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 EUAs 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]

BILLING CODE 4154–06–P

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