DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2010–N–0066]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Human Tissue Intended for Transplantation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–7651, *Juanmanuel.Vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 2, 2010 (75 FR 45127), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0302. The approval expires on January 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–3031 Filed 2–10–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0600]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Cover Sheet, Form 3546

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 14, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0539. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Drug User Fee Cover Sheet; FDA Form 3546—(OMB Control Number 0910–0539)—Extension

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-12), as amended by the Animal Drug User Fee Act (ADUFA), FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet (FDA Form 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

In the **Federal Register** of November 29, 2010 (75 FR 73103), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act Section amended by ADUFA	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
740(a)(1) FDA Form 3546 (Cover Sheet)	76	1	76	1	76
Total					76

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's database system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the

number of submissions received by FDA in fiscal year 2008. The estimated hours per response are based on past FDA experience with the various submissions. The hours per response are based on the average of these estimates.

Dated: February 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–3167 Filed 2–10–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Cancer Biomedical Informatics Grid® (caBIG®) Support Service Provider (SSP) Program (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: cancer Biomedical Informatics Grid ® (caBIG ®) Support Service Provider (SSP) Program (NCI). *Type of Information Collection Request:* Existing Collection in Use Without an OMB Number. *Need and Use of Information Collection:* The NCI Center for Biomedical Informatics and Information Technology (CBIIT) launched the enterprise phase of the caBIG ® initiative in early 2007 with an emphasis on widespread institutional adoption of the program and tools. This emphasis on adoption has generated an expanding community with diverse needs for support, which are met through the resources available through the caBIG ® Enterprise Support Network (ESN), including the caBIG ® Support Service Provider (SSP) Program. The caBIG ® SSPs provide caBIG ® end-users with the freedom to match what caBIG ® has to offer to their unique organizational goals and needs, so having this customized support option available is critically important to advancing the goals of the caBIG ® program. caBIG ® SSP applicants are evaluated against well-defined criteria published in the SSP Program Announcement and must successfully demonstrate that they have the technical capabilities, staffing and scalability, geographic coverage (when applicable), and the domain expertise in biomedicine to effectively serve caBIG ® users. The information submitted by SSP applicants enables NCI to determine whether such applicants are qualified to enter into trademark license negotiations with NCI to use the caBIG ® trademarks in connection with their services and become designated as caBIG ® SSPs. Thus, the collection of information from SSP applicants is critical to both ensuring that the goals and objectives of the caBIG ® program will be maintained and furthered by the organizations designated as SSPs and facilitating NCI's ability to exercise appropriate stewardship of the caBIG ® trademarks. Sections 410 and 411 of the Public Health Service Act (42 U.S.C. 285 and 285a) authorize the collection of the information. *Frequency of Response:* once for the applicants. caBIG ® SSP applications are accepted on a rolling basis and reviewed several times a year. *Affected Public:* Private sector including Business or other for-profits and not-for-profit organizations and institutions. *Type of Respondents:* Technical representatives of commercial, academic or not-for-profit organizations. The annual reporting burden is estimated at 360 hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

A.12—1 ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Commercial Organizations	14	1	1440/60 (24 hours)	336
Nonprofit Organizations	1	1	1440/60 (24 hours)	24
Totals	15			360

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact John Speakman, NCI CBIIT Chief Program Officer, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH, DHHS, 2115 E. Jefferson Street, Suite 6000, Rockville, MD 20892 or call non-toll-free number 301–451–8786 or e-mail your request, including your address to: *john.speakman@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: February 4, 2011.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011–3144 Filed 2–10–11; 8:45 am]

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