Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2012–0004]

Draft Public Health Action Plan—A National Public Health Action Plan for the Detection, Prevention, and Management of Infertility

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is publishing this notice requesting public comment on the draft *National Public Health Action Plan for the Detection, Prevention, and Management of Infertility.* The draft plan can be found at *http://www.regulations.gov* Docket No. CDC–2012–0004. Also found in the docket is a supporting document for reference, the *Outline for a National Action Plan for the Prevention, Detection, and Management of Infertility,* which was subsequently developed into the present Plan.

DATES: Written comments must be received on or before June 15, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2012–0004, by any of the following methods:

- *Internet:* Access the Federal eRulemaking portal at *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health, Attn: National Public Health Action Plan for the Detection, Prevention, and Management of Infertility, Docket No. CDC–2012–0004, 4770 Buford Highway NE., Mailstop K–34, Atlanta, Georgia, 30341.

Instructions: All submissions received must include the agency name and docket number for this notice. All relevant comments received will be posted publicly without change, including any personal or proprietary information provided. To download an electronic version of the plan, access *http://www.regulations.gov.* Written comments, identified by Docket No. CDC–2012–0004, will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Daylight Time, at 2900 Woodcock Blvd., Atlanta, Georgia 30341. Please call ahead to (770) 488–5200 and ask for a representative from the Division of Reproductive Health to schedule your visit. Comments may also be viewed at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Denise Jamieson, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health, 4770 Buford Highway NE., Mailstop K–34, Atlanta, Georgia 30341, (770)488–5200.

SUPPLEMENTARY INFORMATION: In 2007, a CDC-wide ad hoc workgroup formed to examine the full scope of infertility activities across the agency. This workgroup conducted an assessment to identify gaps and opportunities in public health surveillance, research, communications, programs, and policy development, which led to the 2010 publication of a white paper outlining the need for a national plan, with a public health focus, on infertility prevention, detection, and management. In consultation with many governmental and nongovernmental partners, CDC developed the National Public Health Action Plan for the Detection, Prevention and Management of Infertility. Addressing both male and female infertility, the plan outlines and summarizes actions needed to promote, preserve, and restore the ability of women in the United States to conceive, carry a pregnancy to term, and deliver a healthy infant. This goal extends beyond simply addressing the inability to conceive but also focuses on reducing the burden of impaired fecundity by promoting behaviors that maintain fertility; by promoting prevention, early detection, and treatment of medical conditions; and by reducing environmental and occupational threats to fertility. Given the public health focus of this action plan, promoting healthy pregnancy outcomes associated with treating and managing infertility is also important, as is improving the efficacy and safety of infertility treatment.

The document is organized into three chapters: ''Detection of Infertility,'' ''Prevention of Infertility,'' and ''Management of Infertility.'' Each chapter addresses the topic's public health importance, existing challenges, and opportunities for action to decrease the impact of infertility on the public's health. The suggested opportunities provide federal and other government agencies, professional and consumer organizations, and other partners and stakeholders a foundation and platform to work together to decrease the burden of infertility in the United States.

Dated: May 9, 2012.

Kathleen Sebelius,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0009]

Cooperative Agreement To Support Innovation in Vaccine Clinical Trial Design and Collaboration in Pharmacovigilance To Advance Global Access to Safe and Effective Vaccines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for an award of a cooperative agreement to the World Health Organization (WHO) in support of collaborative efforts to advance innovative approaches to vaccine clinical trial design and to enhance the utilization of a range of pharmacovigilance tools as a means to further vaccine safety and potentially facilitate more rapid introduction of new vaccines. The goal of FDA's Center for Biologics Evaluation and Research (CBER) is to enhance technical collaboration and cooperation between FDA, WHO, and its Member States to facilitate strengthening regulatory capacity globally.

DATES: Important dates are as follows:

1. The application due date is June 15, 2012.
2. The anticipated start date is September 15, 2012.
3. The expiration date is June 16, 2012.

ADDRESSES: Submit the paper application to: Vieda Hubbard, Grants Management (HFA–500), 5630 Fishers Lane, Rockville, MD 20857, and a copy to Leslie Haynes, Center for Biologics Evaluation and Research, Office of the Director (HFM–30), 1401 Rockville Pike, Rockville, MD 20852–1448. For more