Security Standards with password and identification protections. File access is limited to individuals who have a need to know the information for performance of their official duties and who have appropriate clearances or permission.

RECORD ACCESS PROCEDURES:

Requests for access to a record should be directed to the Secretary listed at the above address. Requests may be in person or by mail and shall meet the requirements set out in out in 46 CFR 503.65.

CONTESTING RECORD PROCEDURES:

An individual desiring to amend a record shall direct such a request to the Secretary at the above listed address. Such requests shall specify the desired amendments and the reasons therefore and shall meet the requirements set out in of 46 CFR 503.66.

NOTIFICATION PROCEDURES:

Any individual shall be informed whether or not any Commission system of records contains a record pertaining to him or her when requested in accordance with the requirements of 46 CFR 503.63(a).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

N/A.

William Cody,

Secretary.

[FR Doc. 2023–01975 Filed 1–30–23; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0863]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Monthly Monitoring Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 March 2, 2023.

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 title of this information collection is ''Monthly Monitoring Study.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Monthly Monitoring Study

OMB Control Number 0910–NEW

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, FDA's Center for Tobacco Products (CTP) is developing and implementing multiple public education campaigns.

FDA launched ''The Real Cost'' in February 2014, seeking to reduce tobacco use among at-risk youth ages 12 to 17 years old in the United States who are open to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or have already experimented with cigarettes and/or ENDS products. Given the rapidly evolving tobacco landscape in the United States, frequent and nimble data collection strategies are needed to keep pace and provide relevant information to FDA to inform its tobacco prevention media campaign development about changes in tobacco use and emerging products among youth and young adults.

In an effort to inform specified recommendations around ''The Real Cost'' and FDA's other public education programs to reduce tobacco-related death and disease, more research is needed to understand the trends in use and perceptions of novel and emerging tobacco products, as well as awareness and preferences related to emerging tobacco products and specific brands and device types so that FDA can develop new media campaign messages that resonate with youth and young adults. The purpose of the Monthly Monitoring Study is to collect primary data from youth and young adults, ages 15 to 24 years old, in the United States to monitor perceptions and use of emerging and novel tobacco products and emerging trends in brand and device awareness and use.

The study will be conducted using web-based surveys that are self-administered on personal computers or web enabled mobile devices. The study will use an online survey to collect data from up to 27,000 youth and young adults ages 15 to 24 years to monitor perceptions about and trends in use of ENDS and other emerging tobacco products. Participants will be recruited through social media advertisements. To achieve the required pace of data collection, the study will not contact parents of youth under 18 years old for parental permission and will obtain a waiver of parental permission from the institutional review board. The study will include questions about marijuana use to allow the study team to differentiate between use of current and emerging tobacco products and marijuana, which can be used in tobacco products such as ENDS and little cigar/cigarillos. The survey will take approximately 20 minutes to complete per participant. This survey will ask participants to provide feedback on tobacco use and quitting behavior, as well as brand and device preferences, tobacco information sources, peer influence and perceptions, and marijuana use.

The aim of the Monthly Monitoring Study is to answer the following questions:

- What are the trends in brand and device use for ENDS products and other emerging tobacco products among youth and young adults ages 15 to 24 years in the United States? What are their perceptions of these products?
- How is respondent tobacco use affected by environmental factors, including peer influence and other external factors such as COVID–19?
- What are the primary sources of new product information and where are these products purchased/acquired?
- What are the primary sources of health information for ENDS and other emerging tobacco products?

In support of the provisions of the Family Smoking Prevention and Tobacco Control Act that require FDA to protect the public health and to reduce

tobacco use by minors, FDA requests OMB approval to collect data for the Monthly Monitoring Study.

In the **Federal Register** of July 26, 2022 (87 FR 44405), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) The commenter stated that they believed the study should include children as young as age 10 years.

(Response) The age range for inclusion of this study (15 to 24 years) is based on the target audience for CTP/Office of Health Communication and Education's campaigns, which are adolescents and young adults. Additionally, we are limited by the social media mode of data collection (platforms generally do not allow children younger than 13 years old to have accounts) and by the Children's Online Privacy Protection Rule, which does not allow us to contact youth 13 years old and under without parental permission. Furthermore, lowering the age range would greatly increase the time needed to field the survey, as well as the costs. Given that parental permission is not feasible for the social media-based recruitment, we must be granted a waiver of parental permission from our institutional review board. Our institutional review board has not historically granted a waiver of parental permission for respondents younger than 15 years old.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Screener	135,000	1	135,000	0.04167 (2.5 minutes)	5,625
Youth Assent	27,000	1	27,000	0.04167 (2.5 minutes)	1,125
Youth Online Survey	27,000	1	27,000	0.33333 (20 minutes) ..	9,000
Young Adult Screener	135,000	1	135,000	0.04167 (2.5 minutes)	5,625
Young Adult Consent	27,000	1	27,000	0.04167 (2.5 minutes)	1,125
Young Adult Online Survey	27,000	1	27,000	0.33333 (20 minutes) ..	9,000
Total	.....	.....	.....	.....	31,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We expect the screening process (2.5 minutes per response) to yield a 5 to 1 ratio of eligible participants. We will need to screen approximately 270,000 potential participants (135,000 youth and 135,000 young adults) over the study period. Participants determined to be eligible through the screener will complete a youth assent or young adult consent (2.5 minutes per response) and the online survey (20 minutes per response).

Over the course of the study period, we intend to survey approximately 1,500 youth ages 15 to 17 years old, and young adults ages 18 to 24 years old, every 1 to 2 months. The survey will be repeated with a new cross-sectional sample approximately every month or every other month over a period of 18 months. We will obtain a final sample size of 54,000 youth and young adults (27,000 youth and 27,000 young adults) over the course of the study period. Respondents will be allowed to complete an additional, cross-sectional survey after 6 months.

We made the following changes between the 30-day and 60-day publications: In reviewing recruitment metrics for two similar CTP studies, we found an average of 5:1 screening to survey completion ratio. Therefore, we adjusted the number of required screeners and burden hours accordingly.

Dated: January 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01978 Filed 1–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0249]

Authorization of Emergency Use of Two In Vitro Diagnostic Devices in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of mpox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Becton, Dickinson & Company (BD) and DiaCarta, Inc. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization issued to BD for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System is effective as of December 23, 2022. The Authorization issued to DiaCarta, Inc. for the QuantiVirus MPXV Test Kit is effective as of January 10, 2023.

ADDRESSES: Submit written requests for a single copy of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to