This estimate is comprised of the following tasks: (1) one-time creation, recording, and implementation of a brief telephone script requesting a consumer's agreement via a telephone keypad response;[16] (2) modify or create electronic forms or agreements for use in emails to consumers or on a website;[17] (3) one-time revision of any existing paper forms (*e.g.*, credit card or loyalty club forms, or printed consumer contracts) to include a request for the consumer's agreement to receive prerecorded calls;[18] and (4) legal consultation, if needed, regarding compliance.

Any remaining time needed to make the required opt-out disclosure for all prerecorded calls would pose no greater time increment, and arguably less, than a similar, pre-existing Federal Communications Commission disclosure provision that has been in effect since 1993.[19] In any event, because this disclosure applies only to prerecorded calls, which are fully automated, no additional manpower hours would be expended in its delivery.

Other: The revised standard for measuring the three percent call abandonment rate will not impose any new or affect any existing reporting, recordkeeping or third-party disclosure requirements within the meaning of the PRA. The amendment relaxes the present requirement that the abandonment rate be calculated on a ''per day per campaign'' basis by permitting, but not requiring, its calculation over a 30-day period as requested by the industry. Sellers and telemarketers already have established automated recordkeeping systems to document their compliance with the current standard. The proposed amendment likely will reduce their overall compliance burden because it relaxes the current requirement. The current ''per day'' requirement has forced telemarketers to turn off their predictive dialers on many occasions when unexpected spikes in call abandonment rates occur late in the day, and thereby prevented realization of the cost savings that predictive dialers provide.

Estimated incremental labor cost burden: $3,488,000, rounded

Recordkeeping: As indicated above, staff estimates that existing sellers making use of prerecorded calls will require 16,753 hours, cumulatively, to comply with the amendment's recordkeeping requirements during the final year of the current PRA clearance. Staff assumes that the aforementioned tasks will be performed by managerial and/or professional technical personnel, at an hourly rate of $38.93.[20] Accordingly, incremental labor cost in the final year of the current clearance would be $652,194.

Disclosure: Staff estimates that approximately 75% of the disclosure-related tasks previously noted would be performed by managerial and/or professional technical personnel, again, at an hourly rate of $38.93, with 25% allocable to legal staff, at an hourly rate of $54.35.[21]

Thus, of the 66,292 total estimated disclosure burden hours, 49,719 hours would be attributable to managerial and/or professional technical personnel, with the remaining 16,573 hours attributable to legal staff. This yields $1,935,561 and $900,743, respectively, in labor cost—in total, $2,836,304.

Cumulatively, for recordkeeping and disclosure, labor cost would total $3,488,498 for the final year of the current clearance.

Other than the initial recordkeeping costs, the amendment's written agreement requirement will impose *de minimis* costs, as discussed above. The one possible exception that might arise involves credit card or loyalty program agreements that retailers revise to request agreements from consumers to receive prerecorded calls. Retailers might have to replace any existing supplies of such agreements. Staff believes, however, that the one-year phase-in of the written agreement requirement will allow retailers to exhaust existing supplies of any such preprinted forms, so that no material additional cost would be incurred to print revised forms.

Similarly, staff has no reason to believe that the amendment's requirement of an automated interactive opt-out mechanism will impose other than *de minimis* costs, for the reasons discussed above. The industry comments on the amendment uniformly support the view that automated interactive keypress technologies are now affordable, cost-effective, and widely available.[22] Moreover, most, if not all of the industry telemarketers who commented, including many small business telemarketers, said they are currently using interactive keypress mechanisms. Thus, it does not appear that this requirement will impose any material capital or other non-labor costs on telemarketers.

David C. Shonka

Acting General Counsel

[FR Doc. E8–20775 Filed 9–8–08; 8:45 am]

BILLING CODE 6750–01–S

[16] During the one-year phase-in before the written agreement requirement takes effect, the Commission will permit sellers to use prerecorded message calls made to existing customers to secure their agreements to receive prerecorded calls by pressing a key on their telephone keypad. Once a script is written and recorded, it can be used in all calls made by or on behalf of the seller to obtain the required agreements. Sellers will be able to include the request for the agreement in their regular prerecorded calls, thus making the time necessary to request the required agreements, and the cost of doing so, *de minimis* during the year-long phase-in that will overlap with the final year of the current PRA clearance.

[17] This figure includes both the minimal time required to create the electronic form and the time to encode it in HTML for the seller's website.

[18] As previously noted, the Commission has provided suggested language for this purpose that should minimize the time required to modify any paper disclosures.

[19] 47 CFR 64.1200(b)(2) (requiring disclosure of a telephone number ''[d]uring or after the message'' that consumers who receive a prerecorded message call can use to assert a company-specific do-not-call request).

[20] This cost is derived from the median hourly wage from the 2006 National Occupational Employment and Wage Estimates by the Bureau of Labor Statistics for management occupations. *See* (*http://www.bls.gov/oes/current/oes_nat.htm#b11-0000*).

[21] This cost is derived from the median hourly wage for lawyers from the ''National Compensation Survey: Occupational Wages in the United States, June 2006,'' Table 2. *See* (*http://www.stats.bls.gov/ncs/ocs/sp/ncbl0910.pdf*).

[22] *See, e.g.*, Comment by IAC/InterActiveCorp & HSN LLC (December 18,2006), at 3, *available at* (*http://www.ftc.gov/os/comments/tsrrevisedcallabandon/525547-00600.pdf.*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Meeting

ACTION: Meeting Announcement.

SUMMARY: This notice announces the meeting date for the 24th meeting of the American Health Information Community in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.) The American Health Information Community will advise the Secretary and recommend specific actions to achieve a common interoperability framework for health information technology (IT).

Meeting Date: September 23, 2008, from 8:30 a.m. to 3 p.m. (Eastern).

ADDRESSES: Hubert H. Humphrey building (200 Independence Avenue, SW., Washington, DC 20201), The Great Hall/Lobby.

SUPPLEMENTARY INFORMATION: The meeting will include a demonstration of the Nationwide Health Information Network (NHIN); an update on the AHIC

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)