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.

[FR Doc. 2022–26664 Filed 12–7–22; 8:45 am]

BILLING CODE 4163–18–P

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;

Guidance for Industry.'' The guidance document provides blood establishments that collect blood and blood components with FDA's recommendations to reduce the risk of TTM. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, except Source Plasma. Blood establishments are not required to assess Source Plasma donors for malaria risk (see 21 CFR 630.15(b)(8)).

To address the urgent and immediate need for blood and blood components during the Coronavirus Disease 2019 (COVID–19) public health emergency, in April 2020 FDA issued revised recommendations to reduce the risk of TTM during the public health emergency. The recommendations in the April 2020 guidance were based on the Agency's evaluation of the available scientific and epidemiological data on malaria risk, and data on FDA-approved pathogen reduction devices. FDA stated in the April 2020 guidance that we expected implementation of the revised recommendations would not be associated with any adverse effect on the safety of the blood supply and that early implementation of the recommendations may help to address significant blood shortages that occurred as result of the COVID–19 public health emergency. Further, the guidance explained that we expected that the recommendations set forth in the revised guidance would continue to apply outside the context of the COVID–19 public health emergency, and that FDA would replace the April 2020 guidance with an updated guidance that incorporates any appropriate changes based on public comments and our experience with implementation. Although the April 2020 guidance stated that we intended to reissue the guidance within 60 days following the termination of the public health emergency, we are not delaying this issuance because the guidance represents our current thinking on the topic.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because the recommendations present a less burdensome policy for reducing the risk of transfusion-transmitted malaria that is consistent with public health, and interested parties have had the opportunity to comment on the recommendations in the April 2020 guidance. The recommendations, which are unchanged from the April 2020 guidance, will remain in effect outside of the context of the public health emergency related to COVID–19.

In the **Federal Register** of June 17, 2020 (85 FR 36598), FDA announced the availability of the final guidance entitled ''Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry'' dated April 2020. FDA received no comments on the final guidance.

The guidance represents 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338; 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116; and the collections of information for consignee and transfusion recipient physician notification have been approved under OMB control number 0910–0681.

III. Electronic Access

Persons with access to the internet may obtain the 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: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26711 Filed 12–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3012]

Teva Branded Pharmaceutical Products R and D, Inc., et al.; Withdrawal of Approval of 35 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 35 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 9, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 006536	Urecholine (bethanechol chloride) Injection, 5 milligram (mg)/milliliter (mL) Urecholine (bethanechol chloride) Tablets, 5 mg, 10 mg, 25 mg, and 50 mg	Teva Branded Pharmaceutical Products R and D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 011707	Opana (oxymorphone hydrochloride (HCl)) Injection, 1 mg/mL and 1.5 mg/mL	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.