ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| ACF–196T | 72 | 4 | 1.5 | 432 |

*Estimated Total Annual Burden Hours:* 432.

**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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

**OMB Comment**

OMB 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: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2013–03253 Filed 2–12–13; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0893]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes

**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 15, 2013.

**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–NEW and Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

**Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes—(OMB Control Number 0910–NEW)**

The guidance for industry and FDA staff entitled ''Center for Devices and Radiological Health (CDRH) Appeals Processes'' revises, updates, and combines two previous guidance documents: ''Medical Device Appeals and Complaints: Guidance for Dispute Resolution,'' dated February 1998, and ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA,'' dated July 2001.

The document is intended to provide clarity to internal and external audiences regarding CDRH's appeal processes. Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. In most cases, it is up to the party seeking resolution of an adverse action or resolution of a difference of opinion to determine the appropriate process for a given circumstance or issue. The guidance describes these mechanisms and includes the following topics: (1) Appealable actions (i.e., warning letters, post-approval study requirements, premarket decisions, deficiency letters, or requests for additional information); (2) paths and options available at different stages of appeals; (3) use of expedited or ''paper'' appeals versus appeal meetings or teleconferences; (4) recommended format for appeals; (5) appeal authorities; (6) appeal conflicts; and (7) issues that are appropriate for dispute resolution.

This guidance is intended to describe the processes available to outside stakeholders to request additional review of decisions and actions by CDRH employees. There are several processes for resolution, including a request for supervisory review of an action, petitions, and hearings. The proposed information collection seeks approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees under this guidance. The guidance also refers to currently approved information collections found in FDA regulations.

The collections of information in 21 CFR 10.30, 10.33, and 10.35 have been approved under OMB control number 0910–0183; the collections of information in 21 CFR part 12 have been approved under OMB control number 0910–0184; the collections of information for 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information under 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information under 21 CFR

part 814 have been approved under 0910–0231; and the collections of information under 21 CFR part 900 are approved under OMB control number 0910–0309.

In the **Federal Register** of December 28, 2011 (76 FR 81511), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates it will receive 50 requests annually from outside stakeholders requesting additional review of decisions and actions by CDRH employees. The Agency reached this estimate based on data collected about requests received over the last 2 years. FDA estimates it will take outside stakeholders approximately 8 hours to prepare a request based on the Agency's experience with past requests.

Before the proposed information collection provisions contained in this guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Guidance title | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| CDRH: Appeals Processes Guidance Document ..... | 50 | 1 | 50 | 8 | 400 |
| Total ..... | 50 | 1 | 50 | 8 | 400 |

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

Dated: *February 6, 2013.*

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–03315 Filed 2–12–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0001]**

### Annual Computational Science Symposium; Conference

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA), in cosponsorship with the Pharmaceutical Users Software Exchange (PhUSE), is announcing a public conference entitled ''The FDA/PhUSE Annual Computational Science Symposium.'' The purpose of the conference is to help the broader community align and share experiences to advance computational science. At the conference, which will bring together FDA, industry, and academia, FDA will update participants on current initiatives, and collaborative project groups will address specific challenges in accessing and reviewing data to support product development. These project groups will focus on solutions and practical ways to implement them.

**DATES:** The public conference will be held on March 18 and 19, 2013, from 9 a.m. to 5:30 p.m.

**ADDRESSES:** The public conference will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Pl., Silver Spring, MD 20910, 1–240–777–5300.

**FOR FURTHER INFORMATION CONTACT:** Chris Decker, PhUSE FDA Liaison Director, Pharmaceutical Users Software Exchange (PhUSE), 64 High St., Broadstairs CT10 1JT, United Kingdom, 609–514–5105, email: *css@phuse.eu.*.

**SUPPLEMENTARY INFORMATION:** A description of the project groups and planned activities can be found at *http://www.phuse.eu/css.*

#### I. Registration and Accommodations

*A. Registration*

To register, please submit the registration form online at *https://www.phuse.eu/PhUSE–CSS–2013-Registration.aspx.* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference.

The costs of registration for different categories of attendee are as follows:

| Category | Cost |
|---|---|
| Industry representatives registering by February 15, 2013 ..... | $700 |
| Industry representatives registering after February 15, 2013 ..... | $900 |
| Those with government affiliation ..... | $300 |
| Representatives of nonprofit organizations ..... | $300 |
| Those attending for a single day ..... | $650 |

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to: *office@phuse.eu.* All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

*B. Accommodations*

Attendees are responsible for their own accommodations. Attendees making reservations at the DoubleTree by Hilton Silver Spring Hotel are eligible for a reduced conference rate of $199, not including applicable taxes. Those making reservations online should use the following link to receive the special rate: *http://doubletree.hilton.com/en/dt/groups/personalized/D/DCASSDT–PUE–20130316/index.jhtml?WT.mc_id=POG.* If you need special accommodations because of disability, please contact Chris Decker (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days before the meeting.

#### II. Information for Presenters of Posters and Exhibits

Those wishing to present posters at the conference should submit an abstract online at *http://www.phuse.eu/Call_for_NewProjectsCSS.aspx.* Suggested poster abstract topics include:

- Data submission standards development, implementation, and best practices;