

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total annual burden hours
Annual/Final Report to the Secretary (depending on reporting period) .....	25	1	1	50	1,250

*Estimated Total Annual Burden Hours: 1,250.*

*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](mailto: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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-0001]

**Annual Public Meeting; Reagan-Udall Foundation for the Food and Drug Administration**

**AGENCY:** Reagan-Udall Foundation for the Food and Drug Administration.

**ACTION:** Notice of annual meeting.

**SUMMARY:** The Reagan-Udall Foundation (the Foundation) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public meeting. The Foundation will discuss its activities and how it supports FDA.

**DATES:** The public meeting will be held on May 4, 2018, from 10 a.m. until 12 noon. Registration to attend the meeting must be received by May 3, 2018, at 5 p.m. Eastern Time. Requests for oral presentations must be received before May 2, 2018, at 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. The public is also invited to submit written comments by sending them via email to Elisabeth Shaefer (see **FOR FURTHER INFORMATION CONTACT**) before May 3, 2018, at 5 p.m. Eastern Time.

**ADDRESSES:** The public meeting will be held at Alston & Bird, 950 F St. NW, Washington, DC 20006.

**FOR FURTHER INFORMATION CONTACT:** Elisabeth Shaefer, Executive Assistant to the Executive Director, Reagan-Udall Foundation for the FDA, 202-849-2255, [eshaefer@reaganudall.org](mailto:eshaefer@reaganudall.org).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit, organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation, and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research and engagement projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how the Foundation projects can help the Agency to fulfill its mission.

Foundation projects currently include: Innovation in Medical Evidence Development and Surveillance, a public-private partnership that allows researchers to study drug safety concerns of interest to public health; an Expanded Access Navigator that offers instructional

material and resources for physicians, patients, and their caregivers on how to access investigational drugs outside of clinical trials; and a new joint Foundation and FDA regulatory science fellowship program.

**II. Topics for Discussion at the Public Meeting**

FDA Commissioner, Dr. Scott Gottlieb, will deliver a keynote address, followed by a panel discussion on the “Evolution of FDA Science and Engagement” and the role of the Foundation. Panelists will include the current FDA Commissioner, Dr. Scott Gottlieb, and former FDA Commissioners Drs. Robert Califf and Andrew C. von Eschenbach. The panel moderator will be Susan Dentzer, President and Chief Executive Officer of the Network for Excellence in Health Innovation. Find the meeting agenda at <https://reaganudall.org/public-meeting>.

**III. Participating in the Public Meeting**

*Registration:* To register for the public meeting, please visit the following website to register: <https://reaganudall.org/public-meeting>. Persons interested in attending this public meeting must register online by May 3, 2018, at 5 p.m. Eastern Time.

If you need special accommodations due to a disability, please contact Elisabeth Shaefer (see **FOR FURTHER INFORMATION CONTACT**) no later than May 1, 2018.

*Requests for Oral Presentations:* Interested persons may present comments at the public meeting. Comments will be scheduled to begin approximately at 11:30 a.m. Time allotted for comments may be limited to 3 minutes, dependent on the number of requests received. Those desiring to make oral comments should notify Elisabeth Shaefer (see **FOR FURTHER INFORMATION CONTACT**) by May 2, 2018. Please include a brief statement of the general nature of the comments you wish to present along with your name, address, telephone number, and email address. The contact person will notify individuals regarding their request to speak by May 3, 2018.

Dated: April 6, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2018-07544 Filed 4-11-18; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-1076]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice**

**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 May 14, 2018.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0563. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice**

OMB Control Number 0910-0563—  
*Extension*

Congress enacted section 562 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-1), which directed FDA to ensure that it had adequate dispute resolution procedures to provide for appropriate review of scientific controversies between the FDA and members of regulated industry, including possible review by a scientific advisory committee. To implement this provision, we amended the general appeal regulation applicable across all FDA components (21 CFR 10.75; Internal Agency review of decisions) to provide for advisory committee review (§ 10.75(b)(2)). At the same time, and also consistent with the mandates of section 562 of the FD&C Act, we adopted an approach whereby specific implementation procedures regarding scientific controversy associated with review of certain FDA decisions are detailed in center-issued guidance.

Accordingly, FDA developed the guidance entitled, “Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related

to Pharmaceutical Current Good Manufacturing Practice.” We intend the guidance to inform manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes about scientific and technical issues relating to current good manufacturing practice (CGMP). Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during FDA’s assessment of corrective actions undertaken as a result of such inspections. The guidance recommends procedures that we believe encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs and Center levels and for requesting review by the dispute resolution (DR) panel. The guidance is available on our website at: <https://www.fda.gov/downloads/drugs/guidances/ucm070279.pdf>, along with additional information regarding the resolution of scientific disputes at FDA.

In the **Federal Register** of October 27, 2017 (82 FR 49832), we published a notice soliciting public comment on the proposed collection of information. Although no comments were received, we are reconsidering the usefulness of the guidance document in light of changing Agency procedures. Consistent with our regulations at 21 CFR part 10.115 we invite comment on our guidance documents at any time. Ultimately, as our resources permit, we hope to either revise, replace, or withdraw the subject guidance document, however, until that time the guidance remains available. Accordingly, we are seeking to extend OMB approval of the information collection and estimate the burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Annual frequency per response	Total annual responses	Average burden per response	Total hours
Requests for tier-one DR	2	1	2	30	60
Requests for tier-two DR	1	1	1	8	8
Total .....	.....	.....	.....	.....	68

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection.

As reflected in table 1, we estimate only a nominal burden for the information collection and assume: (1) That two manufacturers will submit two requests annually for tier-one DR; (2)

that there will be one appeal to the DR panel (tier-two DR); (3) that it will take respondents approximately 30 hours to prepare and submit each tier-one DR request; and (4) that it will take

approximately 8 hours to prepare and submit each tier-two DR request. We base this estimate on our experience with the information collection. There has been no increase in the burden