(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 15, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act''. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure—(OMB Control Number 0910—New)

The draft guidance suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are outside the device's approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or conditions. The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use in order to determine areas where further pediatric device development could be useful. This recommendation applies to applicants who submit the following applications:

1. Any request for a humanitarian device exemption submitted under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m));

2. Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act (21 U.S.C. 360e);

3. Any product development protocol submitted under section 515 of the FD&C Act.

In the **Federal Register** of February 19, 2013, (78 FR 11654), FDA published a 60-day notice requesting public comment on the proposed collection of information. However, only one comment was interpreted as being related to the proposed collection of information.

One comment stated that FDA should not require all readily available information on pediatric uses of devices because it is unduly burdensome, but rather applicants should be required to perform a reasonable search. FDA disagrees with the comment. In order for FDA to be provided useful, comprehensive information and to fulfill the statutory mandate, all readily available information should be submitted to FDA. Moreover, the requirement is not unduly burdensome because FDA is only requiring all information that is readily available, not all information in general.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Uses outside approved indication	148	1	148	0.5	74

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

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814 (21 CFR part 814), subpart B have been approved under OMB control number 0910–0231, and the collections of information in part 814, subpart H have been approved under OMB control number 0910–0332.

Dated: December 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–29796 Filed 12–13–13; 8:45 am]

BILLING CODE 4160–01–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 on (240) 276–1243.

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: 2014–2017 National Survey on Drug Use and Health: Methodological Field Tests (OMB No. 0930–0110)—Extension

The National Survey on Drug Use and Health (NSDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy (ONDCP), Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

Methodological tests will continue to be designed to examine the feasibility, quality, and efficiency of new procedures or revisions to existing survey protocol. Specifically, the tests will measure the reliability and validity of certain questionnaire sections and items through multiple measurements on a set of respondents; assess new methods for gaining cooperation and participation of respondents with the goal of increasing response and decreasing potential bias in the survey estimates; and assess the impact of new sampling techniques and technologies on respondent behavior and reporting. Research will involve focus groups, cognitive laboratory testing, customer satisfaction surveys, and field tests.

These methodological tests will continue to examine ways to increase data quality, lower operating costs, and gain a better understanding of sources and effects of nonsampling error on the NSDUH estimates. Particular attention will be given to minimizing the impact of design changes so that survey data continue to remain comparable over time. If these tests provide successful results, current procedures or data collection instruments may be revised.

The number of respondents to be included in each field test will vary, depending on the nature of the subject being tested and the target population. However, the total estimated response burden is 8,225 hours. The exact number of subjects and burden hours for each test are unknown at this time, but will be clearly outlined in each individual submission. These estimated burden hours are distributed over three years as follows:

TABLE 1—ESTIMATED BURDEN FOR NSDUH METHODOLOGICAL FIELD TESTS

Time period	Respondent burden hours
May 2014 to May 2015	2,742
May 2015 to May 2016	2,742
May 2016 to May 2017	2,741
Total	8,225

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 *OR* email her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received by February 14, 2014.

Summer King,

Statistician, Center for Behavioral Health Statistics and Quality.

[FR Doc. 2013–29759 Filed 12–13–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Transportation Entry and Manifest of Goods Subject to CBP Inspection and Permit

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

ACTION: 30-Day notice and request for comments; Extension of an existing information collection: 1651–0003.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Transportation Entry and Manifest of Goods Subject to CBP Inspection and Permit. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** (78 FR 57405) on September 18, 2013, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 15, 2014 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13; 44 U.S.C. 3507). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components 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; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Transportation Entry and Manifest of Goods Subject to CBP Inspection and Permit.

OMB Number: 1651–0003.

Form Number: CBP Forms 7512 and 7512A.

Abstract: CBP Forms 7512 and 7512A are used by carriers and brokers to serve as the manifest and transportation entry for cargo moving under bond within the United States. The data on the form is used by CBP to identify the carrier who initiated the bonded movement and to document merchandise moving in-bond. These forms provide documentation