the institution; the Respondent agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; and

(3) To ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the Respondent is involved, a certification that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report. The Respondent must ensure that the institution sends the certification to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. E9–7411 Filed 4–1–09; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-09–08BI]

Proposed Data Collections Submitted for Public Comment and Recommendations

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) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of the National Youth Violence Prevention Resource Center (NYVPRC)—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The origin of the National Youth Violence Prevention Resource Center (NYVPRC) is woven into the federal response to the Columbine High School shootings in 1999. As the Nation took a broad look at the issue of violence occurring in school settings, it became clear that violence among adolescents stretched far beyond the walls of educational institutions and presented a complex threatening public health concern requiring a comprehensive response. To that end, the White House established the Council on Youth Violence in October 1999 to coordinate youth violence prevention activities of all federal agencies. The Council, in collaboration with CDC and other federal agencies, directed the development of NYVPRC to serve as a user-friendly, single point of entry to potentially life-saving information about youth violence prevention.

Since 1999, a substantial body of evidence has evolved to support the belief that youth violence can be prevented through the comprehensive, systematic application of effective approaches. A better understanding of the key influencers on the prevention of youth violence has emerged. Armed with this greater understanding, the NYVPRC's role has been refocused to better position it to respond to emerging needs.

This project will evaluate a pilot implementation of the revised NYVPRC Web site. The revised Web site will target local government and community leaders with youth violence-related online training, information resources and community workspace to build and sustain comprehensive, community-wide prevention efforts. The objectives of the NYVPRC pilot project are to determine (1) The usefulness and favorability of the online training, information resources and community workspaces, (2) the reach of targeted promotional efforts, and (3) progress made on short term outcomes. Four data collection tools will be used to measure these objectives: (1) user feedback surveys, (2) training surveys, (3) implementation interviews and (4) coalition capacity surveys.

The user feedback surveys will elicit feedback from users at various points on the NYVPRC Web site. The training surveys will be conducted during the online training available through the Web site. The implementation interviews and coalition capacity surveys will be conducted at the beginning of the pilot period as a baseline measure and again at the end of the 12-month pilot period. The baseline information will assist CDC in tailoring technical assistance that might be required by the pilot communities. The evaluation will then utilize these baseline measures along with the information collected following the pilot to assess the Web site's success at supporting the development of community-wide youth violence prevention coalitions and subsequent strategic planning.

The pre-post research design of the evaluation will aid CDC in assessing the changes in knowledge, attitudes, and resource capacity associated with the NYVPRC Web site and will inform revision of the Web site materials for a future nationwide launch. There is no cost to respondents for participation.

The total estimated annualized burden hours are 353.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
General Public, coalition members, coalition leaders	Online Training Survey	400	1	15/60
General Public, coalition members, coalition leaders	User Feedback Survey	1000	1	5/60
Coalition Members	Coalition Member Survey	120	2	30/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
Coalition Leaders	Coalition Leader Interviews	50	2	30/60

Dated: March 27, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–7413 Filed 4–1–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0132]

Draft Guidance for Industry: Somatic Cell Therapy for Cardiac Disease; 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 ''Guidance for Industry: Somatic Cell Therapy for Cardiac Disease'' dated March 2009. The draft guidance document provides sponsors of cellular therapies for the treatment of cardiac disease with recommendations on the design of preclinical and clinical studies, and information that should be submitted about the product delivery system. This guidance also provides recommendations on the chemistry, manufacturing and controls information to include in an investigational new drug application (IND) for cardiac cellular therapy.

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 July 1, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. 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 draft guidance document.

Submit written comments on the draft 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:

Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or

Sabina Reilly, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4095.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Somatic Cell Therapy for Cardiac Disease'' dated March 2009. This guidance provides to sponsors developing cellular therapies for the treatment of cardiac disease with recommendations including, but not limited to, the following: (1) Design of preclinical and clinical studies; (2) information to submit on the product delivery system; and (3) the chemistry, manufacturing and controls information to include in an IND for cardiac cellular therapy. This guidance also includes regulatory considerations for the use of intravascular catheter delivery systems.

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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the IND regulations (21 CFR part 312) have been approved under OMB control number 0910–0014, and the Good Laboratory Practice regulations (21 CFR part 58) have been approved under OMB control number 0910–0119.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may 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 the 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/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: March 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–7350 Filed 4–1–09; 8:45 am]

BILLING CODE 4160–01–S