

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:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA): (1) Authorizing the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare an emergency justifying the authorization based on one of four determinations: (1) A determination of a domestic emergency, or a significant potential for a domestic emergency, by the Secretary of Homeland Security; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act² sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination of a military emergency, or a significant potential for a military emergency, by the Secretary of Defense; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents (see 21 U.S.C. 360bbb-3(b)(1)).³

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an

authorization under section 564 of the FD&C Act are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the FDA, HHS, issue an EUA for in vitro diagnostics for detection of the avian influenza A (H7N9) virus to allow the Department to take preparedness measures based on information currently available about the avian influenza A (H7N9) virus detected in China. The determination of a significant potential for a public health emergency, and the declaration that circumstances exist justifying emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for certain in vitro diagnostics for emergency use under section 564(a) of the FD&C Act, 21 U.S.C. 360bbb-3(a).

II. Determination by the Secretary of Health and Human Services

On April 19, 2013, pursuant to section 564(b)(1)(C) of the FD&C Act, 21 U.S.C. 360bbb-3(b)(1)(C), I determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the avian influenza A (H7N9) virus.

III. Declaration of the Secretary of Health and Human Services

Also on April 19, 2013, on the basis of my determination of a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the avian influenza A (H7N9) virus, I declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus pursuant to section 564 of the FD&C Act, 21 U.S.C. 360bbb-3, subject to the terms of any authorization issued under that section.

I also specified that this declaration is a declaration of an emergency with respect to in vitro diagnostics as defined under the PREP Act Declaration for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices signed by then Secretary Michael Leavitt on December 17, 2008.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal**

Register as required under 21 U.S.C. 360bbb-3(h).

Dated: April 19, 2013.

Kathleen Sebelius,
Secretary.

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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:

Matthew Poore, Advanced Liquid Logic Inc.: Based on the report of an inquiry conducted by Advanced Liquid Logic Inc. (Liquid Logic), the Respondent's admission, and additional analysis conducted by ORI, ORI found that Mr. Matthew Poore, former Technician, Liquid Logic, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), contract HHSN272200900030C.

ORI found that the Respondent engaged in research misconduct by falsifying data that were included in one (1) presentation and one (1) report to NIAID and in laboratory records at Liquid Logic.

ORI finds that Respondent knowingly and intentionally falsified reverse transcription-polymerase chain reaction (RT-PCR) results by reporting the results from previous experiments as the actual results, when the experiments had not been performed. Specifically:

- In Liquid Logic laboratory documents, the Respondent falsified the RT-PCR results of human immunodeficiency virus (HIV) viral loads in whole blood patient samples by falsely changing previous results for two (2) samples from negative to positive and one (1) sample from positive to negative. The latter falsified sample result, changed from HIV positive to negative, was included in an April 1-June 30, 2012, quarterly report and a July 12, 2012, presentation to NIAID.

- In Liquid Logic laboratory documents, the Respondent falsified the RT-PCR whole blood lysis results of testing samples as 100 and 200 HIV viral copies per milliliter, when the experiments were not performed by the Respondent. These falsified results were

² 42 U.S.C. 247d-6b.

³ As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113-5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.

included in an April 1–June 30, 2012, quarterly report to NIAID.

- In Liquid Logic laboratory documents, the Respondent falsified the graphs of RT–PCR results of the *Escherichia coli* bacteriophage MS2, an internal control, viral loads for three (3) clinical samples, when the results were actually from prior experiments of two (2) controls and one (1) unrelated clinical sample. The Respondent falsified the MS2 graphs in an effort to conceal that RT–PCR experiments of the clinical samples had not been performed.

Mr. Poore has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on April 1, 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 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; he 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; and

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

David E. Wright,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will be held on Wednesday, May 22, 2013, and Thursday, May 23, 2013, from 9:00 a.m. until 5:00 p.m.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building; 200 Independence Avenue SW., Room 800; Washington, DC 20201. For a map and directions to the Hubert H. Humphrey building, please visit <http://www.hhs.gov/about/hhhmap.html>.

FOR FURTHER INFORMATION CONTACT:

Nancy C. Lee, M.D., Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Department of Health and Human Services, 200 Independence Avenue SW., Room 712E, Washington, DC 20201. Any questions about meeting registration or public comment sign-up should be directed to CFSACMay2013@seamoncorporation.com. Please direct other inquiries to cfsac@hhs.gov.

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002, to advise, consult with, and make recommendations to the Secretary, through the Assistant Secretary for Health, on a broad range of topics including: (1) The current state of knowledge and research and the relevant gaps in knowledge and research about the epidemiology, etiologies, biomarkers, and risk factors relating to CFS, and identifying potential opportunities in these areas; (2) impact and implications of current and proposed diagnosis and treatment methods for CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical academic and research communities about CFS advances; and (4) partnering to improve the quality of life of CFS patients.

The agenda for this meeting is being developed and will be posted on the CFSAC Web site, <http://www.hhs.gov/advcomcfs> when finalized. The meeting will be live-video streamed at www.HHS.gov/Live and archived through the CFSAC Web site: www.hhs.gov/advcomcfs. Listening-only audio via telephone will be available on both days. Call-in information will be posted on the CFSAC Web site.

Individuals who plan to attend should register at the following link by May 17,

2013: <http://www.blsmetings.net/CFSACMay2013>. Attendance by visitors who are not U.S. citizens is welcome, but prior approval is required by sending a request to CFSACMay2013@seamoncorporation.com before May 8, 2013. Members of the media will also need to register. All attendees will be required to show government-issued picture identification (state or federal) for entry into a federal building. Attendees will receive a wrist band that must be worn the entire time. Security requires all non-federal employees to be escorted the entire time they are in the building. Upon leaving the building for any reason, all persons will be required to follow the security steps mentioned above and receive a new wrist band.

Members of the public will have the opportunity to provide public comment at the meeting or via telephone. International calls cannot be accommodated. You are no longer required to submit a written copy of your testimony as in past years unless you wish to have it included in the public record. Individuals wishing to submit public comment for public record must send an electronic copy of their testimony in advance to: CFSACMay2013@seamoncorporation.com by Wednesday, May 15, 2013. A separate sign-up process for requesting time for public comment must be completed by Wednesday, May 15, 2013 at the following link: <http://www.blsmetings.net/CFSACPublicCommentMay2013>. An email to acknowledge receipt of the request for public comment will be sent from this email address. The document for public record must not exceed 5 single-spaced, typed pages, using a 12-point typeface; it is preferred that the document be prepared in the MSWord format. Please note that PDF files, handwritten notes, charts, and photographs that are submitted for distribution to the Committee will not be posted on the CFSAC Web site. However, this material will be made available for the public to view on site during the dates that the meeting is being conducted. Individuals who wish to view this material after the meeting should contact the CFSAC DFO, whose contact information is included in this **Federal Register** notice. Requests to participate in the public comment and provide written testimony will not be accepted through the CFSAC mailbox. Also, the CFSAC mailbox will not respond to questions about specific public comment requests. These requests and/or inquiries should be directed to CFSACMay2013@seamoncorporation.com.