maintained in the Quality System is burdensome and provides no value to ensuring protection of public health. FDA agrees with these comments and has revised the guidance to recommend that only the parts of the Plan that could have an effect on product quality be reviewed and approved by the Quality Unit before implementation of the Plan.

One comment stated that with adequate inventory on hand, an absenteeism-specific business plan might not be needed. FDA disagrees with the comment. As we discussed in the guidance, potential shortages could arise from emergencies not contemplated by inventory policy.

One comment stated that establishing provisions to use resources available at other sites will require significant effort. FDA recommends that these provisions be considered as part of the overall Plan for handling emergencies.

Some comments suggested different timeframes for notifying FDA of activation and deactivation of the Plan, stating that 1 day is too short a time. FDA did not change its recommendation for 1-day notification for Plan activation and deactivation because informing FDA of this activity in as close to real time as possible will assist the FDA in making critical decisions related to managing the causal event.

Some comments stated that testing the implementation of the Plan and producing test batches would be impractical and expensive. FDA agrees with these comments and has revised its recommendation to test the implementation of the Plan and removed its recommendation to produce test batches of the drug product.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Notify FDA of Plan activation and deactivation	2	1	2	16	32
Total					32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Develop initial Plan	70	1	70	500	35,000
Total					35,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26103 Filed 10–15–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the NIH–American Association for Retired Persons (AARP) Interactive Comprehensive Lifestyle Interview by Computer Study (iCLIC) (NCI)

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 Cancer Institute (NCI), 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:* NIH-American Association for Retired Persons (AARP) interactive Comprehensive Lifestyle Interview by Computer Study (iCLIC). *Type of Information Collection Request:* Extension. *Need and Use of Information Collection:* The Nutritional Epidemiology Branch of the Division of Cancer Epidemiology and Genetics of the National Cancer Institute has planned this study to evaluate the feasibility of using these three new computerized questionnaires as well as the Diet and Health Questionnaire (DHQ), a well-established food frequency questionnaire in a population of early-to-late-middle-aged men and women. Participants will be asked to complete computerized questionnaires over a 90 day period, with some questionnaires in a series being completed twice. This evaluation study comprises the necessary performance and feasibility tests for the new computerized questionnaires, which will provide an opportunity to assess the possibility of administering computerized questionnaires in future large prospective cohort studies. The computerized questionnaires will support the ongoing examination between cancer and other health outcomes with nutritional, physical activity, and lifestyle exposures. The computerized questionnaires adhere to The Public Health Service Act, Section 412 (42 U.S.C. 285a–1) and Section 413 (42 U.S.C. 285a–2), which authorizes the Division of Cancer Epidemiology and Genetics of the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention and treatment. *Frequency of Response:* Either 1 or 2 times. *Affected Public:* Individuals. *Type of Respondents:* U.S. adults (aged 50 and over). The annual reporting burden is displayed in the table below. The estimated total annualized burden hours being requested is 6886. The annualized cost to respondents is estimated at $121,743. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Instrument(s) tested	Frequency of response	Average time per response (minutes/hour)	Number of respondents	Annual hour burden
Read Invitation (Attachments 3)	1.00	1/60 (0.017)	16,667.00	278
Pre-Enrollment (Attachment 6)	1.00	10/60 (0.167)	2,312.00	385
Enrollment Process (Attachment 7)	1.00	5/60 (0.083)	2,288.00	191
ASA24 (Attachments 4–1)	2.00	30/60 (0.500)	1,944.00	1,944
ACT–24 (Attachments 4–2)	2.00	15/60 (0.250)	1,944.00	972
LHQ (Attachments 4–3)	1.00	20/60 (0.333)	1,944.00	648
DHQ (Attachments 4–4)	1.00	45/60 (0.750)	1,944.00	1,458
Web Re-entry (Attachment 8)	6.00	5/60 (0.083)	1,944.00	972
Evaluation Survey (Attachment 9)	1.00	1/60 (0.017)	2,288.00	38
Totals			33,275.00	6,886

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) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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 Arthur Schatzkin, M.D., Dr.P.H, Chief, Nutritional Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, Executive Plaza South, Room 3040, 6120 Executive Blvd., EPS–MSC 7242, Bethesda, MD 20892–7335 or call non-toll-free number 301–594–2931 or e-mail your request, including your address to: *schatzka@mail.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: October 12, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–26187 Filed 10–15–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0273]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Quality System Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 17, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Current Good Manufacturing Practice Quality System Regulations—21

CFR Part 820 (OMB Control Number 0910–0073)—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice (CGMP), as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the act.

The CGMP/quality system (QS) regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the FD&C act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies