet the conditions set forth in section 503B are not exempt from current good manufacturing practice (CGMP) requirements in section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).[2] Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.[3] Outsourcing facilities may or may not obtain prescriptions for identified individual patients and can, therefore, distribute compounded drugs to healthcare

[1] Section 503B(a) of the FD&C Act.

[2] Compare section 503A(a) of the FD&C Act (21 U.S.C. 353a(a) (exempting drugs compounded in accordance with that section)) with section 503B(a) of the FD&C Act (not providing an exemption from CGMP requirements).

[3] Section 503B(b)(4) and (5) of the FD&C Act.