o. The image file 'HiPS_E1_x100.jpg'

2. Falsified one (1) figure for the real-time RT–PCR data for endogenous SOX2 expression in human iPSCs derived from dermal (HiPS-E1) and cardiac (HiPS-E2) fibroblasts and iPSCs generated from peripheral blood mononuclear cells derived from coronary artery disease patients (HiPS-ECP1, HiPS-ECP2, and HiPS-ECP3) by substituting real-time RT–PCR data for endogenous OCT4 expression in the forementioned cell lines. Specifically, the false data were included in:

a. Figure 2i (panels #2 & 5) in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts
b. Figure S1D (panels #2 & 5) in the *Blood* 2009 manuscript
c. Supplementary Figure 8D (panels #2 & 5) in the *Nature Medicine* 2009 manuscript
d. Figure 3I (panels #2 & 5) in the poster presented at the 2009 AHA meeting
e. The presentations ''Figures_Sinae Kim_120808.ppt' and 'Figures_Sinae Kim_121508.ppt'

3. Falsified data in two (2) PowerPoint presentations for RT–PCR data of osteogenic-specific gene expression in bone marrow cells by substituting data for RT–PCR data in primary bone-derived and Saos2-osteosarcoma cells.

4. Falsified one (1) figure for the real-time RT–PCR data of OCT4, SOX2, KLF4, c-MYC, NANOG, hTERT, REX1, and GDF3 fold-change expression levels in H1 hESCs, human cardiac and dermal fibroblasts, HiPS-E1, HiPS-E2, HiPS-ECP1, HiPS-ECP2, and HiPS-ECP3 cell lines by substituting data from various other cell lines that did not exist. Specifically, the false data were included in:

a. Figures 2a-h in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts
b. Figure 10 in the RC1 GM092035 grant
c. Figure 9 in the R01 HL079137 grant
d. Figure 5 in the R01 HD067130 grant
e. Figure 3A–H in the poster presented at the AHA meeting
f. The presentations ''Figures_Sinae Kim_120808.ppt' and 'Figures_Sinae Kim_121508.ppt'

5. Falsified research materials when the Respondent distributed cells to laboratory members that she claimed were chemical/non-viral factor induced-mouse iPSCs and human iPSCs generated from peripheral blood of coronary artery disease patients, when she knew they were of other origin.

Dr. Kim has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on June 5, 2012:

(1) To exclude herself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as ''covered transactions'' pursuant to HHS' Implementation (2 CFR part 376, *et seq*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR part 180 (collectively the ''Debarment Regulations''); and

(2) To exclude herself 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.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2012–16572 Filed 7–5–12; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Declaration Regarding Emergency Use of All Oral Formulations of Doxycycline Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of Homeland Security determined on September 23, 2008 that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, Bacillus anthracis. On the basis of that determination, and pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act (''FD&C Act''), the Secretary of Health and Human Services is renewing her July 20, 2011 declaration of an emergency justifying the authorization of emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs under 21 U.S.C. 360bbb–3(a). This notice is being issued in accordance with section 564(b)(4) of the FD&C Act, 21 U.S.C. 360bbb–3(b)(4).

DATES: This Notice and referenced HHS declaration are effective as of July 20, 2012.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: On September 23, 2008, former Secretary of Homeland Security, Michael Chertoff, determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*—although there is no current domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving *Bacillus anthracis.*

On October 1, 2008, on the basis of that determination, and pursuant to section 564(b) of the FD&C Act, 21 U.S.C. 360bbb–3(b), former Secretary of Health and Human Services, Michael O. Leavitt, declared an emergency justifying the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a).[1] On October 1, 2009 and October 1, 2010, I renewed the former Secretary's declaration,[2] and on July 20, 2011, I renewed and amended the declaration to declare that the emergency justifies emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a).[3]

On the basis of the September 23, 2008 determination by the Secretary of Homeland Security and pursuant to section 564(b) of the FD&C Act, I hereby renew my July 20, 2011 declaration that the emergency justifies emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb–3(a). I am issuing this notice in accordance with section 564(b)(4) of

[1] Pursuant to section 564(b)(4) of the FD&C Act, notice of the determination by the Secretary of Homeland Security and the declaration by the Secretary of Health and Human Services was provided at 73 FR 58242 (October 6, 2008).

