

## Substances To Be Evaluated for Toxicological Profile Development

Each year, ATSDR develops a list of substances to be considered for Toxicological Profile development. The nomination process includes consideration of all substances on ATSDR's SPL, as well as other substances nominated by the public. For more information on ATSDR's SPL, visit <https://www.atsdr.cdc.gov/SPL/>.

*Submission of nominations for Toxicological Profile development:* Today's notice invites voluntary public nominations for substances included on the SPL and for substances not listed on the SPL. When nominating a non-SPL substance, please include the rationale for the nomination. ATSDR will evaluate data and information associated with nominated substances and will determine the final list of substances to be chosen for Toxicological Profile development. Substances will be chosen according to ATSDR's specific guidelines for selection. These guidelines can be found in the *Selection Criteria*, which may be accessed at [www.atsdr.cdc.gov/toxprofiles/guidance/ATSDR\\_TP\\_Selection%20Criteria.pdf](http://www.atsdr.cdc.gov/toxprofiles/guidance/ATSDR_TP_Selection%20Criteria.pdf).

**Pamela I. Protzel Berman,**

*Director, Office of Policy, Planning and Partnerships, Agency for Toxic Substances and Disease Registry.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1398]

### Mitigation Strategies to Protect Food Against Intentional Adulteration; Draft Guidance for Industry; Extension of the Comment Period

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

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

**SUMMARY:** The Food and Drug Administration (FDA, we, or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of February 14, 2020, entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration; Draft Guidance for Industry." This supplemental draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register

under the Federal Food, Drug, and Cosmetic Act comply with the requirements of our regulation entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration." FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice of availability published February 14, 2020 (85 FR 8599). Submit either electronic or written comments on the supplemental draft guidance by August 14, 2020.

**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-2018-D-1398 for "Mitigation Strategies

to Protect Food Against Intentional Adulteration: Supplemental Draft Guidance for Industry." 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.

- **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 guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels 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:** Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-3712, [ryan.newkirk@fda.hhs.gov](mailto:ryan.newkirk@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 14, 2020 (85 FR 8599), we published a notice announcing the availability of a supplemental draft guidance for industry entitled “Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry.” This multichapter supplemental draft guidance for industry is intended to help food facilities required to comply, develop, and implement some of the components of a food defense plan, and meet other requirements under 21 CFR part 121.

The Agency has received a request for an extension of the comment period for 120 days. The request conveyed concern that the current comment period does not allow sufficient time to develop a comprehensive response.

FDA has considered the request and is extending the comment period for the notice of availability for 60 days, until August 14, 2020. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: May 21, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Coronavirus 2019 (COVID-19) Data Report, OMB No. 0906-xxxx—Emergency

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 10-day

comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than June 8, 2020.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 10 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title: Coronavirus 2019 (COVID-19) Data Report, OMB No. 0906-xxxx – Emergency*

*Abstract:* HRSA’s Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

#### FY 2020 Coronavirus Aid, Relief, and Economic Security Act

On March 27, 2020, the President signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES Act appropriated \$90 million to HRSA’s RWHAP to prevent, prepare for, and respond to coronavirus disease 2019 (COVID-19). This funding supports 581 RWHAP recipients across the country, including city/county health departments, state health departments, health clinics, community-based organizations, and AIDS Education and Training Centers in their efforts to help prevent or minimize the impact of COVID-19 on RWHAP clients. The award provides RWHAP recipients the flexibility to meet evolving COVID-19 needs in their respective communities, including extending operational hours, increasing staffing hours, purchasing additional equipment, enhancing

workforce training and capacity development, and providing critical services to people with HIV during this pandemic, such as home-delivered meals, emergency housing, and transportation.

HRSA’s HIV/AIDS Bureau identified a new data collection need to support HRSA’s requirement to monitor and report quarterly to the Secretary of HHS the COVID-19 activities conducted with the CARES Act funding. HRSA is proposing to create a new COVID-19 Data Report (CDR) module that will provide monthly reporting on the types of services provided and number of people served for the treatment or prevention of COVID-19 among RWHAP clients (and immediate household members in limited circumstances). This module will be required for all providers (regardless of whether they are recipients or subrecipients) who receive CARES Act RWHAP funding.

*Need and Proposed Use of the Information:* HRSA proposes that service providers who receive CARES Act RWHAP funding report aggregate information on the number of clients and immediate household members tested for COVID-19, the number of clients newly diagnosed (or presumed positive) with COVID-19, the cumulative number of clients with COVID-19, the number of clients who received services in each RWHAP service category (identified in Policy Clarification Notice 16-02 RWHAP Services: Eligible Individuals and Allowable Uses of Funds), and the types of services provided using telehealth technology in the CDR. The information obtained in this module will assist HRSA in understanding how CARES Act RWHAP funding is being used to support RWHAP clients and immediate household members and ensure that HRSA is compliant with federal reporting requirements.

*Likely Respondents:* All RWHAP providers (regardless of whether they are recipients or subrecipients) who receive CARES Act RWHAP funding.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review