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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-0770]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “National HIV Behavioral Surveillance System (NHBS)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on May 13, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) 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;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) 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 submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National HIV Behavioral Surveillance System (NHBS) (OMB Control No. 0920-0770, Exp. 01/31/2023)—Revision—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this data collection is to monitor behaviors of persons at high risk for infection that are related to Human Immunodeficiency Virus (HIV) transmission and prevention in the United States. The primary objectives of the NHBS are to obtain data from samples of persons at risk to: (a) describe the prevalence and trends in risk behaviors; (b) describe the prevalence of and trends in HIV testing and HIV infection; (c) describe the prevalence of and trends in use of HIV prevention services; and (d) identify met and unmet needs for HIV prevention services in order to inform health departments, community based organizations, community planning groups and other stakeholders.

By describing and monitoring the HIV risk behaviors, HIV seroprevalence and incidence, and HIV prevention experiences of persons at highest risk for HIV infection, NHBS provides an important data source for evaluating progress towards national public health initiatives, such as reducing new infections, increasing the use of

condoms, and targeting populations at high risk.

The Centers for Disease Control and Prevention requests approval for a three-year Revision of this information collection. Data are collected through in-person interviews conducted with persons systematically selected from 20 Metropolitan Statistical Areas (MSAs) throughout the United States; these 20 MSAs are chosen based on highest number of HIV infections diagnosed. Persons at risk for HIV infection to be interviewed for NHBS include men who have sex with men (MSM), persons who inject drugs (PWID), and heterosexually active persons at increased risk of HIV infection (HET). A brief screening interview will be used to determine eligibility for participation in the behavioral assessment.

The data from the behavioral assessment will provide estimates of: (1) behavior related to the risk of HIV and other sexually transmitted diseases; (2) prior testing for HIV; and (3) use of HIV prevention services.

All persons interviewed will also be offered an HIV test and will participate in a pre-test counseling session. No other federal agency systematically collects this type of information from persons at risk for HIV infection. These data have substantial impact on prevention program development and monitoring at the local, state, and national levels. CDC estimates that NHBS will involve, per year, in up to 20 MSAs, eligibility screening for 125 persons and eligibility screening plus the behavioral assessment with 500 eligible respondents, resulting in a total of 30,000 eligible survey respondents and 7,500 ineligible screened persons during a three-year period. Data collection will rotate such that interviews will be conducted among one group per year: MSM in Year 1, PWID in Year 2, and HET in Year 3. The type of data collected for each group will vary slightly due to different sampling methods and risk characteristics of the group.

Participation of respondents is voluntary and there is no cost to the respondents other than their time. CDC requests OMB approval for an estimated 6,600 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Persons Screened	Eligibility Screener	12,500	1	5/60
Eligible Participants	Behavioral Assessment MSM	3,333	1	24/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Eligible Participants	Behavioral Assessment PWID	3,333	1	43/60
Eligible Participant	Behavioral Assessment HET	3,333	1	31/60
Peer Recruiters	Recruiter Debriefing	3,333	1	2/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970-0577]

Proposed Information Collection Activity; Evaluation of LifeSet

Correction

In notice document 2022-16791, appearing on pages 48033 through 48034 in the issue of Friday, August 5, 2022, make the following corrections:

1. On page 48034, in the table, on the third row, in the second cell, “LifeSet Team Supervisors” should appear below “LifeSet Specialists”.

2. On the same page, in the same table, remove the fourth row including the text “LifeSet Team Supervisors”.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1593]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 12, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0823. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Accessories

OMB Control Number 0910-0823—*Extension*

FDA’s guidance document entitled “Medical Device Accessories—Describing Accessories and Classification Pathways”¹ is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA’s policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA generally considers an “accessory” and describes the processes under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(6)) to

¹ The guidance document is available on FDA’s website (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-accessories-describing-accessories-and-classification-pathways>).

allow requests for risk- and regulatory control-based classification of accessories.

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) changed how FDA regulates medical device accessories. Specifically, section 707 of FDARA added section 513(f)(6) to the statute and requires that FDA, upon request, classify existing and new accessories notwithstanding the classification of any other device with which such accessory is intended to be used. This means that the classification of an accessory may not be the same as its parent device, depending on the risks of the accessory when used as intended and the level of regulatory controls necessary for reasonable assurance of safety and effectiveness of the accessory. Until an accessory is distinctly classified, its existing classification will continue to apply. This provision does not preclude a manufacturer from submitting a De Novo request for an accessory.

Depending on an accessory’s regulatory history, there are different submission types, tracking mechanisms, and deadlines:

(1) Existing accessory types are those that have been identified in a classification regulation or granted marketing authorization as part of a 510(k), premarket approval application (PMA), or De Novo request (approved under OMB control numbers 0910-0120, 0910-0231, and 0910-0844, respectively). Manufacturers with marketing authorization for an existing accessory may request appropriate classification through a new stand-alone premarket submission (Existing Accessory Request). Upon request, FDA is required to meet with a manufacturer or importer to discuss the appropriate classification of an existing accessory prior to submitting a written request. Existing Accessory Requests will be initially tracked as “Q-submissions” (approved under OMB control number 0910-0756). FDA has a statutory deadline of 85 calendar days to respond to an Existing Accessory Request.

(2) New accessory types are those that have not been granted marketing authorization as part of a 510(k), PMA,