overall sample along a number of relevant dimensions (e.g., assessment of risk of needing long-term care). The analysis will also characterize the sample by key indicator variables, to analyze the role of long-term care planning within the context of overall retirement planning, and to understand long-term care use and payment and policy preferences. Multivariate analyses will also be conducted, primarily of planning activity for long-term care and preferences for public policies for long-term care financing.

The second set of analyses will address the DCEs that respondents conducted to evaluate various features of long-term care insurance policies. DCEs are a form of conjoint analysis, an econometric method used to estimate the relative importance that respondents place on the different features of an individual product (e.g., for long-term care insurance, such features as length of coverage, benefit period, benefit amount, whether there is medical underwriting, and sponsorship). These data will be analyzed using standard discrete choice econometric techniques in which the parameter estimates in the choice models indicate the relative importance to respondents of different features of long-term care insurance. Thus, the ratio of two parameters indicates the marginal rate of substitution between them (i.e., the rate at which respondents changed their selections when attribute levels were varied).

Likely Respondents: Survey invitations will be sent by the data collection partner, GfK, to a random sample of U.S. adults aged 40–70 participating in its standing Internet panel, KnowledgePanel. Adults who read the survey invitation and desire to participate will be redirected to a secure, password-protected Web site hosted by GfK which contains the next two forms. GfK will send 23,077 invitations to participate to members of the sample, yielding an estimated 15,000 completed questionnaires based on an estimated overall response rate of 65 percent.

Burden Statement: The response burden estimates for this data collection are shown in *Exhibit A.12–1.* An IRB-approved consent form must be acknowledged by respondents before they are allowed to begin the survey. Respondents will be asked to read basic information about the research study, the study purpose, procedures, duration of the survey, possible risks or discomforts from the survey, benefits of participating, incentive for participation, privacy protections, individuals' rights, and whom to contact with questions. Respondents will then be required to click a box indicating that they have read the information, confirm that they are between the ages of 40 and 70, and that they voluntarily consent to participate in the study or decline to participate. Only those who consent and certify that they meet the age qualifications will continue to the full survey instrument. Estimates for the time needed to complete the survey are based on cognitive testing of the questionnaire conducted during Fall 2012 in Durham, North Carolina, and Washington, DC. As part of the cognitive testing, the length of time to complete the questionnaire was measured. The cognitive testing suggests that the questionnaire requires approximately 45 minutes to complete. The initial series of questions take approximately 25 minutes to complete and the DCE section takes approximately 15–20 minutes to complete. Each respondent will answer the questionnaire only once and there are no planned follow-up surveys. Respondents will have the ability to pause the survey and restart it at a later time at their convenience.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Task	Number of respondents	Burden per response (hours)	Estimated total hours of burden
Self-administered, Web-based questionnaire	15,000	0.75	11,250

Source: RTI International estimates.

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2013–28991 Filed 12–3–13; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case: *Timothy Sheehy, B.A., BSc., SAIC-Frederick, Inc.*

FOR FURTHER INFORMATION CONTACT: David E. Wright, Ph.D., Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

SUPPLEMENTARY INFORMATION:

Timothy Sheehy, B.A., BSc., SAIC-Frederick, Inc.: Based on the report of an investigation conducted by SAIC-Frederick, Inc., and additional analysis conducted by ORI in its oversight review, ORI found that Mr. Timothy Sheehy, former Manager, DNA Extraction and Staging Laboratory (DESL), SAIC-Frederick, Inc., the Operations and Technical Services (OTC) Contractor for the Frederick National Laboratory for Cancer Research (FNLCR), Frederick, MD, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), contract HHSN2612008000001E awarded by FNLCR/NCI, NIH, to SAIC-Frederick, Inc., and the intramural program at the Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, NCI.

ORI found that the Respondent engaged in research misconduct by fabricating and/or falsifying U.S. Public Health Service (PHS)-supported data in Table 1 included in *Cancer Epidemiol Biomarkers Prev* 19(4):973–977, 2010 (hereafter referred to as the ''*CEBP* paper'').

Specifically, ORI found that Respondent fabricated the quantitative and qualitative data for RNA and DNA purportedly extracted from 900 formalin-fixed, paraffin-embedded (FFPE) colorectal tissue samples presented in Table 1 of the *CEBP* paper and falsely reported successful methodology to simultaneously recover nucleic acids from FFPE tissue specimens, when neither the extractions nor analyses of the FFPE samples were done. Thus, the main conclusions of the CEBP paper are based on fabricated data and are false.

Mr. Sheehy has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on November 8, 2013:

(1) To have his research supervised; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of

Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(4) that a letter will be submitted to the editors of *CEBP* requesting that the journal retract the publication.

David E. Wright,

Director, Office of Research Integrity.

[FR Doc. 2013–28887 Filed 12–3–13; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0579]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Forms FDA 3486 and 3486A

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 January 3, 2014.

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 0910–0458. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Forms FDA 3486 and 3486A—(OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of such products. In addition, under section 361 of the PHS Act (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States or possessions. Further, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with current good manufacturing practice (CGMP) assuring that they meet the requirements of the FD&C Act. Establishments manufacturing biological products, including human blood and blood components, must comply with the applicable CGMP regulations (parts 211, 606, and 820 (21 CFR parts 211, 606, and 820)) and current good tissue practice (CGTP) regulations (part 1271 (21 CFR part 1271)) as appropriate. FDA regards biological product deviation (BPD) reporting and human cells, tissues and cellular and tissue-based products (HCT/P) deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 (21 CFR 600.14), in brief, requires the manufacturer who holds the biological product license for other than human blood and blood components, and who had control over a distributed product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drugs Evaluation and Research (CDER) as soon as possible, but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171, in brief, requires licensed manufacturers of human blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services, who had control over a distributed product when the deviation occurred, to report to CBER as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Similarly, § 1271.350(b), in brief, requires HCT/P establishments that manufacture non-reproductive HCT/Ps described in § 1271.10 to investigate and report to CBER all HCT/P deviations