

Hourly wage and labor category	Hours per respondent	Total hourly labor cost	Number of respondents	Approx. total annual labor costs
\$20.88 Clerical Workers .....	1	20.88	.....	32,552
.....	.....	.....	.....	367,176

Because the FACT Act and the Rule contemplate that the affiliate marketing notice can be included in the GLBA notices, the capital and non-labor cost burden on regulated entities would be greatly reduced. Covered entities typically already provide notices to their customers so there are no new capital or non-labor costs, as the Affiliate Marketing notice may be consolidated into their annual privacy notice. Thus, staff estimates that any capital or non-labor costs associated with compliance for these entities are *de minimis*.

**Request for Comments**

Pursuant to section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency’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 maintaining records and providing disclosures to consumers. All comments must be received on or before February 6, 2023.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before February 6, 2023. Write “Paperwork Reduction Act Comment: FTC File No. P072108” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the <https://www.regulations.gov> website.

Due to the public health emergency in response to the COVID-19 outbreak and the agency’s heightened security screening, postal mail addressed to the Commission will be subject to delay. We encourage you to submit your comments online through the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write “Paperwork Reduction Act Comment: FTC File No. P072108” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission,

Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will become publicly available at <https://www.regulations.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment

has been posted publicly at [www.regulations.gov](http://www.regulations.gov), we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 6, 2023. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

**Josephine Liu,**  
*Assistant General Counsel for Legal Counsel.*  
 [FR Doc. 2022-26623 Filed 12-7-22; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket No. CDC-2022-0070]

**Availability of Final Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** General notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR), located within the Department of Health and Human Services (HHS) announces the availability of the final *Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns* (2022 Guidelines). The 2022 Guidelines provide updates to the 2013 publication, *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from the CDC and the Council of State and Territorial Epidemiologists (CSTE)*. The updates provide state, tribal, local, and territorial health departments guidance for a

revised and expanded approach to evaluating concerns about unusual patterns of cancer in communities, including those associated with local environmental concerns. The 2022 Guidelines finalize the draft guidelines issued on May 25, 2022.

**DATES:** The 2022 Guidelines are available December 8, 2022.

**FOR FURTHER INFORMATION CONTACT:** Amy Lavery, Centers for Disease Control and Prevention, National Center for Environmental Health, Division of Environmental Health Science and Practice, 4770 Buford Highway NE, Mailstop F-60, Atlanta, GA 30341; Telephone: 770-488-4024; Email: [CCGuidelines@cdc.gov](mailto:CCGuidelines@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

CDC/ATSDR is announcing the availability of final *Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns* (2022 Guidelines). The 2022 Guidelines are an update to the 2013 guidelines, *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists* (2013 Guidelines). CDC/ATSDR develops guidance for state, tribal, local, and territorial (STLT) health departments on how to respond to cancer cluster concerns. The 2022 Guidelines are a tool to assist STLT public health agencies in applying a systematic approach when responding to inquiries about suspected unusual patterns of cancer in residential or community settings.

In the 2022 Guidelines, CDC/ATSDR has updated and expanded the 2013 Guidelines to provide STLT public health agencies and other interested parties with access to information about current scientific tools and approaches to assess and respond to potential unusual patterns of cancer in communities.

CDC/ATSDR developed the 2022 Guidelines using input from a variety of sources, including STLT public health agencies, subject matter experts from academia and non-governmental organizations, an internal CDC/ATSDR steering committee, public comments received from an announcement in the **Federal Register** (84 FR 21786), and focus groups conducted with community members and organizations that have been involved with cancer concerns in their communities. CDC/ATSDR also gathered input from a comprehensive literature review and media scan and evaluated advances in the field of environmental epidemiology

(e.g., geospatial methods) and community engagement strategies.

