

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.
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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Draft Guidance for Industry: Somatic Cell Therapy for Cardiac Disease; Availability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 The draft guidance document provides sponsors of cellular therapies for the treatment of cardiac disease with recommendations on the design of preclinical and clinical studies,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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 1, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.
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