the instructions provided by the manufacturer (21 CFR 606.65(e)), including the directions provided in the instructions for use of the approved or cleared collection, processing, and storage system. To prepare blood components using the BC method, blood establishments must use blood collection, processing and storage systems approved or cleared for such use.

This guidance provides recommendations to manufacturers who wish to obtain FDA approval or clearance to market blood collection, processing, and storage systems intended for the manufacture of blood components for transfusion using the BC method. With the availability of such FDA-approved or cleared systems, blood establishments in the United States would have the option of manufacturing Whole Blood-derived blood components using the BC method and licensed blood establishments could submit Biologics License Application (BLA) supplements to FDA.

In the **Federal Register** of October 18, 2024, (89 FR 83886), FDA announced the availability of the draft guidance of the same title dated October 18, 2024. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to comments received, FDA made several clarifying edits. For example, FDA made clarifying revisions regarding timeframes for overnight ambient temperature holds, use of additive solutions that are currently not approved by FDA, and efforts to transition to systems that do not contain di(2-ethylhexyl) phthalate (DEHP). In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 18, 2024.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312.47 relating to the submission of investigational new drug applications and related meetings, including pre-IND meetings, ''pre-NDA'' stages, and pre-new drug application meetings, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314.102 relating to submission of new drug marketing applications, as well as related meetings between sponsors or applicants and FDA or other communication with appropriate FDA officials to obtain advice and other information necessary to support submissions, and to discuss appropriate regulatory pathways, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 807, subpart E relating to the submission of a premarket notification ((510(k)) for a medical device have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 812 relating to the submission of Investigational Device Exemption applications have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814 relating to the submission of a premarket approval application (PMA) have been approved under OMB control number 0910–0231.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19080 Filed 9–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at: *samhsapra@samhsa.hhs.gov.*

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

Proposed Project: National Survey on Drug Use and Health (OMB No. 0930–0110)

The National Survey on Drug Use and Health (NDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older within the 50 states and the District of Columbia. Consistent with NSDUH designs since 1991, the 2027 NSDUH will include residents of noninstitutional group quarters (*e.g.,* shelters, rooming houses, dormitories) and civilians residing on military bases. Excluded from the NSDUH are people without fixed household address (*e.g.,* homeless people not in shelters) and residents of institutional group quarters, such as jails and hospitals.

The 2027 sampling frame will exclude U.S. territories. Although data collection pilots were conducted to assess operational feasibility in Puerto Rico (2023–2025) and in the U.S. Virgin Islands (2024), SAMHSA determined that additional testing and discussions with other statistical agencies are needed before expanding full-scale

NSDUH data collection to Puerto Rico and the U.S. Virgin Islands.

The 2027 NSDUH will continue to use both in-person and web-based modes of data collection. Consistent with all NSDUH surveys conducted since 2002, each respondent who completes the full interview will be given a $30 incentive. The delivery method will depend on the interview mode: in-person respondents will receive a $30 cash incentive, while web-based respondents will receive either an electronic gift card by email or a physical gift card by mail, based on their preference.

NSDUH provides nationally representative data on the use of tobacco, alcohol, and drugs; substance use disorders; mental health issues; recovery from substance use disorders and mental health issues; and receipt of substance use and mental health treatment at the national, state, and substate levels. NSDUH data also help to identify the extent of substance use and mental illness among different population subgroups, estimate trends over time, and determine the need for treatment services. Substance use topics covered include lifetime, past-year, and past-month use; age at first use; substance use treatment history; perceived need for treatment; and substance use disorders. Mental health topics include major depressive episodes; suicidal ideation and attempts; general mental illness; and use of mental health care. NSDUH estimates allow researchers, clinicians, policymakers, and the general public to better understand and improve the nation's behavioral health.

The NSDUH questionnaire must be updated periodically to reflect changing substance use and mental health issues and to continue producing current data. For the 2027 NSDUH, planned changes from the 2026 questionnaire include: (1) revisions and additions to the Special Drugs module to prevent inconsistent reporting of last use of specific drugs with earlier modules; (2) revisions to the Risk/Availability module to ask about using marijuana rather than smoking marijuana; (3) addition to the Mental Health Services Utilization module to capture past 12-month use of a Crisis Line service; (4) reinstatement of a question in the Youth Experiences module about perceived attitudes of close friends; (5) revisions to the Consumption of Alcohol module to ask about polysubstance use in the past 30 days rather than the last time the respondent used drugs; (6) additions to the Emerging Issues module to measure past 12-month use of glucagon-like peptide-1 medications (GLP–1s), selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), mood stabilizers, and antipsychotic medications; (7) reinstatement of questions in the Employment module about workplace testing for drug and alcohol use; and (8) revisions to the Health Insurance and Income modules to include updated state program names for Medicaid, the Children's Health Insurance Program, and Temporary Assistance for Needy Families.

