

for consumers, regulators, and Exchanges as well as to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application. *Form Number:* CMS-10520 (OMB control number: 0938-1249); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households); Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 314; *Total Annual Responses:* 314; *Total Annual Hours:* 384,014. (For policy questions regarding this collection contact Nidhi Singh Shah at 301-492-5110.)

Dated: June 7, 2022

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022-12651 Filed 6-10-22; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-0362]

#### Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry; Correction

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

**ACTION:** Notice of availability; correction.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is correcting a notice that appeared in the **Federal Register** of Tuesday, May 24, 2022. The document announced the availability of a draft guidance entitled "Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry." The draft guidance document was published with incorrect information of a comment period due date. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Myrna Hanna, 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 May 24, 2022 (87 FR 31567), in FR Doc. 2022-11118, on page 31567, the following correction is made:

1. On page 3156, in the first column, the **DATES** caption is corrected to read:

**DATES:** Submit either electronic or written comments on the draft guidance by July 25, 2022, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

Dated: June 3, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-12619 Filed 6-10-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0686]

#### Advisory Committee; Science Advisory Board to the National Center for Toxicological Research; Renewal

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

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the renewal of the Science Advisory Board to the National Center for Toxicological Research (NCTR) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Advisory Board to the National Center for Toxicological Research for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 2, 2024, expiration date.

**DATES:** Authority for the Science Advisory Board to the National Center for Toxicological Research will expire on June 2, 2024, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Donna L. Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993-0002, 301-796-8892, [Donna.Mendrick@fda.hhs.gov](mailto:Donna.Mendrick@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to and by the General Services Administration, FDA is announcing the renewal of the Science Advisory Board to the National Center for Toxicological Research (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee

in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee advises the Director, NCTR, in establishing, implementing, and evaluating research programs that assist the Commissioner in fulfilling his regulatory responsibilities. The Committee provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of toxicological research. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Federal members will be appointed as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/toxicological-research-science-advisory-board-national-center-toxicological-research/charter-science-advisory-board-national-center-toxicological-research> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: June 3, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-12655 Filed 6-10-22; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0530]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tropical Disease Priority Review Vouchers**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by July 13, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0822. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-769-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Tropical Disease Priority Review Vouchers**

*OMB Control Number 0910-0822—Extension*

Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical

disease products. Section 524 of the FD&C Act serves to stimulate new drug development for drugs to treat a “tropical disease” (as defined in section 524(a)(3)) by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524 of the FD&C Act, a sponsor of a “tropical disease product application,” as defined in section 524(a)(4), may be eligible for a voucher that can be used to obtain a priority review for any other application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (PHS Act).

Accordingly, we have developed the guidance for industry entitled “Tropical Disease Priority Review Vouchers” (available at <https://www.fda.gov/media/72569/download>). The guidance explains how FDA implements provisions of section 524 of the FD&C Act and how sponsors may qualify for a priority review voucher based on eligibility criteria set forth in the statute, how to use priority review vouchers, and how priority review vouchers may be transferred to other sponsors.

The guidance also communicates that, under the FDA Reauthorization Act of 2017, section 524 requires attestation by the sponsor of eligibility for a priority review voucher upon submission of the marketing application.

*Description of Respondents:* Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

In the **Federal Register** of December 2, 2021 (86 FR 68503), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request .....	4	1	4	8	32
Notifications of Intent to Use a Voucher .....	2	1	2	8	16
Letters Indicating the Transfer of a Voucher Letter .....	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher .....	2	1	2	8	16
Attestation of eligibility .....	4	1	4	2	8
Total .....					88

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

Based on our evaluation of the information collection since last OMB review and approval, the burden

estimate decreased based on receipt of fewer vouchers and other information collection activities. Our estimated

burden for the information collection reflects an overall decrease of 34 hours