

OMB control number 0910-0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this draft guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm> or <http://www.regulations.gov>.

Dated: June 6, 2012.
Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: 2013 National Survey on Drug Use and Health—(OMB No. 0930-0110)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and 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, ONDCP, Federal

government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

Data from clinical interviews completed in 2008 were combined with the main interview short scale data to develop a predictive model that was applied to the full main sample to estimate SMI. Follow-up clinical interviews continued to be conducted with NSDUH respondents from 2009 to 2012. Data from these interviews were analyzed annually to update the calibration of the screening measure. To maximize trend validity, this model has been applied to 2009-2011 data. With the completion of 1500 clinical interviews in 2012, SAMHSA will have accumulated a large enough sample (4,500) to update and improve the models. Therefore, the MHSS clinical interviewing will be discontinued in 2013.

For the 2013 NSDUH, a few questionnaire changes are proposed. The instrument has been updated to include new questions on military service, medical marijuana, physician substance use screening, and respondent characteristics.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2013 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

ESTIMATED BURDEN FOR 2013 NSDUH

| Instrument | Number of respondents | Responses per respondent | Hours per response | Total burden hours | Hourly wage rate | Annualized costs |
|------------------------------|-----------------------|--------------------------|--------------------|--------------------|------------------|------------------|
| Household Screening | 145,474 | 1 | 0.083 | 12,074 | \$14.45 | \$174,469 |
| Interview | 67,500 | 1 | 1.000 | 67,500 | 14.45 | 975,375 |
| Screening Verification | 5,400 | 1 | 0.067 | 362 | 14.45 | 5,231 |
| Interview Verification | 10,125 | 1 | 0.067 | 678 | 14.45 | 9,797 |
| Total | 145,474 | | | 80,614 | | 1,164,872 |

Written comments and recommendations concerning the proposed information collection should be sent by July 12, 2012 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to

send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,
Statistician.
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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