Overall, these changes are expected to generate data on new areas of interest, such as mental health medications and Crisis Line service utilization. They will also reinstate questions previously used by other federal agencies in their reporting and revise additional items to prevent misreporting.

The revisions to the Special Drugs module will allow the 2027 NSDUH to collect more consistent information across the survey and lower interview completion time by avoiding redundant questions for some respondents. Several questions in the Risk/Availability module were revised to ask about ''using'' marijuana rather than ''smoking'' marijuana. This wording change is intended to measure other ways of using marijuana that are common with youth, such as vaping or edibles. In the Mental Health Services Utilization module, the addition of a question capturing past 12-month use of a Crisis Line service is to provide new data on emerging topics. Reinstating items in the Youth Experience and Employment module will collect data needed by several government agencies for their ongoing reporting while revising polysubstance use questions in the Consumption of Alcohol module to a standardized past 30-day reference period will bring this data more in line with other NSDUH drug use questions. The new questions measuring use of mental health medications, GLP–1s, and Crisis Line services were added because the NSDUH did not previously include these items and they are of growing interest to data users. Questions about workplace testing for drug and alcohol use were also reinstated in the Employment module to collect data needed by several government agencies for their ongoing reporting. Finally, annual updates of state Medicaid, Children's Health Insurance Program, and Temporary Assistance to Needy Families program names were made to ensure question accuracy.

As with all NSDUH/NHSDA [1] surveys conducted since 1999, the sample size of the NSDUH for 2027 will be sufficient to permit prevalence estimates for each of the 50 states and the District of Columbia. The total annual burden estimate for the NSDUH is shown below in Table 1. The primary set of new items is included in the Emerging Issues Module, which appears near the end of the interview. By this point, respondents are familiar with the survey format and questionnaire structure. The additional questions will take about one minute for an average respondent to complete, as they are short, contained within a module, and use straightforward survey logic. Overall, while new questions are being added, it is not expected that the addition will result in any significant increase in participant burden, as the survey branches efficiently to keep it short for most respondents.

TABLE 1—ANNUALIZED ESTIMATED BURDEN FOR 2027 NSDUH

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	297,529	1	297,529	0.083	24,695
Interview	67,507	1	67,507	1.008	68,047
Screening Verification	6,248	1	6,248	0.067	419
Interview Verification	7,088	1	7,088	0.067	475
Total	378,372	.....	378,372	.....	93,636

[1] Prior to 2002, the NSDUH was referred to as the National Household Survey on Drug Abuse (NHSDA).

Send comments to SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57A, Rockville, MD 20852 *OR* email him a copy at *samhsapra@samhsa.hhs.gov.* Written comments should be received by November 16, 2026.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2026–19079 Filed 9–16–26; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0054]

Agency Information Collection Activities; Revision; Exportation of Used Self-Propelled Vehicles

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than November 16, 2026) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0054 in the subject line and the agency name. Please submit written comments and/or suggestions in English. Please use the following method to submit comments:

Email. Submit comments to: CBP_PRA@cbp.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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) 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) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to 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. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Exportation of Used Self-Propelled Vehicles.

OMB Number: 1651–0054.

Form Number: N/A.

Current Actions: Revision.

Type of Review: Revision.

Affected Public: Individuals and Businesses.

Abstract: U.S. Customs and Border Protection (CBP) regulations require an individual attempting to export a used self-propelled vehicle to furnish documentation to CBP at the port of export. Exportation of a vehicle is permitted only upon compliance with these requirements. The required documentation includes, but is not limited to, a Certificate of Title or a Salvage Title, the Vehicle Identification Number (VIN), a Manufacturer's Statement of Origin, etc. CBP will accept originals or certified copies of the Certificate of Title. Supporting documentation may be submitted through the Document Image System (DIS). The purpose of this information is to help ensure that stolen vehicles or vehicles associated with other criminal activity are not exported.

Collection of this information is authorized by 19 U.S.C.1627a, which provides CBP with authority to impose export reporting requirements on all used self-propelled vehicles. It is also authorized by Title IV, Section 401 of the Anti-Car Theft Act of 1992, 19 U.S.C. 1646(c), which requires all persons exporting a used self-propelled vehicle to provide to CBP, at least 72 hours prior to export, the VIN and proof of ownership of each automobile. This information collection is provided for by 19 CFR Part 192. Further guidance regarding these requirements is provided at: *https://www.cbp.gov/trade/basic-import-export/export-docs/motor-vehicle.*

Type of Information Collection: Exportation of Self-Propelled Vehicles.

Estimated Number of Respondents: 1,400,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 1,400,000.

Estimated Time per Response: 5 minutes (0.0833333 hours).

Estimated Total Annual Burden Hours: 116,667.

Dated: September 15, 2026.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2026–19073 Filed 9–16–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2026–0694; OMB No. 1660–0076]

Agency Information Collection Activities: Proposed Collection; Comment Request; Hazard Mitigation Grant Program (HMGP) Application Reporting

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of extension without revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this