

with diverse experiences and perspectives to inform ACF policies and programs. The information collected would allow for ongoing, two-way collaborative and actionable communications between ACF and its State, local and/or Tribal partners, program participants, communities served or affected by ACF programs, and or others experienced with or interested in ACF programs or similar programs.

ACF envisions using information collected to inform a variety of efforts and activities such as the improvement, planning, and implementation of research studies, program changes, development and dissemination of resources and products developed under ACF studies, regulatory activities, guidance, outreach and/or training activities. The specific types of information gathering methods included under the umbrella of this clearance will vary, but will use well-established methodologies, including but not limited to:

- Semi-structured discussions or conference calls
- Focus groups
- Telephone or in-person interviews
- Questionnaires/Surveys
- Roundtable and/or Breakout Sessions
- Open-ended requests
- Contextualizing Existing Data

Data collection will take place through a variety of activities—both in-person and virtual—dependent on the specific project. ACF will submit individual requests under this clearance. ACF requests OMB provide a response on individual generic information collections within 10 business days.

**Respondents:** Respondents could include current or prospective service providers, training and technical assistance providers, grant recipients, contractors, current and potential participants in ACF programs or other comparable groups and other individuals with lived experience with ACF or similar programs, experts in

fields pertaining to ACF programs, other key groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, State or local government officials, those in broader fields of study related to human services, or others involved in or prospectively involved in ACF programs.

**Burden Estimates:** The burden table below is illustrative. Estimates for the number of respondents and time per response have been made based on discussion with ACF program offices, but as this is a new umbrella generic, it may be possible that we will need to adjust estimates throughout the three-year approval period. If needed, ACF will submit a change request for these updates. While we will not exceed the total burden cap for this generic without requesting a change for updates, we may use more or less burden within each instrument type.

Example types of information collections	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Semi-Structured Discussions and Focus Groups .....	10,000	1	2	20,000
Interviews .....	4,500	1	1	4,500
Questionnaires/Surveys .....	8,000	1.5	.5	6,000
Templates and Open-ended requests .....	1,000	1	10	10,000
<b>Estimated Totals</b> .....	<b>23,500</b>	.....	.....	<b>40,500</b>

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2023-D-5259]

**Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Extension of Comment Period**

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

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that published in the **Federal Register** of December 22, 2023. In that notice, FDA requested comments on the draft guidance for industry entitled, “Master Protocols for

Drug and Biological Product Development.” The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the draft guidance published December 22, 2023 (88 FR 88623). Submit either electronic or written comments by March 21, 2024, to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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–2023–D–5259 for “Master Protocols for Drug and Biological Product Development.” 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the

Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Scott N. Goldie, Center for Drug Evaluation and Research, Office of Biostatistics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055; or James Myers 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.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 22, 2023, FDA published a notice of availability for a draft guidance entitled, “Master Protocols for Drug and Biological Product Development.” This action opened a docket with a 60-day comment period. The Agency received requests for an extension of the comment period for the draft guidance. After considering the requests, and in light of the fact that the original comment period is scheduled to close on February 20, 2024, FDA has decided to extend the comment period for 30 days, until March 21, 2024. The Agency believes that this extension allows adequate time for interested persons to submit comments to ensure that FDA can consider the comments before it begins work on the final version of the guidance.

Dated: February 13, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2007–D–0369]

**Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by April 16, 2024 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 guidance 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>.