

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75	1	3	3	10	30

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

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the number of responses per respondent equals the total annual responses. The average burden per response (in hours) is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Dated: October 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-26132 Filed 10-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0281]

Pilot Program To Evaluate Proposed Proprietary Name Submissions; Public Meeting on Pilot Program Results Will Not Be Held

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it will not hold a public meeting to discuss the results of a 2-year voluntary pilot program that enabled participating pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations for FDA to review. FDA anticipated holding a public meeting at the end of fiscal year 2011 to discuss the results of the pilot program, but the Agency did not receive sufficient pilot submissions to form a basis for discussion. Interested parties may submit to the docket any additional comments on the pilot program. As previously announced, FDA plans to publish a draft guidance describing the best test methods for proprietary name evaluation.

DATES: Submit either electronic or written comments by November 10, 2011.

ADDRESSES: Submit electronic comments on the pilot program or this document 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding human drug products: Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993-0002.

Regarding human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM-17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), Congress reauthorized and expanded the Prescription Drug User Fee program for fiscal years 2008 to 2012 (PDUFA IV). In performance goals agreed to in conjunction with the reauthorization of PDUFA IV, FDA agreed to publish a concept paper on and implement a pilot program to enable pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review. (See IX.B at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm>.)

In June 2008, FDA held a public technical meeting (see 73 FR 27001, May 12, 2008) to discuss a draft concept paper describing the pilot program and FDA's thinking about how pharmaceutical firms could participate in the pilot program to evaluate proposed proprietary names and submit the data generated to FDA for review. After considering comments from the meeting and the public docket, FDA announced the availability of the concept paper entitled "PDUFA Pilot Project Proprietary Name Review" in the **Federal Register** of October 7, 2008

(73 FR 58604). As stated in the concept paper, the goals of the pilot program were to minimize the use of names that are misleading or that are likely to lead to medication errors, to make FDA's application review more efficient, and to make regulatory decisions more transparent.

In the **Federal Register** of October 1, 2009 (74 FR 50806), FDA announced the opportunity for firms to register for and submit data to the voluntary pilot program. FDA stated that at the end of fiscal year 2011, or after accruing 2 years experience with pilot program submissions, the Agency would evaluate the results to determine whether the model of industry conducting reviews, submitting the results to FDA, and FDA reviewing the data is feasible and whether it is a better model than FDA conducting de novo reviews of proprietary names. FDA planned to hold a public meeting to discuss the results of the pilot program and recommended additions and/or changes to methods based on the report results. FDA also stated that, following the meeting, FDA would publish draft guidance on best test practices for proprietary name review.

FDA began accepting requests to participate in the pilot program on October 1, 2009, and the pilot program ended on September 30, 2011. Although three applicants registered to participate during the 2-year period, FDA received only one complete submission for pilot program review, which is not a sufficient number to assess the feasibility of industry conducting reviews of proposed proprietary names. Therefore, the public meeting that was anticipated to occur at the end of fiscal year 2011 to assess the pilot program for evaluation of proposed proprietary names will not be held because of insufficient participation. The pilot program docket (docket number FDA-2008-N-0281) has remained open for comment during the 2-year pilot program, and FDA has invited comments on human factor testing. In lieu of a public meeting, interested persons may submit any additional comments to the docket. After the close of the public comment period, FDA intends to publish a draft guidance

describing the best test methods for proprietary name evaluation.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the pilot project or this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: October 4, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2011-26099 Filed 10-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: Advisory Council on Blood Stem Cell Transplantation (ACBSCT).

Date and Time: November 08, 2011, 10 am to 4 pm EDT.

Place: The meeting will be via audio conference call and Adobe Connect Pro.

Status: The meeting will be open to the public.

Purpose: Pursuant to Public Law 109-129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended,) the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) advises the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program.

Agenda: The Council will hear reports from five ACBSCT Work Groups: Cord Blood Bank Collections, Realizing the Potential of Cord Blood, Scientific Factors Necessary to Define a Cord Blood Unit as High Quality, Cord Blood Thawing and Washing, and Access to Transplantation. The Council also will hear presentations and discussions, which may include the following topics: CAO study and report; FDA licensure and unmet need.

The public can join the meeting by:

1. Calling Conference Phone Number: 888-790-3527 and providing Participant Code: 8064893, for the audio portion, *AND*

2. Connecting to the ACBSCT Adobe Connect Pro Meeting for the visual portion using the following URL: <https://hrsa.connectsolutions.com/acbsct/> (if the link does not work, copy and paste it into your browser). The conference call leader is Patricia A. Stroup.

Call (301) 443-0437 or send an e-mail to ptongele@hrsa.com if you are having trouble connecting to the meeting site.

Participants should call no later than 9:45 am EDT in order for logistics to be set up.

If you have never attended an Adobe Connect Meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm.

For quick overview, please access: http://www.adobe.com/go/connectpro_overview. Those planning to participate are asked to complete and submit an online registration form by visiting our Web site at <http://www.ACBSCT.com> and selecting the tab titled "Registration." Individuals with no Internet access should request the registration form by contacting Gabrielle Kardolus at (301) 585-1261 or at Gabrielle.Kardolus@luxcg.com and fax the registration form to Gabrielle Kardolus at (301) 585-7741. The registration deadline is November 2, 2011. The next face-to-face ACBSCT meeting is planned for Spring 2012. Details regarding the next meeting will be published in a subsequent **Federal Register** notice.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Passy Tongele, DoT, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: ptongele@hrsa.gov. Requests should contain the name, address, telephone number, e-mail address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

For Further Information Contact: Patricia Stroup, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: October 3, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-26168 Filed 10-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel.
Date: November 9, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Martha F. Matocha, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm. 1070, Bethesda, MD 20892, 301-435-0813, matocham@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333; 93.702, ARRA Related Construction Awards., National Institutes of Health, HHS)

Dated: October 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-26218 Filed 10-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections