3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 610, 630, and 640 have been approved under OMB control number 0910–0116; and the collections of information for consignee 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. 2020–13051 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–2014–N–0086]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by July 17, 2020.

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 0910–0716. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Potential Tobacco Product Violations Reporting

OMB Control Number 0910–0716—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended section 201 *et seq.* of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

The public is crucial in helping FDA enforce tobacco regulations to protect America's youth. FDA created the Tobacco Call Center (with a toll-free number: 1–877–CTP–1373) to assist the public with reporting potential violations of the Tobacco Control Act. FDA will evaluate any information reported and may conduct followup investigations if necessary. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (*e.g.,* cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated, including the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's website (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report) and seeks renewal of Form FDA 3779. The public and interested stakeholders are able to report information regarding possible violations of the Tobacco Control Act by submitting information online, via email, postal mail, or by calling FDA's Tobacco Call Center. Instructions on how to report possible violations of the Tobacco Control Act can be found at (*https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation*).

In the **Federal Register** of October 15, 2019 (84 FR 55161), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two PRA related comments were received.

(Comment 1) FDA received a comment urging the Agency to publicize the availability of the Potential Tobacco Product Violations Report (PTVR) form more broadly. The comment further urged that if FDA does not already have a dissemination plan for this information collection actively, it must create one because it is important that consumers, retailers, and other stakeholders are aware of this form in order to be most helpful. The comment indicated that it is important that FDA disseminate the violations reporting form more broadly to the public so people are aware of how they can report the various types of violations.

(Response) There are multiple options available for industry and the public to report potential violations of the Tobacco Control Act, and FDA has publicized the form on multiple occasions, including when the FDA Commissioner issued public statements regarding the youth vaping epidemic and potential electronic nicotine delivery systems-related seizures. FDA's website (*https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation*) has a link to submit the online PTVR form (*https://www.accessdata.fda.gov/scripts/ptvr/index.cfm*).

As referenced previously in this notice, there are many additional options for submission, which can be found at *https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation.*

(Comment 2) FDA received a comment which stated that the original

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.