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.