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;

• User experience and evaluation of current processes and tools and their effects on organizational performance;

• Needs and specifications for proposed new tools and processes;

• Business processes driving the development of information systems; and

• The effect of processes and tools on problem solving quality, efficiency, and cost.

All abstracts must be received by February 15, 2013, and authors whose posters have been accepted will be notified by February 28, 2013.

The conference will make available an exhibition hall. The exhibitor price for this conference is $3,500. Neither PhUSE nor FDA endorse any commercial software or vendor.

Dated: February 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03324 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]

Global Quality Systems—An Integrated Approach To Improving Medical Product Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public workshop entitled ''Global Quality Systems—An Integrated Approach to Improving Medical Product Safety.'' This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

DATES: The public workshop will be held on June 10 and 11, 2013, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Louisville Marriott Downtown, 280 West Jefferson St., Louisville, KY, 502–627–5045 or toll-free 800–533–0127; *http://www.marriottlouisville.com/.*

Attendees are responsible for their own accommodations. To make reservations at the Louisville Marriott Downtown, at the reduced conference rate, contact the Louisville Marriott Downtown before May 2, 2013, and cite meeting code ''AFDO Conference.''

FOR FURTHER INFORMATION CONTACT: Krystal Reed, Association of Food and Drug Officials, 2550 Kingston Rd., suite 311, York, PA 17402, 717–757–2888, FAX: 717–650–3650, *email: kreed@afdo.org.*

SUPPLEMENTARY INFORMATION:

Registration: You are encouraged to register by May 14, 2013. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration is as follows:

COST OF REGISTRATION

Member	$450.00
Non-Member	$550.00
To be added to registration fee for registration postmarked after May 14, 2013	$100.00

If you need special accommodations due to a disability, please contact Krystal Reed (see **FOR FURTHER INFORMATION CONTACT**) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to ''AFDO.'' Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit *http://www.afdo.org/conference.* (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**.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 717–757–2888, FAX: 717–650–3650, or email: *afdo@afdo.org*

The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following:

• Future of Combination Product Regulation.

• Unique Device Identifier Progress.

• Health Canada Update.

• The Safety of our Drugs and Devices—the Complex Reality.

• Nanotechnology.

• Drug and Medical Device Trends.

• Case for Quality (Center for Devices and Radiological Health) Presented by Steve Silverman.

• Working Luncheon Interactive Session—Lessons Learned From the Mistakes of Others.

• Complaint Handling—It's Not Just About Compliance—It's an Effective Business Driver.

• FDA's Cosmetic Regulatory Agenda.

• Challenges With Implementation of U.S.P. 35 on a Global Basis.

• Pilot Program for Abbreviated Drug Inspections.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03323 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–2011–N–0724]

Documents To Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following revised final versions of documents that support making regulatory submissions in