On May 25, 2022 CDC/ATSDR published a notice in the **Federal Register** announcing the availability of the draft 2022 Guidelines (87 FR 31888). The notice gave the public an opportunity to submit comments by July 25, 2022. CDC/ATSDR received 46 sets of comments from state health departments, community members, academicians, clinicians, cancer registries, non-governmental organizations, and private consultants on behalf of trade associations (<https://www.regulations.gov/docket/CDC-2022-0070/comments>). A summary of the comments received and the modifications CDC/ATSDR made to the draft 2022 Guidelines after careful consideration are below:

- Commenters stated the terms “cancer cluster” and “unusual patterns of cancer” were used interchangeably throughout the document without clear definition of both terms.
  - *Response:* CDC/ATSDR provided a clear definition of both terms.
  - Commenters noted that it was unclear whether every proactive evaluation must result in the criteria assessment. Commenters questioned how the criteria assessment differs from the response from an incoming inquiry.
    - *Response:* CDC/ATSDR added language to clarify the response to both proactive monitoring and incoming inquiries and provided examples on how to respond to unusual patterns of cancer identified in the proactive monitoring. CDC/ATSDR refined the flow chart in Figure 1, which provides a summary of the enhanced process for evaluating patterns of cancer routinely and evaluating community inquiries about unusual patterns of cancer and environmental concerns. CDC/ATSDR also clarified the discussion on proactive evaluation and routine monitoring of cancer data, including clarifying the need for collaboration with other health agency programs to determine the need for further evaluation through the criteria assessment.
    - Commenters noted that the discussion of challenges and limitations was important to mention early in the guidelines document, rather than in later sections of the document.
      - *Response:* CDC/ATSDR added information on limitations and challenges related to implementation of the recommendations provided within the guidelines early in the document and then reinforced these limitations later in the document.
      - Several comments were focused on clarifying phases and the intent of

various criteria, as well as the need for examples to enhance clarity.

- *Response:* CDC/ATSDR made editorial changes to improve clarity and provided examples when possible, such as including examples of specific partners within a public health agency to engage on unusual patterns of cancer.
  - CDC/ATSDR endeavored to improve clarity with respect to certain components of the criteria. For example, CDC/ATSDR changed step 8 of the criteria from “Is there known biologic plausibility of the cancer(s) of concern with suspected environmental contaminants in terms of disease etiology?” to “Is there a plausible pathway of exposure between the suspected environmental contaminants and the cancer(s) of concern in terms of disease etiology?” This change allowed for a clearer depiction of the intent of step 8 of the criteria.
    - Some commenters raised the issue of how frequent and regular routine monitoring of cancer may place additional burdens on public health agency resources.
      - *Response:* 50% of states reported through the STLT survey that they already conduct routine monitoring of cancer incidence data. However, CDC/ATSDR acknowledged, within the 2022 Guidelines, that resource limitations may impact the frequency with which routine monitoring can be carried out. CDC’s National Environmental Public Health Tracking Program (<https://www.cdc.gov/nceh/tracking/default.htm>) worked with state cancer registries and tracking partners to make three- and five-year rates more readily available, to reduce the burden on states with respect to monitoring.
      - Commenters suggested that providing more references would be helpful.
        - *Response:* CDC/ATSDR added additional references throughout the 2022 Guidelines.
        - Commenters noted that more guidance and instructions are needed on the use of the Cancer Inquiry intake form.
          - *Response:* CDC/ATSDR is developing an instructions document for STLT public health agencies to use as a supplement to the Cancer Inquiry intake form.
          - Commenters noted that more details and resources were needed on use of the standardized incidence ration, such as specific minimum thresholds.
            - *Response:* CDC/ATSDR is developing additional education and resource tools and will post on the National Center for Environmental Health’s Health Studies website once available.

For more information about the process of updating the 2022 Guidelines, please visit <https://www.cdc.gov/nceh/cancer-environment/index.html>.

*Availability of the Final 2022 Guideline:* The Final 2022 Guidelines can be found in the Supporting & Related Materials tab of this docket found on the Federal eRulemaking Portal: <https://www.regulations.gov>, identified by Docket No. CDC-2022-0070.

**Angela K. Oliver,**

*Executive Secretary, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2000-D-0187 [Formerly Docket No. 2000D-1267]]

#### Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled “Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.” The guidance document provides blood establishments that collect blood and blood components with FDA’s recommendations to reduce the risk of transfusion-transmitted malaria (TTM). The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, except Source Plasma. The guidance announced in this notice supersedes the guidance entitled “Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry” dated April 2020.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 8, 2022.

**ADDRESSES:** You may submit either electronic or written comments on Agency 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-2000-D-0187 for “Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; 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, 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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jessica Gillum, 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:**

##### **I. Background**

FDA is announcing the availability of a final guidance entitled “Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria;