

Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 1, 2013.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02210-2204:

1. *Hometown Community Bancorp, MHC*, Oxford, Massachusetts; to acquire 100 percent of the voting shares of Hometown Community Bancorp, Inc., Oxford, Massachusetts, which will acquire Hometown Bank, A Cooperative Bank, Webster, Massachusetts.

In addition, Hometown Community Bancorp, Inc., Oxford, Massachusetts, also has applied to become a bank holding company, by acquiring Hometown Bank, A Cooperative Bank, Webster, Massachusetts.

Board of Governors of the Federal Reserve System, May 31, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013-13284 Filed 6-4-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

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

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, 21 U.S.C. 360bbb-3. On May 29, 2013, the Secretary 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 Middle East respiratory syndrome coronavirus (MERS-CoV).

On the basis of this determination, she also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Middle East respiratory syndrome coronavirus (MERS-CoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration are effective May 29, 2013.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., 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:

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) authorizing (1) 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 that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear ("CBRN") agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act¹ sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent or agents; 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 CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.²

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 Middle East respiratory syndrome coronavirus (MERS-CoV) to allow the Department to take preparedness measures based on information currently available about the Middle East respiratory syndrome coronavirus (MERS-CoV). 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 Middle East respiratory syndrome coronavirus (MERS-CoV) 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 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On May 29, 2013, pursuant to section 564 of the FD&C Act, 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 Middle East respiratory syndrome coronavirus (MERS-CoV).

III. Declaration of the Secretary of Health and Human Services

Also on May 29, 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

² 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.

¹ 42 U.S.C. 247d-6b

abroad and that involves Middle East respiratory syndrome coronavirus (MERS-CoV), I declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Middle East respiratory syndrome coronavirus (MERS-CoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated May 29, 2013.

Kathleen Sebelius,
Secretary.

[FR Doc. 2013-13333 Filed 6-4-13; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Issues Related to Incidental Findings That Arise in the Clinical, Research, and Direct-To-Consumer Contexts

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the ethical, legal, and social issues raised by incidental findings that arise from genetic and genomic testing, imaging, and testing of biological specimens conducted in the clinical, research, and direct-to-consumer contexts.

DATES: To ensure consideration, comments must be received by July 5, 2013. Comments received after this date will be considered only as time permits.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by email to info@bioethics.gov or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C-100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202-233-3960. E-Mail: hillary.viers@bioethics.gov. Additional information may be obtained at <http://www.bioethics.gov>.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Bioethics Commission is charged with identifying and promoting policies and practices that ensure ethically responsible conduct of scientific research and healthcare delivery. Undertaking these duties, the Bioethics Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Bioethics Commission is considering the distinct ethical issues raised by incidental findings in the contexts of clinical care, research, and direct-to-consumer testing. Emerging medical technologies, changing cost structures, and evolving medical practice make the likelihood of discovering incidental findings in the clinical, research, and direct-to-consumer contexts a growing certainty. At its meeting on April 30, 2013, the Bioethics Commission heard from ethicists, practitioners, and recipients of incidental findings in each of these contexts, and began its consideration of the ethical obligations that clinicians, researchers, and providers of direct-to-consumer testing owe to patients, participants, and consumers.

The Bioethics Commission is interested in receiving views of individuals, groups, and professional communities regarding the ethics surrounding incidental findings resulting from large-scale genetic testing, imaging, and testing of biological specimens in the clinical, research, and/or direct-to-consumer contexts. The Bioethics Commission is particularly interested in receiving public commentary regarding:

- Information about the likelihood of incidental findings arising in large-scale genetic testing, imaging, and testing of biological specimens in the clinic, research, and/or direct-to-consumer contexts and any case studies of such;
- What, if anything, patients, participants, and/or consumers should be told about incidental findings resulting from large-scale genetic testing, imaging, and testing of biological specimens *before* tests are conducted;

- Any duties or ethical obligations that clinicians, researchers, and direct-to-consumer companies might have to actively look for certain incidental findings;

- Best practices, methods, and mechanisms for determining *when* incidental findings ought to be returned to patients, participants, and/or consumers and *how* the return of these findings should occur;

- The acceptability of holding back information—such as establishing “no return” policies, or stipulations in advance of clinical intervention, research, and/or consumer interactions that no incidental findings will be returned; and,

- Any best practices or recommendations regarding incidental findings that apply no matter the type of test or context.

To this end, the Commission is inviting interested parties to provide input and advice through written comments.

Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: May 22, 2013.

Lisa M. Lee,
Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2013-13329 Filed 6-4-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: Solicits Public Input on the Renewal of “Combating the Silent Epidemic of Viral Hepatitis, Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis”

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is seeking broad public input as it begins efforts to renew the 2011 Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis to include actions which can be undertaken over the course of the next three years, 2014–2016.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5:00 p.m. EST on July 5, 2013.

ADDRESSES: Electronic responses are strongly preferred and may be addressed