with L92H, R191Q, and wtNE, when they were cells transfected with I31T, P110L, and G185R mutants; Figure 5B as HL–60 cells transfected with wtNE, mutNE, and EGFP, when they were cells transfected with P110L, I31T, and INE; Figure 6B as HL–60 cells transfected with G185R, mock, D145–152, and P110L NE mutants, when they were cells transfected with I31T, P110L, G185R, and 32. The false ß-actin Western blot in Figure 6B was also included in HL73063–01, Figure 8 (where the I31Tlane was labeled correctly), and HL79615–01, Figure 7.

4. Falsified the reported methodology for flow cytometry experiments in Figure 4A, NEM, Figures 1 and 2, and Tables 2 and 3, CMA, and Figures 4, 5, and 6, ISB, to validate the key hypothesis showing accelerated apoptosis in SCN and CN patients. The methodology claimed that flow cytometry experiments were gated for GFP+ populations, or that cell purity was greater than 96%, when based on the available original records, the experiments were not performed as stated.

5. Falsified Figure 2, CMA, Figure 2, HL73063–01, Figure 3, HL79615–01, and Figure 5, CA89135–01A1, demonstrating that the overnight cultures of CD34+ and CD33+ bone marrow cells from SCN/AML patients showed normal cell survival, and only the CD15+ overnight cultures showed accelerated apoptosis, when the actual record available contradicted this result. Respondent used flow cytometry data files to generate histograms with the desired result to support the hypothesis that the progression from SCN to leukemia (AML) involves acquired G–CSFR mutations that override the pro-apoptotic effect of the NE mutations in primitive progenitor cells.

Dr. Aprikyan has entered into a Settlement Agreement in which he denied ORI's findings of research misconduct based on the UW Faculty Adjudication Hearing Panel decision. The settlement is not an admission of liability on the part of the Respondent. Respondent entered into the Agreement solely because contesting the findings would cause him undue financial hardship and stress, lead to lengthy and costly appellate proceedings, and he wished to seek finality. Respondent agreed not to appeal the ORI findings of research misconduct set forth above. He has agreed, beginning on March 12, 2013:

(1) If within two (2) years from the effective date of the Agreement, Respondent receives or applies for U.S. Public Health Service (PHS) support, Respondent agreed to have his research supervised for a period of two (2) years; Respondent agreed that prior to the submission of an application for PHS support for a research project on which his participation is proposed and prior to his 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 his 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) If within two (2) years from the effective date of the Agreement, Respondent receives PHS support, Respondent agreed that for two (2) years, 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; and

(3) Respondent agreed not to serve 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 for a period of two (2) years beginning with the effective date of the Agreement.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

David E. Wright,

Director, Office of Research Integrity.

[FR Doc. 2013–08207 Filed 4–8–13; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–12MX]

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 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Research to Inform the Prevention of Asthma in Healthcare—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Healthcare is the largest industry in the United States and performs a vital function in society. Evidence from both surveillance and epidemiologic research indicates that healthcare workers have an elevated risk for work-related asthma (WRA) associated with exposure to groups of agents such as cleaning products, latex, indoor air pollution, volatile organic compounds (VOCs) and bioaerosols. Recent epidemiologic studies of WRA among healthcare workers have utilized job exposure matrices (JEMs) based on probability of exposure, however, specific exposures/etiologic agents are not well characterized and quantitative exposure measurements are lacking. In this project, NIOSH will augment the existing JEM with quantitative exposure data, which will significantly enhance the existing JEMs and develop a survey questionnaire for asthma in healthcare.

Since asthma continues to be a problem among healthcare workers, the overall goal of this project is to prevent work-related asthma among healthcare workers. The primary objective is to identify modifiable occupational risk factors for asthma in healthcare that will inform strategies for prevention. Specific Aims that support the Primary Objective are:

Aim 1. Measure frequency of asthma onset, related symptoms, and exacerbation of asthma in selected healthcare occupations

Aim 2. Assess associations between asthma outcomes and exposures to identify modifiable risk factors

In order to accomplish the goal and aims of this project NIOSH has developed a survey designed to collect information about work history, workplace exposures and asthma health from workers in the healthcare industry. Aim 1 of this project will be completed using data exclusively from this survey. While aim 2 will be completed using asthma outcome data from the survey and exposure data from the JEM

developed from survey data and exposure data from previously environmental sampling at healthcare facilities.

Approximately 15,000 health care workers in the New York City area will be recruited for this study. The goal is to conduct a cross-sectional epidemiologic survey of approximately 5,000 healthcare workers who are members of Service Employees International Union (SEIU) Local 1199. Only health care workers whose job titles are in one of nine job titles will be recruited. These nine job titles include: certified nursing assistants (CNAs), central supply, environmental services, licensed practical nurses (LPNs), lab techs, operating room (OR) techs, registered nurses (RNs), respiratory therapists, and dental assistants. Furthermore, recruitment of health care workers will only be from hospitals and nursing homes.

