party claims for damages arising from or related to competition activities.

Registration Process for Participants:

To register for this challenge participants should either:

- Access the *www.challenge.gov* Web site and search for the ''Health Design Challenge''.
- Access the ONC Investing in Innovation (i2) Challenge Web site at:
  - *http://www.health2con.com/devchallenge/challenges/onc-i2-challenges/.*
  - A registration link for the challenge can be found on the landing page under the challenge description.

Amount of the Prize:

Each submission will be considered for all four prize categories listed below. A review panel will select winners based on defined criteria (below). An individual submission can win multiple awards.

- Overall Design: $16,000 (1st), $6,000 (2nd), and $4,000 (3rd).
- Best Medication Section—$5,000 (1st), $3,000 (2nd), and $1,000 (3rd).
- Best Medical/Problem History Section—$5,000 (1st), $2,000 (2nd), and $1,000 (3rd).
- Best Lab Summaries—$5,000 (1st), $2,000 (2nd), and $1,000 (3rd).

Awards may be subject to Federal income taxes and HHS will comply with IRS withholding and reporting requirements, where applicable.

Payment of the Prize:

Prize will be paid by contractor.

Basis Upon Which Winners Will Be Selected:

The review panel will make selections based upon the following criteria:

- Overall Appeal.
- Patient Usefulness—Does it address the needs of a patient?
- Caregiver Usefulness—Does it ease the responsibilities of a caregiver?
- Physician Usefulness—Can a physician integrate it into their workflow?
- Visual Hierarchy—Can the most important information be easily found?
- Information Density—Is it easy to digest the information that is presented?
- Accessibility—Can a varied population make use of this document?

Additional Information:

Authority: 15 U.S.C. 3719.

Dated: October 15, 2012.

Farzad Mostashari,

National Coordinator for Health Information Technology.

[FR Doc. 2012–25954 Filed 10–19–12; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0471]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Cover Sheet; Form FDA 3397

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 November 21, 2012.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0297. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements to those applications. Under this authority, pharmaceutical companies pay a fee for certain new drug applications (NDAs), biologics license applications (BLAs), or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs, BLAs, and/or supplemental applications to those applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2011, there are an estimated 260 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105–115). The total number of annual responses is based on the number of submissions received by FDA in FY 2011. CDER received 3,363 annual responses that include the following submissions: 114 NDAs; 4 BLAs; 1,900 manufacturing supplements; 1,209 labeling supplements; and 136 efficacy supplements. CBER received 768 annual responses that include the following submissions: 6 BLAs; 698 manufacturing supplements; 44 labeling supplements; and 20 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

FDA is revising Form FDA 3397 in the following ways: (1) By updating the applicable Web sites; (2) by adding a Privacy Act Notice pursuant to the Privacy Act of 1974, 5 U.S.C. 552a(3)j; (3) by adding 351(k) applications to the CDER and CBER lists of applications and supplements for which Form FDA 3397 need not be submitted; (4) by adding ''or proper name'' to instruction number 3; and (5) by making minor editorial changes.

In the **Federal Register** of May 18, 2012 (77 FR 29663), 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]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 3397	260	15.89	4,131	0.5 (30 min.)	2,065.5

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

Dated: October 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–25898 Filed 10–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Arthritis 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: Arthritis 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 December 20, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg, 31, rm 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: AAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22151, rintatolimod injection (proposed trade name AMPLIGEN), submitted by Hemispherx Biopharma, Inc., for the treatment of patients with chronic fatigue syndrome.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

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 December 6, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2:30 p.m. Those individuals interested in making 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 November 28, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 29, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 16, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–25878 Filed 10–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: November 14, 2012, 8:30 a.m.–5:30 p.m.; November 15, 2012, 8:30 a.m.–3:30 p.m.