also conserve agency resources by reducing the current volume of inquiries individual FDA offices and employees must handle concerning advisory committee schedules and procedures.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.


Joanne Less,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–4258 Filed 3–1–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Reinstatement of OMB No. 0925–0601/exp. 02/28/2010, Request for Human Embryonic Stem Cell Line To Be Approved for Use in NIH Funded Research

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a reinstatement of approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on September 25, 2009, page 48973 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number.

Proposed Collection: Title: Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research. Type of Information Collection Request: Revision, OMB 0925–0601, Expiration Date 02/28/2010, Form Number: NIH 2890. Need and Use of Information Collection: The form is used by applicants to request that human embryonic stem cell lines be approved for use in NIH funded research. Frequency of response: Applicants may submit applications at any time; this request is a one-time submission. Affected Public: Business or other for-profit: Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. Type of Respondents: Adult scientific professionals. The annual reporting burden is as follows: Estimated Number of Respondents: 160,135; Estimated Number of Responses per Respondent: 1; Average Burden Hours per Response: 14; and Estimated Total Annual Burden Hours Requested: 2,251,500. The estimated annualized cost to respondents is $78,802,500.

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) 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) 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) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number (301) 435–0941, or E-mail your request, including your address to: currie_m@od.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.


Mikia Currie,
Office of Policy for Extramural Research Administration, OD, NIH.

[FR Doc. 2010–4301 Filed 3–1–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Evaluation of Adolescent Pregnancy Prevention Approaches—Baseline Data Collection.

OMB No.: ICRA: 0970–0360.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Evaluation of Adolescent Pregnancy Prevention Approaches (PPA). PPA is being undertaken to expand available evidence on effective ways to reduce teen pregnancy. The evaluation will document and test a range of pregnancy prevention approaches in up to eight program sites. Program impacts will be estimated using a random assignment design, involving random assignment at the school, individual, or other level, depending on the program setting. The findings of the evaluation will be of interest to the general public, to policymakers, and to organizations interested in teen pregnancy prevention.

This proposed information collection activity focuses on collecting baseline data from a self-administered questionnaire which will be used to perform meaningful analysis to determine significant program effects. Through a survey instrument, respondents will be asked to answer carefully selected questions about demographics and risk and protective factors related to teen pregnancy. As appropriate to each program being evaluated, youth records, performance, and program participation data will also be collected.

Respondents: The data will be collected through private, self-administered questionnaires completed by study participants, i.e. adolescents assigned to a select school or community teen pregnancy prevention program or a control group. Surveys will be distributed and collected by trained professional staff. Youth school records, performance, and program participation data will also be collected from participating schools and organizations, as appropriate to the site.
Federal Register / Vol. 75, No. 40 / Tuesday, March 2, 2010 / Notices 9419

ANNUAL BURDEN ESTIMATES

<table>
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<th>Instrument</th>
<th>Annual number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
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<td>8</td>
<td>1</td>
<td>.8</td>
<td>64</td>
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Estimated Total Annual Burden Hours: 1,864.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: OPREinfo@collection@acf.hhs.gov.

OMB Comment

ONE is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.


Steven M. Hamner,
OPRE Reports Clearance Officer.
[FR Doc. 2010–4209 Filed 3–1–10; 8:45 am]
BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0001]

Oncologic Drugs 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). The meeting will be open to the public.

Name of Committee: Oncologic Drugs 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 March 22, 2010, from 8 a.m. to 5 p.m. This meeting is a rescheduling of a postponed meeting originally announced in the Federal Register of December 17, 2009 (74 FR 66986) to take place on February 10, 2010.


Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: nicole.vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency’s Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session of March 22, 2010, the committee will discuss new drug application (NDA) 022–481, proposed trade name PIXUVRI (pixantrone dimaleate) injection, by Cell Therapeutics, Inc. The proposed indication (use) for this product is as a single agent treatment for patients with recurring or refractory (difficult to treat), aggressive Non-Hodgkin’s Lymphoma who have received two or more prior lines of therapy.

During the afternoon session, the committee will discuss NDA 022–374, proposed trade name OMAPRO (omacetaxine mepesuccinate) for injection, by ChemGenex Pharmaceuticals. The proposed indication (use) for this product is for the treatment of adults with chronic myeloid leukemia bearing a genetic alteration known as the Bcr-Abl T315I mutation, and who have failed prior therapy with the drug imatinib.

Due to the postponement of the February 10, 2010, Oncologic Drugs Advisory Committee meeting because of severe weather conditions and the urgency to reschedule this meeting, FDA regrets that it was unable to publish this notice prior to the March 22, 2010, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Background materials from the originally scheduled February 10, 2010, Oncologic Drugs Advisory Committee meeting are currently available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link. Should any additional background materials become available, they will be posted 2 days before the March 22, 2010, meeting at this same Web site.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 17, 2010. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 12, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to