DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Breast and Cervical Cancer Early Detection Federal Advisory Committee

Correction: This notice was published in the **Federal Register** on November 5, 2012, Volume 77, Number 214, Page 66469. A teleconference line has been added for public participation. To participate, please dial toll-free 1 (866) 756–7359 and enter passcode 8958302 for access. Participation by teleconference is limited by the number of ports available.

Contact Person for More Information: Alicia Ortner, Committee Specialist, CDC, 4770 Buford Hwy, M/S K–57, Atlanta, Georgia 30341. Telephone (770) 488–4880. Email: *aortner@cdc.gov.* The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 21, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–28858 Filed 11–28–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0099]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments regarding the requirement for the use of constituent materials in licensed biological products.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Revision of the Requirements for Constituent Materials in Biological Products—21 CFR 610.15(d) (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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	No. 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.

Dated: November 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28907 Filed 11–28–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1038]

Draft Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products; 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: Preclinical Assessment of Investigational Cellular and Gene Therapy Products,'' dated November 2012. The draft guidance document provides sponsors and individuals that design and implement preclinical studies with recommendations on the substance and scope of preclinical information needed to support clinical trials for investigational products regulated by the Center for Biologics Research and Evaluation (CBER), Office of Cellular, Tissue, and Gene Therapies (OCTGT). The product areas covered by this guidance are cellular therapy, gene therapy, therapeutic vaccination, and xenotransplantation. The guidance is intended to clarify current expectations regarding the preclinical information that supports an investigational new drug application (IND) and a biologics license application (BLA) for these product areas.

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 either electronic or written comments on the draft guidance by February 27, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), 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 draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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: Preclinical Assessment of Investigational Cellular and Gene Therapy Products,'' dated November 2012. The draft guidance document provides sponsors and individuals that design and implement preclinical studies with recommendations on the substance and scope of preclinical information needed to support clinical trials for investigational products regulated by OCTGT. The product areas covered by this guidance are cellular therapy, gene therapy, therapeutic vaccination, and xenotransplantation. The guidance is intended to clarify current expectations regarding the preclinical information that supports an IND and a BLA for these product areas.

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 draft 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 21 CFR part 312 has been approved under 0910–0014; the collections of information in 21 CFR part 601 has been approved under 0910–0338; and the collections of information in 21 CFR part 58 has been approved under 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 either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28882 Filed 11–28–12; 8:45 am]

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