DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–09AI]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of the Action Plan for the National Public Health Initiative on Diabetes and Women's Health—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Diabetes can have unique and profound effects on women's lives and health. For instance, diabetes is a more common cause of coronary heart disease among women than men, and the prognosis of heart disease is worse for women with diabetes than men with diabetes. The burden of diabetes for women is also unique because the disease can affect both mothers and their unborn children. It is projected that from 2000 to 2025, women will represent more than half of all cases of diabetes in the United States.

The National Public Health Initiative on Diabetes and Women's Health (''The Initiative'') was established to provide support and resources for the creation and implementation of a national public health Action Plan. The Initiative is co-sponsored by the American Diabetes Association (ADA), the American Association of Diabetes Educators (AADE), the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), and the Centers for Disease Control and Prevention (CDC).

The Initiative's Action Plan identifies gaps in diabetes-related research and programmatic activities, and strategic objectives, within the areas of community health, diabetes state programs, education and community outreach, quality of care, research, and surveillance.

CDC proposes to conduct a survey to assess collective progress toward achieving the objectives outlined in the Action Plan. The survey will also request information about the specific strategies, steps, resources and partnerships that have been employed to meet the objectives. Respondents will be the 4 co-sponsors of The Initiative, 20 CDC-funded, state-based diabetes prevention and control programs (DPCPs), and approximately 100 private-sector public health organizations with a focus on diabetes and/or women's health. Survey responses will be compiled into a progress report and disseminated to respondents, allowing them to learn about each other's activities and the steps needed to replicate successful diabetes prevention and control efforts.

Information will be collected once per year for a period of 3 years, and the progress report will be updated annually to reflect recent activities and progress. Private-sector partners and state-based partners will submit one survey response per organization per year. Co-sponsors will receive a modified version of the survey. Due to the size and complexity of the activities managed by co-sponsors, the co-sponsoring organizations will have the option of submitting multiple survey responses from different areas of the organization, in order to capture the full range of activities conducted. It is estimated that each co-sponsor will submit an average of three responses. Participation in the survey is voluntary.

Information will be collected electronically through a web-based survey tool. There are no costs to respondents other than their time. The total estimated annualized burden hours are 66.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)
Co-Sponsors	Co-Sponsor Survey	4	3	.5
State-based DPCPs	Partner Survey	20	1	.5
Private Sector Partners	Partner Survey	100	1	.5

Dated: November 10, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–27726 Filed 11–18–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0533]

Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus''. This draft guidance provides recommendations for assessing blood donor suitability and blood product safety and maintaining blood and blood product availability in response to pandemic (H1N1) 2009 virus. It is intended for establishments that manufacture Whole Blood and blood components intended for use in

transfusion and blood components intended for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 3, 2009. The abbreviated comment period is necessary because pandemic (H1N1) 2009 virus has the potential to cause disruptions in the blood supply and given this possibility, the agency needs to finalize the guidance as soon as possible.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus'' dated November 2009. This draft guidance provides recommendations for assessing blood donor suitability and blood product safety and maintaining blood and blood product availability in response to pandemic (H1N1) 2009 virus. It is intended for establishments that manufacture Whole Blood and blood components intended for use in transfusion and blood components intended for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes. At the present time, FDA is working with other HHS agencies to monitor the pandemic (H1N1) 2009 virus and its potential impact on blood availability and blood safety. The agency notes that the Centers for Disease Control and Prevention (CDC) has issued a document entitled ''Interim Infection Control Guidance on 2009 H1N1 Influenza for Personnel at Blood and Plasma Collection Facilities.''[1] We recognize the importance of the CDC recommendations for infection control in blood and plasma collection establishments.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. The collection of information in 21 CFR part 606 has been approved under OMB control number 0910–0116. The collection of information for 21 CFR part 601 has been approved under OMB control number 0910–0338.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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[1] *http://www.cdc.gov/h1n1flu/infectioncontrol.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Tuesday, December 15, 2009, from 1:30 p.m. to approximately 5 p.m.

Location: National Institutes of Health, Bldg. 29, conference rm. 121. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm*. Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401