

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2025-D-0918]

Malaria: Developing Drugs for Treatment; Draft Guidance for Industry; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Malaria: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in the overall development program for drug and biological products for the treatment of malaria, caused by clinically relevant *Plasmodium* species.

DATES: Submit either electronic or written comments on the draft guidance by December 22, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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>.

- 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-2025-D-0918 for “Malaria: Developing Drugs for Treatment.” 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. 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: Elizabeth O’Shaughnessy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, 6164, Silver Spring, MD 20993; 301-796-0781.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Malaria: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in the overall development program for drug and biological products for the treatment of malaria, caused by clinically relevant *Plasmodium* species. Specifically, this draft guidance is intended to serve as a focus for continued discussions on the design of malaria treatment trials among the Agency, pharmaceutical sponsors, the academic community, and the public.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Malaria: Developing Drugs for Treatment.” 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 applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312, pertaining to the submission of investigational new drug applications, and submission of supporting nonclinical, preclinical and clinical data, including a pediatric clinical development plan, have been approved under OMB control number 0910–0014. The collections of information for FDA approval to market new drugs in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information for FDA licensure of biological products in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 58 pertaining to good laboratory practice have been approved under OMB control number 0910–0119.

III. Electronic Access

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18407 Filed 9–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Integration Telehealth Evidence Collection Tool, OMB No. 0906–xxxx—New

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to

submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 24, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Integration Telehealth Evidence Collection Tool, OMB No. 0906–xxxx—New.

Abstract: This clearance request is for OMB approval of a new information collection, the Behavioral Health Integration Evidence Based Telehealth Network Program (BHI EB–TNP) Integration Telehealth Evidence Collection Tool. Under the BHI EB–TNP, HRSA administers grants in accordance with section 330I(d)(1) of the Public Health Service Act (42 U.S.C. 254c–14(d)(1)). The purpose of the BHI EP–TNP program is to integrate behavioral health services into primary care settings using telehealth technology through telehealth networks and evaluate the effectiveness of such integration. This program supports evidence-based projects that utilize telehealth technologies through telehealth networks in rural and underserved areas to: (1) improve access to integrated behavioral health services in primary care settings, and (2) expand and improve the quality of health information available to health care providers by evaluating the effectiveness of integrating telebehavioral health services into primary care settings and establishing an evidence-based model that can assist health care providers.

HRSA collaborated with grantees in the development of a set of outcome measures to evaluate the effectiveness of grantees' telebehavioral services and monitor grantees' progress/effectiveness by analyzing performance reporting data. The measures address behavioral health and substance use disorder priorities and will help to assess the effectiveness of evidence-based practices with the use of telehealth for patients, providers, and payers. The data collection instrument will include 27 total data elements addressing patient encounter information.

Need and Proposed Use of the Information: HRSA developed the BHI EB–TNP instrument with the program's four goals in mind:

- (1) Improving access to the behavioral health services needed,
- (2) Reducing rural and underserved population practitioner isolation,
- (3) Improving health system productivity and efficiency, and
- (4) Improving patient outcomes.

HRSA worked with program grantees to develop outcome measures to evaluate and monitor the progress of the grantees in each of these categories, with specific indicators to be reported annually through a performance monitoring data collection platform/website. Measures capture awardee-level and aggregate data that illustrate the impact and scope of program funding along with assessing these efforts. The measures are intended to inform HRSA's progress toward meeting program goals, specifically improving access to telebehavioral health services that support primary care providers.

Likely Respondents: BHI EB–TNP grantees.

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 the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.