II. Notice of Opportunity for a Hearing

For the reasons stated above and as explained in the September 18, 2024, complete response letter, notice is given to Vanda and all other interested persons that the Center Director proposes that FDA issue an order refusing to approve NDA 218489 under section 505(c) of the FD&C Act, on the grounds that the application fails to meet the criteria for approval under section 505(d) of the FD&C Act because there is a lack of substantial evidence that the drug is effective, and the drug has not been shown to be safe, for the proposed conditions of use, including for the proposed indication of ''the treatment of [symptoms of] or [nausea in] in gastroparesis'' (sections 505(d)(4) and 505(d)(5) of the FD&C Act).[1]

Vanda may request a hearing before the Commissioner of Food and Drugs (the Commissioner) on the Center Director's proposal to refuse to approve NDA 218489. Pursuant to § 314.200(c)(1) (21 CFR 314.200(c)(1)), if Vanda decides to seek a hearing, it must file: (1) a written notice of participation and request for a hearing on or before 30 days after the notice is published in the **Federal Register** and (2) the studies, data, information, and analyses relied upon to justify a hearing, as specified in § 314.200, on or before 60 days after the date the notice is published in the **Federal Register**.

As stated in § 314.200(g), a request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing to resolve. We note in this regard that because CDER proposes to refuse to approve NDA 218489 based on the multiple deficiencies summarized above, any hearing request from Vanda should address all those deficiencies. Failure to request a hearing within the time provided and in the manner required by § 314.200 constitutes a waiver of the opportunity to request a hearing. If a hearing request is not properly submitted, FDA will issue a notice refusing to approve NDA 218489.

[1] Section 505(d) of the FD&C Act provides that FDA shall refuse to approve an application if, among other reasons, ''upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions'' or ''there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof[.]'' Sections 505(d)(4) and 505(d)(5) of the FD&C Act.

The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest. See § 314.200(g)(6). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16. See 21 CFR 314.201.

Paper submissions under this notice of opportunity for a hearing should be filed in one copy, except for those submitted as ''Confidential Submissions'' (see ''Written/Paper Submissions'' and ''Instructions'' in **ADDRESSES**). Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday, and on the internet at *https://www.regulations.gov*. This notice is issued under section 505(c)(1)(B) of the FD&C Act and §§ 314.110(b)(3) and 314.200.

Dated: January 13, 2025.

Patrizia Cavazzoni,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2025–01027 Filed 1–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0187]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled ''Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.'' The draft guidance document provides blood establishments that collect blood and blood components with FDA's revised recommendations to reduce the risk of transfusion-transmitted malaria (TTM). The guidance recommends selectively testing blood donations from donors at risk for malaria using an FDA-licensed donor screening nucleic acid test (NAT) for *Plasmodium species (spp.),* the causative agents of malaria. The draft guidance, when finalized, is intended to supersede the document entitled ''Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria,'' dated December 2022.

DATES: Submit either electronic or written comments on the draft guidance by March 17, 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–2000–D–0187 for ''Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.'' 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 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, 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 draft document entitled ''Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.'' This guidance document provides blood establishments that collect blood and blood components with FDA's revised recommendations to reduce the risk of TTM. Specifically, the guidance recommends selectively testing blood donations from donors at risk for malaria using an FDA-licensed donor screening NAT for *Plasmodium species (spp.),* the causative agents of malaria.

The recommendations contained in this draft guidance apply to the collection of Whole Blood and blood components, except Source Plasma. We do not require blood establishments to screen Source Plasma donors for malaria risk factors because Source Plasma undergoes further manufacturing steps to effectively remove or inactivate pathogens such as *Plasmodia spp.* (see 21 CFR 630.15(b)(8)). Licensed plasma derivatives manufactured from Source Plasma have not transmitted malaria.

The draft guidance, when finalized, is intended to supersede the document entitled ''Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria,'' dated December 2022.

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 ''Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.'' 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.

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 601 and Form FDA 356h have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01028 Filed 1–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NCATS RDCRC Grant Application Review.

Date: February 3–5, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Address: National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Suite 1E504, Bethesda, MD 20892, (301) 435–0810, *lourdes.ponce@nih.gov.*

Name of Committee: National Center for Advancing Translational Sciences Special