

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]

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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

to Corinna.Dan@hhs.gov. Written responses should be addressed to: U.S. Department of Health and Human Services, 200 Independence Ave. SW., Room 443-H, Washington, DC 20201. Attention: 2014 Viral Hepatitis Action Plan.

FOR FURTHER INFORMATION CONTACT: Corinna Dan, RN, MPH, Office of HIV/AIDS and Infectious Disease Policy, (202) 401-9581.

SUPPLEMENTARY INFORMATION: On May 12, 2011, the U.S. Department of Health and Human Services (HHS) issued *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (Action Plan). The Action Plan details more than 150 actions to be undertaken over the course of three years by agencies and offices across HHS and partners at the Federal Bureau of Prisons, the U.S. Department of Veterans Affairs, and the U.S. Department of Housing and Urban Development that will improve the prevention, diagnosis, and treatment of viral hepatitis in the United States. A copy of the Action Plan and the Viral Hepatitis Action Plan Interagency Implementation Progress Report—Year 1 are available at <http://www.aids.gov/news-and-events/hepatitis/>.

The Action Plan put a spotlight on this silent epidemic and its growing impact in the United States, where as many as 5.3 million persons are living with chronic hepatitis B or C infection and millions more are at risk of infection. While viral hepatitis has been addressed by various federal research, prevention, care, and treatment programs, much of this work has been conducted independently, sometimes in isolation from other related efforts. Following the Institute of Medicine's (IOM) 2010 report, *Hepatitis and Liver Cancer*, which recommended steps to reduce the threats posed by hepatitis B and hepatitis C, Dr. Howard K. Koh, Assistant Secretary for Health, convened an interagency workgroup composed of subject matter experts from various HHS agencies to review the IOM recommendations and develop a comprehensive strategic viral hepatitis action plan that would:

- Address IOM recommendations for viral hepatitis prevention, care, and treatment;
- set forth actions to improve viral hepatitis prevention and ensure that infected persons are identified and provided care and treatment; and,
- improve coordination of all activities related to viral hepatitis across HHS and promote collaborations with

other government agencies and nongovernmental organizations.

Critical input into the Action Plan was also provided by stakeholders from other federal agencies, professional societies, and state, local, and community partners. The actions presented in the Action Plan represent efforts to be undertaken in calendar year 2011, 2012, or 2013. Some of the actions outlined in the Action Plan can be accomplished by using existing resources through improved coordination and integration, while others are subject to the availability of funds.

The Action Plan is organized into six priority areas which correspond to the 2010 IOM recommendations:

Priority 1—Educating Providers and Communities To Reduce Health Disparities

- GOAL 1.1 Build a U.S. health care workforce prepared to prevent and diagnose viral hepatitis and provide care and treatment to infected persons.
- GOAL 1.2 Decrease health disparities by educating communities about the benefits of viral hepatitis prevention, care, and treatment.

Priority 2—Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer

- GOAL 2.1 Identify persons infected with viral hepatitis early in the course of their disease.
- GOAL 2.2 Link and refer persons infected with viral hepatitis to care and treatment.
- GOAL 2.3 Improve access to and quality of care and treatment for persons infected with viral hepatitis.
- GOAL 2.4 Advance research to facilitate viral hepatitis prevention and enhance care and treatment for infected persons.

Priority 3—Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease

- GOAL 3.1 Build a network of state and local surveillance systems with sufficient capacity to monitor viral hepatitis transmission and disease.
- GOAL 3.2 Monitor viral-hepatitis-associated health disparities.
- GOAL 3.3 Monitor provision and impact of viral hepatitis prevention, care, and treatment services.
- GOAL 3.4 Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.

Priority 4—Eliminating Transmission of Vaccine-Preventable Viral Hepatitis

- GOAL 4.1 Eliminate mother-to-child transmission of hepatitis B.
- GOAL 4.2 Achieve universal hepatitis A and B vaccination for vulnerable adults.
- GOAL 4.3 Design and test new or improved viral hepatitis vaccines and determine the indications for their optimal use.

