mandate reporting and data collections necessary to ensure that health insurance issuers are meeting the requirements of the Affordable Care Act. These information collection requirements are set forth in 45 CFR part 156.

Information collected by the Exchanges or Medicaid and CHIP agencies will be used to determine eligibility for coverage through the Exchange and insurance affordability programs (*i.e.,* Medicaid, CHIP, and advance payment of the premium tax credits); evaluate how CMS can best communicate eligibility and enrollment updates to issuers; and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs. *Form Number:* CMS–10592 (OMB control number: 0938–1341); *Frequency:* Annually, Monthly, Occasionally; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 250; *Total Annual Responses:* 250; *Total Annual Hours:* 131,750. (For policy questions regarding this collection contact Anne Pesto at 443–844–9966.)

Dated: April 1, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–07185 Filed 4–6–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0016]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our recordkeeping and records access requirements for food facilities.

DATES: Submit either electronic or written comments on the collection of information by June 8, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 8, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2011–N–0016 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352

OMB Control Number 0910–0560—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 of our regulations (21 CFR 1.326 through 1.363) set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves our ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

Information maintained under these regulations helps us identify and quickly locate contaminated or potentially contaminated food and inform the appropriate individuals and food facilities of specific terrorist threats. Our regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters; an adequate description of the food, including the quantity and packaging; and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all the required information and are retained for the required time period.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded our access to records. Specifically, FSMA expanded our access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that we reasonably believe is likely to be affected in a similar manner. In addition, we can access records if we believe that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. To gain access to these records, our officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner.

The information collection provisions of § 1.361 are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations at 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361 in table 1.

Description of Respondents: Respondents to this collection of information are persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States who are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	6.61	2,508,449
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.5	85,388
Total					2,593,837

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

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate to account for advances in information and communication technology that have occurred in the last decade. Because the transition from paper-based to electronic records systems is widespread, we estimate that the average burden per recordkeeping has decreased by 50 percent. With regards to records maintenance, we estimate that approximately 379,493 facilities each spend half the amount of time from the 13.228 hours previously reported to 6.61 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 2,508,449 hours annually. In addition, we estimate that new firms entering the affected businesses incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, we estimate the number of new firms entering the affected businesses is 5 percent of 379,493, or 18,975 firms. Thus, we estimate that approximately 18,975 facilities each spend, on average, 4.5 hours learning about the recordkeeping and records access requirements, for a total of 85,388 hours annually. This estimate reflects a reduction from 4.79 to 4.5 average hours per facility to account for the increase in facilities using internet, which increased from 71 to 99 percent. We estimate that approximately the same number of firms (18,975) exit the group of affected businesses in any given year, resulting in no growth in the number of total firms reported on line 1 of table 1.

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07275 Filed 4–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0626]

Pulmonary-Allergy Drugs Advisory Committee; Postponed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC) scheduled for April 21, 2020, is postponed. The Food and Drug Administration (FDA), like other government agencies, is taking the necessary steps to ensure the Agency is prepared to continue our vital public health mission in the event that our day-to-day operations are impacted by the COVID–19 public health emergency. Therefore, we are canceling or postponing all non-essential meetings through the month of April. We will reassess on an ongoing basis for future months. Therefore, this meeting is being postponed. The meeting was announced in the **Federal Register** on February 20, 2020.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting, which was announced in the **Federal Register** of February 20, 2020 (85 FR 9780).

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07262 Filed 4–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5550]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 23 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 January 8, 2020. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of February 7, 2020. The document indicated that FDA was withdrawing approval of the following seven ANDAs after receiving a withdrawal request from CASI Pharmaceuticals, Inc., c/o Target Health, Inc., 261 Madison Ave., 24th Floor, New York, NY 10016: ANDA 073191, Triamterene and Hydrochlorothiazide Capsules USP, 50 milligrams (mg)/25 mg; ANDA 076075, Econazole Nitrate Cream, 1%; ANDA 076192, Ribavirin Capsules USP, 200 mg; ANDA 076514, Midodrine Hydrochloride (HCl) Tablets USP, 2.5 mg, 5 mg, and 10 mg; ANDA 086809, Spironolactone Tablets USP, 25 mg; ANDA 090288, Naratriptan Tablets USP, Equivalent to (EQ) 1 mg base and EQ 2.5 mg base; and ANDA 203384, Epinastine HCl Ophthalmic Solution, 0.05%. Before FDA withdrew the approval of these ANDAs, CASI Pharmaceuticals, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because CASI Pharmaceuticals, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 073191, 076075, 076192, 076514, 086809, 090288, and 203384 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 Wednesday, January 8, 2020 (85 FR 909), in FR Doc. 2020–00076, on page 909, the following correction is made:

1. On pages 909 and 910, in the table, the entries for ANDAs 073191, 076075, 076192, 076514, 086809, 090288, and 203384 are removed.

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07265 Filed 4–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program Part F; AIDS Education and Training Centers; National HIV Curriculum e-Learning Platform: Technology Operations and Maintenance Project

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA's HIV/AIDS Bureau will award $100,000 in supplemental funding to the University of Washington to support the AIDS Education and Training Centers' (AETC) National HIV