Completion of the survey by SEIU1199 members will be done either online or over the telephone. After the initial recruitment period, SEIU1199 members will have approximately two weeks to complete the online survey. After this two week period, the SEIU1199 Communication Center will begin calling members who have not completed the online survey and attempt to complete the survey with them by telephone interview. NIOSH anticipates 20% of the responses to be made using the online survey and the remaining 80% to be by telephone interview.

There are no costs to respondents for this study. Summary results of this study will be made available to SEIU1199 members who completed the survey through a letter mailed to their homes. Summary results will also be published in the SEIU1199 newsletter for the remaining members. Results of this this study will also be disseminated to other industry stakeholders besides SEIU1199. These stakeholders and the desired consequences of the dissemination are:

1. Healthcare workers will learn about hazards in their work environment and become better prepared to participate in the development of strategies to minimize risk.

2. Health and safety staff at the facilities where participants are employed, who can potentially use the information for prevention.

3. Researchers can build on the findings to conduct additional research that will advance our understanding of asthma in healthcare and how to prevent it.

4. Clinicians will learn how occupational exposures can impact the respiratory health of their patients who work in healthcare, which should improve the care they provide.

5. Professional societies and government agencies will use findings from this and other studies to develop recommendations for preventing asthma and related symptoms in healthcare workers.

Finally, manuscripts of results and conclusions will be drafted and published in peer reviewed journals.

The target sample size for this study is 5,000. Based on the SEIU1199 membership data, the percentage of eligible union members that fall into the targeted nine job categories is known. Therefore, a participant job-category distribution estimate can be made.

Completion of either the online or telephone survey will take approximately 30 minutes. There is no cost to respondents other than their time. The total estimated annual burden hours are 1,255.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)
Certified Nursing Assistants	Online	149	1	30/60
	Telephone	594	1	30/60
Central Supply Workers	Online	4	1	30/60
	Telephone	17	1	30/60
Dental Assistants	Online	9	1	30/60
	Telephone	36	1	30/60
Environmental Service Workers	Online	114	1	30/60
	Telephone	457	1	30/60
Licensed Practical Nurses	Online	70	1	30/60
	Telephone	280	1	30/60
Lab Technicians	Online	39	1	30/60
	Telephone	155	1	30/60
Operating Room Technicians	Online	14	1	30/60
	Telephone	55	1	30/60
Registered Nurses	Online	84	1	30/60
	Telephone	336	1	30/60
Respiratory Therapists	Online	18	1	30/60
	Telephone	72	1	30/60

Ron A. Otten,

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

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0258]

Molecular Diagnostic Instruments With Combined Functions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Molecular Diagnostic Instruments with Combined Functions.'' This draft guidance document provides industry and Agency staff with FDA's current thinking on regulation of molecular diagnostic instruments that have both device functions and non-device functions, and on the type of information that FDA recommends that applicants include in a submission for a molecular diagnostic instrument that measures or characterizes nucleic acid analytes and has combined functions. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 8, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Molecular Diagnostic Instruments with Combined Functions'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrew Grove, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5515, Silver Spring, MD 20993–0002, 301–796–6198; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, RKWL Bldg., suite 601, 11400 Rockville Pike, Rockville, MD 20852, 1–800–835–4709.

SUPPLEMENTARY INFORMATION:

I. Background

Molecular diagnostic instruments, for example, real-time thermocyclers, are critical components of certain in vitro diagnostic devices. They are often used to perform multiple unrelated assays, such as those that detect methicillin-resistant *Staphylococcus aureus,* Hepatitis C virus, and genetic markers of cystic fibrosis. These types of instruments cannot generally be approved alone, *i.e.,* without an accompanying assay, because their safety and effectiveness cannot be evaluated without reference to the assays that they run and their defined performance parameters. However, the same instruments may also be used for additional purposes that do not require FDA approval or clearance, such as for basic scientific research. In the past, FDA has provided informal advice in response to individual inquiries regarding the permissibility of having such non-device functions on an instrument intended to be used with approved in vitro diagnostic assays. This draft guidance is meant to communicate FDA's policy regarding molecular diagnostic instruments with combined functions.

This draft guidance applies to molecular diagnostic instruments that are medical devices used with assays that measure or characterize nucleic acid analytes, human or microbial, and that combine both approved and non-approved functions in a single instrument. This draft guidance applies to the instrument itself (hardware) as well as to any firmware or software intended to operate on or to control the instrument. This draft guidance also addresses software that is distributed as a stand alone device for use with an approved molecular diagnostic assay.

The draft guidance does not apply to instruments approved for use with assays that are intended to screen donors of blood and blood components, human cells, tissues, and cellular and tissue-based products for communicable diseases.

The recommendations in this draft guidance are not intended to imply that assays/reagents that have not received FDA marketing authorization may be marketed by an instrument manufacturer for clinical use on a molecular diagnostic instrument with combined approved and non-approved functions. They are also not intended to change FDA's position regarding the marketing of Research Use Only and Investigational Use Only assays for clinical use.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on molecular diagnostic instruments with combined functions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Molecular Diagnostic Instruments with Combined Functions,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1763 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number