fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a Study Data Technical Conformance Guide (the Guide) and an update to the Study Data Standards Catalog, which will be revised and renamed the Data Standards Catalog (the Catalog). The Guide supplements the guidance for industry, ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data,'' (eStudy Data guidance) (available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*), and provides technical recommendations to sponsors for the electronic submission of standardized animal and human study data and related information contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and investigational new drug applications (INDs). The eStudy Data guidance, when finalized, will implement the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act with respect to standardized study data contained in NDA, ANDA, BLA, and IND submissions.

The Guide integrates and updates the Study Data Specifications and the CDER Common Data Standards Issues document and is available on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. It is not intended to replace the need for sponsors to communicate directly with review divisions regarding data standards implementation approaches or issues. The Guide, when finalized, will supersede the Study Data Specifications (Versions 1.0–2.0) and the CDER Study Data Common Issues Document (Versions 1.0–1.1). The Guide is organized as follows:

Section 1: Introduction—provides information on regulatory policy and guidance background, purpose, and document control.

Section 2: Planning and Providing Standardized Study Data—recommends and provides details on preparing an overall study data standardization plan and a study data reviewer's guide.

Section 3: Exchange Format—Electronic Submissions—presents the specifications, considerations, and recommendations for the file formats currently supported by FDA.

Section 4: Study Data Submission Format: Clinical and Non-Clinical—presents general considerations and specifications for sponsors using, for example, the following standards for the submission of study data: Clinical Data Interchange Standards Consortium, Study Data Tabulation Model, Analysis Data Model, and Standard for Exchange of Nonclinical Data.

Section 5: Therapeutic Area Standards—presents supplemental considerations and specific recommendations when sponsors submit study data using FDA supported TA standards.

Section 6: Terminology—presents general considerations and specific recommendations when using controlled terminologies/vocabularies for clinical trial data.

Section 7: General Electronic Submission Format—provides specifications and recommendations on submitting study data using the electronic Common Technical Document format.

Section 8: Data Fitness—provides general recommendations on standards compliance, data traceability expectations, legacy data conversion, versioning, and data validation rules.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the Guide and the Catalog at either *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm* or *http://www.regulations.gov.*

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02554 Filed 2–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Advancing the Development of Pediatric Therapeutics: Pediatric Bone Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Pediatric and Maternal Health Staff in the Center for Drug Evaluation and Research and the Office of Pediatric Therapeutics are announcing a 1-day public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT): Pediatric Bone Health.'' The purpose of this initial workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of bone health in pediatric patients.

Date and Time: The public workshop will be held on March 4, 2014, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held in the Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. The hotel's telephone number is 301–897–9400.

Contact: Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1732, Fax: 301–796–9858, email: *denise.picabranco@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA has engaged experts in pediatrics to address challenging issues related to the evaluation of effects on bone health for products used to treat pediatric patients. Identification of signals in animal studies and adult clinical trials that warrant further clinical investigation and identification of biomarkers that may be predictive of bone health in children will be discussed. Additionally, strategies and methods to address the challenges of assessing long-term bone health for products used to treat pediatric patients will be discussed.

I. Participation in the Public Workshop

There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *PediatricBoneHealth@fda.hhs.gov* before February 28, 2014.

For those without Internet access, please contact Denise Pica-Branco (see *Contact*) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (see *Contact*) at least 7 days in advance.

II. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02552 Filed 2–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICE

National Institutes of Health

Proposed Information Collection; 60-day Comment Request: Population Assessment of Tobacco and Health (PATH) Study

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function 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) The quality, utility, and clarity of the information to be collected; and (4) The approaches used to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received by April 7, 2014.

FOR FURTHER INFORMATION CONTACT: *To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing or request more information on the proposed project, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard, Room 5185; or call non-toll-free number (301) 443–8755; or Email your request, including your address to: *PATHprojectofficer@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

Proposed Collection: Population Assessment of Tobacco and Health (PATH) Study—Second Wave of Data Collection–0925–0664–Revision—National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925–0664, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the second wave of data collection. The PATH Study is a large national longitudinal cohort study on tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The PATH Study conducts annual interviews and collects biospecimens from adults to help inform the development, implementation, and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study provides it with the capacity to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA and FDA's evaluations of associations between its regulations and tobacco use behaviors and health indicators in the population.

OMB approval is requested for 3 years. There are no capital, operating, or maintenance costs to report. There are no costs to respondents other than their time. The total estimated annualized burden hours are 75,124.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent and instrument	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response (in hours)	Estimated total annual burden hours requested
Adults—Extended Interview	38,740	1	1	38,740
Adults—Baseline youth respondents who age into adult cohort—Consent for Extended Interview	2,717	1	2/60	91
Adults—Baseline youth respondents who age into adult cohort—Extended Interview	2,500	1	68/60	2,833
Adults—Adult respondents who refused biospecimen collection at Baseline but who consent for Wave 2—Consent for Biological Samples	1,452	1	4/60	97
Adults—Baseline youth respondents who age into the adult cohort—Consent for Biological Samples	2,500	1	4/60	167
Adults—Biospecimen Collection: Urine	12,387	1	10/60	2,065
Adults—Biospecimen Collection: Buccal Cell	2,387	1	18/60	716