[2] Pursuant to section 564(b)(4) of the FD&C Act, notices of the renewal of the declaration of the Secretary of Health and Human Services were provided at 74 FR 51,279 (Oct. 6, 2009) and 75 FR 61,489 (Oct. 5, 2010).

[3] Pursuant to section 564(b)(4) of the FD&C Act, notice of the renewal and amendment of the declaration of the Secretary of Health and Human Services was provided at 76 FR 44,926 (July 27, 2011).

the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb–3(b)(4).

Dated: June 28, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–16588 Filed 7–5–12; 8:45am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10433, CMS–10438, CMS–10439 and CMS–10440]

Agency Information Collection Activities: Proposed Collection; Comment Request; Webinars

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* As required by the final rule that published on March 27, 2012 (77 FR 18310), entitled *CMS–9989–F: Establishment of Exchanges and Qualified Health Plans*; Exchange Standards for Employers, each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, essential health benefits, and actuarial value. In order to meet those standards, the Exchange is responsible for collecting data and validating that QHPs meet these minimum requirements as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other requirements determined by the Exchange. In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153 and in the final rule that published on March 23, 2012 (77 FR 17220) entitled CMS- 9975–F: Standards for Reinsurance, Risk Corridors, and Risk Adjustment, have general information reporting requirements that apply to non-QHPs outside of the Exchanges. *Form Number:* CMS–10433 (OCN: 0938–New); *Frequency:* Annually; *Affected Public:* States and Private Sector: Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 3400; *Number of Responses:* 3400; *Total Annual Hours:* 224,435 hours in year one and 166,435 hours in years two and three (For policy questions regarding the QHP Certification data collection, contact Lourdes Grindal-Miller at (301) 492- 4345. For policy questions regarding risk adjustment and reinsurance data collection, contact Milan Shah call (301) 492- 4427. For all other issues, call (410) 786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of information collection*: Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program; *Use:* In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Section 1311(b)(1)(B) of the Affordable Care Act requires that the Small Business Health Option Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (QHPs) offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act requires HHS to establish criteria for certification of health plans as QHPs and that these criteria must require plans to utilize a uniform enrollment form that qualified employers may use. Further, section 1311(c)(5)(B) requires HHS to develop a model application and Web site that assists employers in determining if they are eligible to participate in SHOP. Consistent with these authorities, HHS has developed a single, streamlined form that employees will use apply to the SHOP. Section 155.730 of the Exchanges Final Rule (77 FR 18310) provides more detail about this ''single employee application,'' which will be used to determine employee eligibility, QHP selection, and enrollment of qualified employees and their dependents.

The information will be required of each employee upon initial application with subsequent information collections for the purposes of confirming accuracy of previous submissions or updating information from previous submissions. Information collection will begin during initial open enrollment in October 2013, per § 155.410 of the Exchanges Final Rule. Applications for the SHOP will be collected year round, per the rolling enrollment requirements of § 155.725 of the Exchanges Final Rule.

Employees will be able to submit an application for the SHOP online, using a paper application, over the phone through a call center operated by an Exchange, or in person through an agent, broker, or Navigator, per § 155.730(f) of the Exchanges Final Rule. If an employee does not enroll in coverage through the SHOP, the information will be erased after a specified period of time. If an employee enrolls in coverage through the SHOP, the information will be retained to document the enrollment, to allow reconciliation with issuer records, and to provide information for future coverage renewals or changes in coverage.

Every qualified employee of an employer participating in the SHOP who wishes to apply for coverage through the SHOP will need to complete an application to determine his or her eligibility, QHP selection, and enrollment of the employee and his or her dependents. The applicant will also be asked to verify his or her