Profile Form is based upon an estimate of 74 respondents per year and an estimated three hours per response.

6. PSO Change of Listing Information Form: The average annual burden for the collection of information requested by the PSO Change of Listing Information Form is based upon an estimate of 51 respondents per year and an estimated time of five minutes per response.

7. PSO Voluntary Relinquishment Form: The average annual burden for the collection of information requested by the PSO Voluntary Relinquishment Form is based upon a total average estimate of four respondents per year and an estimated time of thirty minutes per response.

8. OCR Patient Safety Confidentiality Complaint Form: The overall annual burden estimate of one hour for the collection of information requested by the form is based on an estimate of one respondent per year and an estimated twenty minutes per response.

9. Common Formats: AHRQ estimates that 5% FTE of a patient safety manager at a facility will be spent to administer the Common Formats, which is approximately 100 hours a year.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
1. PSO Certification for Initial Listing Form	11	1	18	198
2. PSO Certification for Continued Listing Form	40	1	8	320
3. PSO Two Bona Fide Contracts Requirement Form	56	1	1	56
4. PSO Disclosure Statement Form	3	1	3	9
5. PSO Profile Form	74	1	3	222
6. PSO Change of Listing Information	51	1	05/60	4.25
7. PSO Voluntary Relinquishment Form	4	1	30/60	2
8. OCR Patient Safety Confidentiality Complaint Form	1	1	20/60	.33
9. Common Formats	1,000	1	100	100,000
Total		NA	NA	100,811.58

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Total burden hours	Average hourly wage rate *	Total cost
1. PSO Certification for Initial Listing Form	198	$49.07	$9,715.86
2. PSO Certification for Continued Listing Form	320	49.07	15,702.40
3. PSO Two Bona Fide Contracts Requirement Form	56	49.07	2,747.92
4. PSO Disclosure Statement Form	9	49.07	441.63
5. PSO Profile Form	222	49.07	10,893.54
6. PSO Change of Listing Form	4.25	49.07	208.55
7. PSO Voluntary Relinquishment Form	2	49.07	98.14
8. OCR Patient Safety Confidentiality Complaint Form	.33	49.07	15.35
9. Common Formats	100,000	49.07	4,907,000
Total			4,946,824.23

* Based upon the mean of the hourly average wages for healthcare practitioner and technical occupations, 29–0000, National Compensation Survey, May 2023, ''U.S. Department of Labor, Bureau of Labor Statistics.'' *https://www.bls.gov/oes/current/oes290000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Mamatha Pancholi,

Deputy Director.

[FR Doc. 2024–17813 Filed 8–9–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3528]

Advancing Rare Disease Therapies Through a Food and Drug Administration Rare Disease Innovation Hub; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting, entitled ''Advancing Rare

Disease Therapies Through an FDA Rare Disease Innovation Hub.'' The purpose of the public meeting is to discuss the establishment of a Rare Disease Innovation Hub, which will enhance collaboration and cooperation across the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER), as well as other centers and offices across FDA, to advance rare disease therapies. In particular, this meeting will be an opportunity for those in the rare disease community, including patients and caregiver groups, industry organizations, and scientific/academic organizations, to provide input on the priorities of the Rare Disease Innovation Hub and how the Hub can best engage with members of the rare disease community. The public meeting will be facilitated by the Reagan-Udall Foundation for the FDA.

DATES: The public meeting will be held on October 16, 2024, from 10 a.m. to 1 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by 11:59 p.m. Eastern Time on October 31, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (Great Room), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit written comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 31, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3528 for ''Advancing Rare Disease Therapies Through an FDA Rare Disease Innovation Hub; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Janet Goldberg, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Cynthia Rothblum-Oviatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5390, Silver Spring, MD 20993–0002, 301–796–0957.