Priority 5—Reducing Viral Hepatitis Caused by Drug Use Behaviors

- GOAL 5.1 Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.
- GOAL 5.2 Mobilize community resources to prevent viral hepatitis caused by injection drug use.
- GOAL 5.3 Provide persons who inject drugs with access to care and substance abuse treatment to prevent transmission and progression of disease.
- GOAL 5.4 Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.
- GOAL 5.5 Advance research to improve prevention of viral hepatitis among persons who use drugs.

Priority 6—Protecting Patients and Workers From Health Care-Associated Viral Hepatitis

- GOAL 6.1 Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.
- GOAL 6.2 Reduce iatrogenic transmission of viral hepatitis associated with blood, organs, and tissues.
- GOAL 6.3 Reduce occupational transmission of viral hepatitis.
- GOAL 6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.

Following the Action Plan's release, agencies and offices across HHS began working to implement the actions assigned to them in the Action Plan. To support these efforts, HHS convened a Viral Hepatitis Action Plan Implementation Group (VHIG) and charged it with coordinating, supporting, and overseeing activities related to the Action Plan. The VHIG comprises representatives from across HHS and other federal agencies and is chaired by Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases.

The opportunity provided by the renewal of the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis for 2014, 2015, 2016 offers many benefits such as:

- Identification of measures to assess progress on addressing viral hepatitis in the U.S.;
- identification of gaps in viral hepatitis services and data;
- inclusion of new input from stakeholders;
- recommendations for effective viral hepatitis program models; and,
- application of lessons learned since the release of the 2011 Action Plan.

Accordingly, this request for information seeks public comment on several key dimensions of a renewed Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis, including but not limited to the following:

1. Considering the six priority areas and related goals, please respond to the following questions:

a. Are there critical gaps in viral hepatitis activities which should be given a major focus in a renewed Action Plan? Provide background and rationale for their inclusion. These gaps may have been included in the 2011 Viral Hepatitis Action Plan or they may be new.

b. Are there effective models and best practices that should be considered for replication? Please include rationale for their use in the field/area of viral hepatitis.

2. What are the specific measures that should be used to track progress of implementation of the Viral Hepatitis Action Plan and/or the progress of addressing the epidemics of viral hepatitis? Provide background and rationale for the use of these measures.

3. What specific activities within and/or components of the Affordable Care Act offer substantial opportunities to support improved viral hepatitis health care services and data? Describe how this might evolve.

4. How can government better engage with non-governmental stakeholders around the implementation of the National Viral Hepatitis Action Plan? Provide examples/suggestions of how this could be integrated into a renewed Action Plan and its implementation.

5. What additional information not specifically addressed elsewhere in this RFI that would be important for the government to bear in mind in developing a renewed National Viral Hepatitis Action Plan?

Dated: May 21, 2013.

Ronald O. Valdiserri,

*Deputy Assistant Secretary for Health,
Infectious Diseases, Office of the Assistant
Secretary for Health.*

[FR Doc. 2013-13332 Filed 6-4-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0099]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revision of the Requirements for Constituent Materials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 5, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0666. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrahi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Revision of the Requirements for Constituent Materials—(OMB Control Number 0910-0666)—Extension

In the **Federal Register** of April 13, 2011 (76 FR 20513), FDA issued a final

rule amending the regulation for the use of constituent materials in licensed biological products. Under 21 CFR 610.15(d), the Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drugs Evaluation and Research (CDER) may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Thus, the provision provides manufacturers of biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections. Manufacturers seeking approval of an exception or alternative must submit a request in writing. The request must be clearly identified with a brief statement describing the basis for the request and the supporting data. The request may be submitted as part of the original biologics application, as an amendment to the original, pending application or as a prior approval supplement to an approved application. The information to be collected assists FDA in identifying and reviewing requests for an exception or alternative to the requirements for constituent materials.

Respondents to this information collection provision are manufacturers of biological products. Since implementation of the final rule, FDA has received no submissions of requests for an exception or alternative for constituent materials. Therefore, FDA is estimating one respondent and annual response annually to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials. The average burden per response is based on FDA experience with similar information collection requirements.

In the **Federal Register** of November 29, 2012 (77 FR 71193), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.15	1	1	1	1	1

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.