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:

Parag Patel, D.O., Advocate Health Care Network d/b/a Advocate Health Care: Based on an investigation conducted by Advocate Health Care Network d/b/a Advocate Health Care (Advocate Health Care) and additional analysis conducted by ORI in its oversight review, ORI and Advocate Health Care found that Dr. Parag Patel, Cardiologist, Department of Medicine, Advocate Health and Hospitals Corporation d/b/a Advocate Lutheran General Hospital, Park Ridge, Illinois, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant U01 HL089458.

ORI and Advocate Health Care found that the Respondent engaged in research misconduct by directing or intimidating fellows and others to influence left ventricular ejection fraction (LVEF) scores of ≤ 35% and requesting attending physicians to reassess scores of LVEF to be reported as ≤ 35% for research subjects after being diagnosed with acute myocardial infarction, thereby causing and being responsible for falsification of research records. These falsifications made subjects eligible for enrollment into the ''Vest Prevention of Early Sudden Death Trial'' (VEST) when they otherwise may not have been eligible.

The Respondent, Advocate Health Care, and the U.S. Department of Health and Human Services (HHS) want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter. Respondent neither admits nor denies ORI's and Advocate Health Care's findings of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent.

Dr. Patel has voluntarily agreed for a period of two (2) years, beginning on February 21, 2014:

(1) To have any U.S. Public Health Service (PHS)-supported research in which he is involved be supervised; Respondent agreed that prior to the submission of an application for 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 Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution as outlined below; 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 the requirements for Respondent's supervision plan are as follows:

- A committee of two to three qualified physicians at the institution's discretion, who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance; the committee will review primary data from Respondent's participation in PHS-supported research on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee's meeting dates, Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's research contribution; and
- The committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts; the review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application/publication are supported by the research record;

(3) 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; and

(4) 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.

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

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2014–05921 Filed 3–17–14; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–0263]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited 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) ways to enhance the quality, utility, and clarity of the 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. Written comments should be received within 60 days of this notice.

Proposed Project

Requirements for the Importation of Nonhuman Primates into the United States—Revision—(OMB No. 0920–0263, expiration date: 4/30/2016)—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is submitting this revision to obtain authority to collect electronic information from importers/filers on nonhuman primate and nonhuman primate products over which CDC has authority, notably those found in 42 CFR part 71. This request is consistent with requirements of the Security and Accountability for Every (SAFE) Port Act that states that all agencies that require documentation for clearing or licensing the importation and exportation of cargo participate in the International Trade Data System (ITDS), and is also consistent with CDC authorities under Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264).

This electronic data is specified by CDC using Partner Government Agency (PGA) Message Sets and is collected by Customs and Border Protection (CBP) from importers/filers when they submit the information needed through International Trade Data System ITDS and the Automated Commercial Environment (ITDS/ACE) to clear an import. CDC has developed a PGA message set for each regulated import specified in 42 CFR part 71, and each PGA Message Set includes only those data requirements necessary in order to determine whether or not a CDC-regulated import poses a risk to public health and that the importer has met CDC's regulatory requirements for entry. CDC included the PGA Message Sets for review because there is no set form or format for the electronic submission of import related data to CBP and CDC. CDC is permitted access to the Automated Commercial Environment (ACE) data pursuant to 6 CFR 29.8(b) and 49 CFR 1520.11(b), which permit federal employees with a need to know to have access to this data.

CDC is maintaining its authority to collect hard copies of required documentation, as currently authorized by the Office of Management and Budget, because the use of ITDS/ACE will not be required for imports entering the United States until a later date. CDC will accept both hard copy and electronic filing of import-related documentation until the use of ACE is required for cargo entering the United States.

Through this revision, CDC is requesting a net increase in the estimated number of burden hours in the amount of 798 hours. Of these additional hours, 608 hours pertain to requests for CDC Message Set data via ITDS/ACE, and 190 hours pertain to required statements/documentation of products being rendered non-infectious.

CDC is maintaining its authority to collect hard copies of required documentation, as currently authorized by the Office of Management and Budget (OMB), because the use of ITDS/ACE will not be required for imports entering the United States until a later date. CDC will accept both hard copy and electronic filing of import-related documentation until the use of ACE is required for cargo entering the United States.

Respondents to this data collection have not changed and remain new and registered importers of live nonhuman primates and importers of nonhuman primate products. The number of additional hours requested for this information collection total 798 hours. The total burden for this information collection request is 943 hours. There are no costs to respondents except for their time to complete the forms, and complete and submit data and documentation.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name/CFR reference	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New Importer).	1	1	10/60	1
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration).	12	1	10/60	2
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer).	1	1	10	10
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer).	12	1	30/60	6
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form).	25	6	15/60	38
Nonhuman Primate Importer	Quarantine release 71.53(l) (No form).	25	6	15/60	38
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials.	10	15	20/60	50
Importer/Filer	CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates.	150	1	15/60	38
Importer/Filer	CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products.	2,280	1	15/60	570
Importer/Filer	Documentation of Non-infectiousness 71.53(t).	2,280	1	5/60	190
Total					943

Leroy Richardson,

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

[FR Doc. 2014–05880 Filed 3–17–14; 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

Title: Federal Strategic Action Plan on Services for Victims of Human Trafficking: Enhancing the Health Care System's Response to Human Trafficking

OMB No.: New Collection

Description:

In 2013, the U.S. Department of Health and Human Services co-chaired an inter-agency process with the Departments of Justice and Homeland Security to create the first Federal Strategic Action Plan on Services for Victims of Human Trafficking in the United States. The Plan addresses the needs for the implementation of coordinated, effective, culturally appropriate and trauma informed care for victims of human trafficking. The purpose of this initiative is to develop a pilot training project that will strengthen the health systems' response to human trafficking in four key ways

1. Increase knowledge about human trafficking among health care providers;

2. Build the capacity of health care providers to deliver culturally appropriate and trauma-informed care to victims of human trafficking;

3. Increase the identification of victims of human trafficking; and

4. Increase services to survivors of human trafficking.

The evaluation will measure immediate outcomes, e.g., from pre-intervention to post-intervention, as well as intermediate outcomes at a 3 month post intervention.

Respondents:

The target audience for training and evaluation will be 200 health care providers from hospitals, clinics, and private health practices. The health care providers will be from federal, state/territorial, and local health departments, the Veterans' Administration, professional associations, and tribal institutions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Pre-training survey	200	1	0.40	80.00
Post-training survey	200	1	0.40	80.00
Email Follow-up	200	1	0.40	80.00
Telephone Follow-up	40	1	0.40	16.00
	.....	.....	.....	256.00

Estimated Total Annual Burden Hours: 256

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 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. 2014–05824 Filed 3–17–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification for a New Dietary Ingredient'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On November 25, 2013, the Agency submitted a proposed collection of information entitled ''Premarket Notification for a New Dietary Ingredient'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0330. The approval expires on February 28, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.