SUPPLEMENTARY INFORMATION:

I. Background

CBER and CDER are launching a CBER–CDER Rare Disease Innovation Hub (the Hub) to advance rare disease therapy development through greater communication, collaboration, and coordination across CBER and CDER, in coordination with other centers and offices across FDA. Helmed by senior leadership from CBER and CDER, the Hub will work to develop and implement a rare disease comprehensive cross-center strategic agenda that takes full advantage of our current clinical and scientific expertise across both centers and is based on a shared vision and comprehensive approach to (1) align review efforts; (2) identify and enable innovative approaches in the areas of novel endpoints, biomarker development, and innovative trial designs; and (3) streamline communications with the rare disease community.

The Directors of CBER and CDER (Directors) will lead the Hub, co-chairing the Rare Disease Innovation Hub Steering Committee, which will include senior leaders from CBER's Office of Therapeutic Products, CDER's Office of New Drugs, and across FDA, such as the Center for Devices and Radiological Health, Oncology Center of Excellence, Office of Orphan Products Development, and Office of Combination Products. The Rare Disease Innovation Hub will leverage the activities of the CDER Accelerating Rare disease Cures program and CBER Rare Disease Program and enhance existing cross-center collaborations. In addition, the Hub will be anchored by the new Director for Strategic Coalitions for the Hub (Associate Director for Rare Disease Strategy), who will serve as a single point of connection and engagement with stakeholders on behalf of the Hub, including patient and caregiver groups, trade organizations, and scientific/academic organizations, on cross-cutting rare disease-related issues. The Directors will develop approaches to ensure appropriate FDA staff involvement or appropriate settings for further external engagement and will seek input from the community to inform the priorities of the Hub.

The Reagan-Udall Foundation for the FDA will facilitate the public meeting. 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.

II. Topics for Discussion at the Public Meeting

This public meeting is being convened for FDA to provide information on the Rare Disease Innovation Hub, including its proposed priorities and initiatives, and to serve as an opportunity for those in the rare disease community, including patients and caregiver groups, industry organizations, and scientific/academic organizations, to provide input on the priorities of the Rare Disease Innovation Hub and how the Hub can best engage with members of the rare disease community. In particular, FDA is interested in receiving comments on the following:

1. What specific rare disease-related scientific, regulatory, or policy issues should be prioritized for consideration by the Rare Disease Innovation Hub?
2. To the extent the issues identified in response to Question 1 are related to specific types of rare diseases or conditions, please explain.
3. What specific types of rare disease-related activities do you believe would benefit from enhanced collaboration, focused attention, or increased transparency (to the extent legally permissible) under the Rare Disease Innovation Hub? Please identify in your comments rare disease-related activities or initiatives currently being undertaken by CDER or CBER that you believe would benefit from being undertaken by the Rare Disease Innovation Hub as a joint endeavor.
4. Please comment on approaches that the Rare Disease Innovation Hub should follow for engagement with patients and caregiver groups, industry organizations, and scientific/academic organizations (including different approaches for different types of engagement, as appropriate).

Comments will be accepted until 11:59 p.m. Eastern Time on October 31, 2024.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://reaganudall.org/news-and-events/events/advancing-rare-disease-therapies-through-an-fda-rare-disease-innovation-hub.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register online by October 15, 2024, at 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Lea Ann Browning-McNee, Director of Communication and Stakeholder Engagement, Reagan-Udall Foundation for FDA, 202–849–2075, *Lmcnee@reaganudall.org,* no later than October 9, 2024, at 5 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by October 4, 2024. All requests to make oral presentations must be received by 11:59 p.m. on September 25, 2024. If selected for a presentation, you will be contacted by Lea Ann Browning-McNee, Director of Communication and Stakeholder Engagement, Reagan-Udall Foundation for FDA regarding submission of a single slide in PowerPoint format. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

(Notice of this meeting is given pursuant to 21 CFR 10.65.)

Dated: August 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17924 Filed 8–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3609]

Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled ''Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food.'' This public meeting will assist in developing the post-market chemicals assessment program we will establish under the new FDA Human Foods Program. The purpose of the public meeting is to hear from interested parties about approaches to systematic post-market assessment of chemicals in food.