the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Richard T. Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993–0002, 301–796–1697.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.'' This guidance provides recommendations to applicants on the CMC, human pharmacokinetics and bioavailability, and labeling documentation for liposome drug products submitted in NDAs and ANDAs reviewed by CDER. Although this guidance does not intend to provide recommendations specific to liposome drug products to be marketed under biologics license applications (BLAs), many scientific principles described in this guidance may also apply to these products.

In the **Federal Register** of August 21, 2002 (67 FR 54220), FDA announced the availability of a draft version of this guidance. FDA published a revised draft guidance on October 30, 2015 (80 FR 66906), because of the need to address changes in technology since the draft was first published in 2002, and to add ANDAs to the scope. Most of the changes to the 2015 revised draft guidance were made to clarify statements in the 2002 draft guidance. FDA received comments in response to the draft and revised draft guidance, and this guidance reflects FDA's careful consideration of those comments.

The guidance does not provide recommendations on clinical efficacy and safety studies, nonclinical pharmacology and/or toxicology studies, liposome formulations of vaccine adjuvants or biologics, or drug-lipid complexes.

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 ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.'' 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: March 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06926 Filed 4–4–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0438]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 4, 2018.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0438–60D and project title for reference, to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Teen Pregnancy Prevention Performance Measures Data Collection, Office of Adolescent Health.

Type of Collection: Revision.

OMB No.: 0990–0438.

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revision of the Teen Pregnancy Prevention (TPP) Performance Measures from funded grantees. The performance measures data include grantee-level measures (dissemination, partners,

training, sustainability), and program-level data (reach, dosage, fidelity and quality). The data collection will provide OAH with the data needed to comply with accountability and federal performance requirements for the 1993 Government Performance and Results Act (Pub. L. 103–62); it will inform stakeholders of progress in meeting the goals of the program and of sustainability efforts; it will provide OAH with metrics for monitoring TPP grantees and it will facilitate grantees' continuous quality improvement in program implementation. Clearance is requested for three years.

The likely respondents would be the estimated 85 TPP grantees. TPP grantees will report all of the data to OAH twice per year.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Grantee-level measures	TPP grantees	85	2	1	170
Program-level Measures	TPP grantees	85	2	372/60	1054
Total			4		1224

Dated: March 30, 2018.

Terry S. Clark,

Asst. Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018–06959 Filed 4–4–18; 8:45 am]

BILLING CODE 4168–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Regents of the National Library of Medicine, May 8, 2018, 9:00 a.m. to May 9, 2018, 12:00 p.m., National Library of Medicine, Building 38, 2nd Floor, The Donald A.B. Lindberg Room, 8600 Rockville Pike, Bethesda, MD, 20892 which was published in the **Federal Register** on March 7, 2018, 83 FR 45 Page 9746.

The meeting will be open to the public on May 9, 2018 from 9:00 a.m. to 10:30 a.m. and will then be closed from 10:30 a.m. to 12:00 p.m., to review intramural programs and projects. The meeting is partially closed to the public.

Dated: March 30, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–06898 Filed 4–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (Secretary), in accordance with section 6031 of the 21st Century Cures Act, announces a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

The meeting is open to the public and will include information on federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED), including data evaluation, and recommendations for action. Committee members will also discuss ISMICC member relationship to implementation workgroups, establishing the prevalence of SMI and SED, communication with non-federal organizations to engage non-federal support for ISMICC, and future meetings.

Committee Name: Interdepartmental Serious Mental Illness Coordinating Committee.

DATE/TIME: June 8, 2018/9:00 a.m.–5:00 p.m. (EDT).

ADDRESSES: The meeting will be held at the Hubert H. Humphrey Building, 200 Independence Avenue SW, Room 800, Washington, DC 20201.

The meeting can be accessed via webcast at *www.hhs.gov/live,* or by joining the teleconference at toll-free number 1–888–928–9713, passcode 7160920.

The public comment section is scheduled for 1:00 p.m. Eastern Daylight Time (EDT), and individuals interested in submitting a comment, must notify the Designated Federal Official (DFO), Ms. Pamela Foote, on or before May 24, 2018 via email to: *Pamela.Foote@samhsa.hhs.gov.*

Two minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be included in the official record of the meeting.

Substantive meeting information and a roster of Committee members is available at the Committee's website *https://www.samhsa.gov/about-us/advisory-councils/smi-committee.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in serious mental illness (SMI) and serious emotional disturbance (SED), research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMIs, SEDs, and advances in access to services and support for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to serious mental illness have on public health, including public health outcomes such as (A) rates of suicide, suicide attempts, incidence and prevalence of SMIs, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal