

use of investigational drugs for treatment of patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives. FDA issued a guidance in 2016 (updated in 2017) in a question-and-answer format to respond to the most frequently asked questions on various provisions of the regulation regarding expanded access.

The Cures Act added section 561A to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-0) to include new requirements regarding expanded access. Under section 561A of the FD&C Act, a manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions is required to make its policy for evaluating and responding to expanded access requests (expanded access policy) readily available to the public, such as by posting the policy on a publicly available website. In addition, FDARA (Pub. L. 115-52) amended the FD&C Act to require that the expanded access policy for an investigational drug be posted by the earlier of (1) the first initiation of a phase 2 or phase 3 study with respect to such investigational drug or (2) within 15 days after the drug receives a fast track, breakthrough, or regenerative advanced therapy designation.

This revised draft guidance includes responses to stakeholder questions received since publication of the updated final guidance in 2017 and includes the Agency's recommendations related to new requirements of the Cures Act and FDARA that are related to expanded access. This guidance revises the guidance for industry of the same title issued in June 2016 and updated in October 2017. Significant changes to the 2017 version of the guidance include additional recommendations related to institutional review board review, informed consent, and new requirements established by the Cures Act and FDARA.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on "Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130; the collections of information under the Expanded Access regulations (21 CFR 312.300 through 312.320) have been approved under OMB control number 0910-0814; and the collections of information in 42 CFR part 11 have been approved under OMB control number 0925-0586.

III. Electronic Access

Persons with access to the internet may obtain the revised draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0796]

Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications by the Food and Drug Administration's Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of

1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on studies regarding communications by FDA's Center for Devices and Radiological Health (CDRH). This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

DATES: Either electronic or written comments on the collection of information must be submitted by January 3, 2023.

ADDRESSES: You may submit 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 January 3, 2023. 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-2013-N-0796 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications Regarding Products Regulated by FDA’s Center for Devices and Radiological Health.” 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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Testing Communications by FDA’s Center for Devices and Radiological Health

OMB Control Number 0910-0678—Extension

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications by FDA’s CDRH involves many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about product use. Knowledge of consumer, caregiver, and healthcare professional decision-making processes will provide a better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels.

Second, as initial testing, the collected information will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, the collected information will allow FDA to ascertain the effectiveness of the messages and the distribution method in achieving the objectives of the message campaign. Evaluation of message campaigns is a vital link in continuous improvement of communications at FDA.

FDA expects to conduct studies under this generic information collection using a variety of research methods. We estimate that the burden to respondents will average 16 minutes each (varying from 5 minutes to 90 minutes). FDA estimates the burden of this collection of information based on prior experience with the various types of data collection methods described earlier.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN^{1 2}

Type of respondent/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
General Public					
Individual indepth interviews	420	1	420	0.75 (45 minutes)	315
General public focus group interviews.	288	1	288	1.50 (1 hour, 30 minutes)	432
Intercept interviews: central location	200	1	200	0.25 (15 minutes)	50
Intercept interviews: telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-administered surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	0.50 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	0.17 (10 minutes)	204
Total (general public)					2,121
Healthcare Professional					
Healthcare professional individual in-depth interviews.	72	1	72	0.75 (45 minutes)	54
Healthcare professional focus group interviews.	144	1	144	1.50 (1 hour, 30 minutes)	216
Total (healthcare professional) ..					270
Total (overall)					2,391

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

² Numbers have been rounded.

Over the next 3-year approval period, we anticipate increasing our capability to conduct more communication surveys, which aligns with CDRH's strategic priorities. We have adjusted our burden estimates accordingly. Additionally, we have added an estimated hour burden for "healthcare professional individual indepth interviews." These changes reflect an overall increase of 315 burden hours and a corresponding increase of 276 responses annually.

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-2336]

Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled

"Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program." This guidance provides stakeholders with information regarding FDA's implementation of the Over-the-Counter Monograph Drug User Fee Program authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by January 3, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidances at any time as follows:

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-2022-D-2336 for "Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program." Received comments 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