Human Subjects—FDA

Clinical Trials: *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.*

Office of Good Clinical Practice: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.*

Consumer Protection—FTC

Bureau of Consumer Protection: *http://business.ftc.gov/privacy-and-security.*

Authority: 15 U.S.C. 3719.

Dated: May 31, 2012.

Farzad Mostashari,

National Coordinator for Health Information Technology.

[FR Doc. 2012–13834 Filed 6–6–12; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day 12–12BZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Data collection for the residential care facility and adult day service center components of the National Study of Long-Term Care Providers—NEW—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, ''shall collect statistics on health resources * * * [and] utilization of health care, including extended care facilities, and other institutions.''

NCHS seeks approval to collect data for the residential care facility (RCF) and adult day services center (ADSC) components of a planned new survey, the National Study of Long-Term Care Providers (NSLTCP). A one year clearance is requested.

As background here are some details on the plans for the whole study, of which this data collection is two components. The entire NSLTCP is being designed to (1) Broaden NCHS' ongoing coverage of paid, regulated long-term care (LTC) providers; (2) merge with existing administrative data on LTC providers (i.e. Centers for Medicare and Medicaid Services (CMS) data on nursing home, home health, and hospice care); (3) update data more frequently on LTC providers for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC provider types and monitor the supply and use of these providers.

The data will be collected in the 50 states and the District of Columbia from two types of LTC facilities: 11,701 RCFs and 5,000 ADSCs. The data to be collected from RCCs and ADSCs include basic characteristics, services offered, staffing, and practices of providers, as well as distributions of the demographics, physical functioning, and cognitive functioning of users (RCC residents and ADSC participants) aggregated to the RCC/ADSC level.

Expected users of data from this collection effort include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation and the Agency for Healthcare Research and Quality; provider associations, such as LeadingAge (formerly the American Association of Homes and Services for the Aging), National Center for Assisted Living, American Seniors Housing Association, Assisted Living Federation of America, and National Adult Day Services Association; universities; foundations; and other private sector organizations, such as AARP.

Expected burden from data collection is 30 minutes for respondents. We estimate that 10% of RCC and ADSC directors will be called for 15 minutes of data retrieval when there are errors or omissions in their returned surveys. There is no cost to respondents other than their time to participate. The total estimate of annualized burden is 8,769 hours.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)
RCC Director	RCC Questionnaire	11,701	1	30/60
ADSC Director	ADSC Questionnaire	5,000	1	30/60
RCC and ADSC Directors	Data Retrieval	1,670	1	15/60

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–13795 Filed 6–6–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Native Employment Works (NEW) Program Plan Guidance and Report Requirements.

OMB No.: 0970–0174.

Description

The Native Employment Works (NEW) program plan is the application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance provides instructions for preparing a NEW program plan and explains the process for plan submission every third

year. The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

Respondents

Federally recognized Indian Tribes and Tribal organizations that are NEW program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
NEW program plan guidance	26	1	29	754
NEW program report	48	1	15	720

Estimated Total Annual Burden Hours: 1,474.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–13812 Filed 6–6–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0110]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

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 July 9, 2012.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0437. 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 Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting—21 CFR Part 803 (OMB Control Number 0910–0437)—Extension

Section 519(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a)(1)) requires every manufacturer or importer to report ''whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices: (A) May have caused or contributed to a death or serious injury, or (B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.''

Section 519(b)(1)(A) of the FD&C Act requires ''whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death or serious illness, of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.''

Section 519(b)(1)(B) of the FD&C Act requires ''whenever a device user facility receives or otherwise becomes aware of: (i) Information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility * * *, shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.''

Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems. Information from these