burden of this collection of information of 1,500 hours was too low and that the commenter believes more violations occur than 1,500. The commenter pointed to the number of Warning Letters and Civil Money Penalties FDA issued in 2019 to support this statement.

(Response) After reviewing the PTVR submissions again over the past 5 years we have made an adjustment to our burden estimate. The number of complaints submitted by the public is not reflective of the total number of reported violations of the FD&C Act and implementing regulations. In 2019, FDA received over 3,000 annual PTVR complaint reports and issued over 14,600 Warning Letters, 4,700 Civil Money Penalties, and 17 No-Tobacco-Sale-Orders. Reports of potential violations from the public are critical in helping FDA enforce tobacco regulations to protect America's youth. The PTVR form was designed to provide the public with a means of reporting violations of the FD&C Act to the Center for Tobacco Products. FDA conducts our own investigations and inspections to followup on complaints that may be submitted through PTVR submissions. FDA evaluates each report submitted to determine if the activity is a potential violation of the FD&C Act or related regulations before deciding what followup action, if any, is necessary. FDA now estimates we will receive 5,370 reports annually.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and Form FDA 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act via telephone, online form, mail or email.	2,685	2	5,370	0.25 (15 minutes)	1,343

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by telephone, online form, mail or email) will take 0.25 hour (*i.e.,* 15 minutes) per response. This estimate is based on the type and rate of reporting that has been submitted through the Potential Tobacco Violation Report Form in the past.

FDA estimates the number of annual respondents to this collection of information will be 2,685, who will each submit 2 reports by telephone, online form, mail or email. Each report is expected to take 0.25 hour to complete and submit; therefore, total burden hours for this collection of information is estimated to be 1,343 hours (5,370 responses × 0.25 hour per response).

We have adjusted our burden estimate based on the updated number of reports received to approximately 5,370 forms annually, which more accurately reflects the projected number of submissions based on current trends. Using these new figures, our estimated burden for the information collection signifies an overall increase to reflect 2,685 respondents per year and 1,343 hours.

Dated: June 5, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13071 Filed 6–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0601]

Mylan Institutional LLC et al.; Withdrawal of Approval of 16 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on March 9, 2020. The document announced the withdrawal of approval (as of April 8, 2020) of 16 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following four ANDAs after receiving a withdrawal request from Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202: ANDA 065488, Azithromycin Oral Suspension, Equivalent to (EQ) 100 milligrams (mg) base/5 milliliters (mL); EQ 200 mg base/5 mL; ANDA 078410, Topiramate Tablets, 25 mg, 50 mg, 100 mg, and 200 mg; ANDA 090441, Imipramine Hydrochloride Tablets, 10 mg, 25 mg, and 50 mg; and ANDA 200563, Ciprofloxacin Oral Suspension, 250 mg/5 mL and 500 mg/5 mL. Before FDA withdrew the approval of these ANDAs, Lupin Pharmaceuticals, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Lupin Pharmaceuticals, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 065488, 078410, 090441, and 200563 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, March 9, 2020 (85 FR 13661), in FR Doc. 2020–04691, the following correction is made:

On page 13661, in the table, the entries for ANDAs 065488, 078410, 090441, and 200563 are removed.

Dated: June 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13070 Filed 6–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0187 (Formerly Docket No. 2000D–1267)]

Revised Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria; 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 final guidance entitled ''Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry.'' The revised guidance provides blood establishments that collect blood and blood components with FDA's recommendations to reduce the risk of transfusion-transmitted malaria. The recommendations contained in this 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. The guidance announced in this notice supersedes the guidance entitled ''Recommendations for Donor Questioning, Deferral, Reentry, and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry'' dated August 2013 and updated August 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on June 17, 2020. The Agency is soliciting public comment, but is implementing this guidance immediately, because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

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 ''Revised 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: Stephen Ripley, 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 ''Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry.'' This document was posted on FDA's website on April 2, 2020 (see section III for electronic access to the guidance). The revised guidance document provides blood establishments that collect blood and blood components with FDA's recommendations to reduce the risk of transfusion-transmitted malaria. The recommendations contained in this guidance apply to the collection of Whole Blood and all 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)).

The guidance revises the recommendations in the August 2013 guidance, updated August 2014, by reducing from 1 year to 3 months the recommended deferral period for certain

blood donors who are residents of a non-endemic country and who travel to malaria-endemic areas. In addition, the guidance provides notice of an alternative procedure to permit the collection of blood and blood components from such donors without a deferral period, provided the blood components are pathogen-reduced using an FDA-approved pathogen reduction device, effective against *Plasmodium falciparum,* according to manufacturer's instructions for use. The revised recommendations are based on the current epidemiological data on malaria, the risk of transfusion-transmitted malaria and the availability of FDA-approved devices. FDA expects implementation of these revised recommendations will not be associated with any adverse effect on the safety of the blood supply. Furthermore, early implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing Coronavirus Disease 2019 (COVID–19) public health emergency.

The guidance announced in this notice supersedes the guidance entitled ''Recommendations for Donor Questioning, Deferral, Reentry, and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry'' dated August 2013 and updated August 2014.

In light of the COVID–19 public health emergency, FDA is issuing this guidance for immediate implementation in accordance with § 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))). FDA expects that the revised recommendations will increase the availability of blood and blood components while maintaining the safety of blood and blood components.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115(g)(2)). The guidance represents the current thinking of FDA on ''Revised 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

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (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; 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 either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders,* or *https://www.regulations.gov.*

Dated: June 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13066 Filed 6–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1893]

Patient-Focused Drug Development: Collecting Comprehensive and Representative Input; Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; 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 final guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' This guidance is the first of a series of four methodological guidance documents that FDA committed to develop to address in a stepwise manner how to collect and submit information from patients and caregivers for medical product development and regulatory decision making. This guidance finalizes the draft guidance of the same title issued on June 13, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on June 17, 2020.

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–2018–D–1893 for ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' 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.