Successor organization; a discussion on the health information technology Strategic Plan; and final reports from the Confidentiality, Privacy & Security Workgroup and the Population Health/ Clinical Care Connections Workgroup.

FOR FURTHER INFORMATION: Visit *http://www.hhs.gov/healthit/ahic.html.*

A Web cast of the Community meeting will be available on the NIH Web site at: *http://www.videocast.nih.gov/.*

If you have special needs for the meeting, please contact (202) 690–7151.

Dated: August 26, 2008.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. E8–20675 Filed 9–5–08; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

FDA Clinical Trial Requirements Regulations, Compliance, and Good Clinical Practice Conference; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Dallas District, in cooperation with the Society of Clinical Research Associates(SoCRA), is announcing a workshop on FDA Clinical Trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, November 19, 2008, from 8 a.m. to 5 p.m. and Thursday, November 20, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Westin Crown Center, 1 East Pershing Rd., Kansas City, MO 64118, 816–474–4400, FAX: 816–391–4438.

Contact: David Arvelo, Food and Drug Administration, 4040 N. Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *david.arvelo@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575 (member), $650 (nonmember), $525 (government employee nonmember), or $450 (government employee member). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA 18914. To register via the Internet go to *http://www.socra.org/html/FDA_Conference.htm* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Westin Crown Center at the reduced conference rate, contact the Westin Crown Center (see Location) before October 21, 2008. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited; therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact David Arvelo (see *Contact*) at least 21 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The FDA Clinical Trial Requirements Regulations, Compliance, and GCP Conference, helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA and confidence in the conduct of clinical research; (2) medical device, drug, biological product, and food additive aspects of clinical research; (3) investigator initiated research; (4) Pre-investigational new drug (IND) application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of Institutional Review Boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections, and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: September 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20730 Filed 9–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the National Diabetes Education Program Comprehensive Evaluation Plan

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 of Diabetes and Digestive and Kidney Diseases (NIDDK), 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.

Proposed Collection: Title: The National Diabetes Education Program Comprehensive Evaluation Plan. *Type of Information Collection Request:* Extension of a currently approved collection (#0925–0552). *Need and Use of Information Collection:* The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goals of the NDEP are to: Improve the treatment and health outcomes of people with diabetes, promote early diagnosis, and, ultimately, prevent the onset of diabetes. The NDEP objectives are: (1)

To increase awareness of the seriousness of diabetes, its risk factors, and strategies for preventing diabetes and its complications among people at risk for diabetes; (2) to improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes; (3) to improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care; (4) to promote health care policies that improve the quality of and access to diabetes care.

Multiple strategies have been devised to address the NDEP objectives. These have been described in the NDEP Strategic Plan and include: (1) Creating partnerships with other organizations concerned about diabetes; (2) developing and implementing awareness and education activities with special emphasis on reaching the racial and ethnic populations disproportionately affected by diabetes; (3) identifying, developing, and disseminating educational tools and resources for the program's diverse audiences; (4) promoting policies and activities to improve the quality of and access to diabetes care.

The NDEP evaluation will document the extent to which the NDEP program has been implemented, and how successful it has been in meeting program objectives. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This generic clearance request is for the collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. Approval is requested for a survey of audiences targeted by the National Diabetes Education Program including people at risk for diabetes, people with diabetes and their families and the public.

Frequency of Response: On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3759, *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .153; and *Estimated Total Annual Burden Hours Requested:* 575. There are no Capital, Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Total hour burden
Screening interview with ineligible persons	1659	1	.03	50
Eligible respondents	2100	1	.25	525
Totals	3759	.....	.....	575

Request for Comments: 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, NIDDK, NIH, Building 31, Room 9A06, 31 Center Drive, Bethesda, MD 20892, call the non-toll-free number 301–494–6110 or e-mail your request, including your address to: *Joanne_Gallivan@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: June 9, 2008.

Elizabeth E. Greene,

Executive Officer, NIDDK, National Institutes of Health.

Editorial Note: This document was received in the Office of the Federal Register on September 3, 2008.

[FR Doc. E8–20636 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Simulations for Drug Related Science Education

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 26, 2008, (Vol. 73 No. 124, page 36337) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after September 24, 2008, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Simulations for Drug Related Science Education. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a request for a one-time clearance to evaluate an interactive multimedia module developed by *ArchieMD.* This evaluation seeks to determine whether the multimedia module *Archie MD: The Science of Drugs* (1) Increases students' knowledge in brain and heart biology and the effects drugs have on the body (2) Increases positive attitudes towards science education for high school students (3) Reinforce or instill negative