plant, Pataya Food Industries Ltd., located at 90/6 Moo 7, Settakit Road, Tambol Tarsai, Amphur Maung, Samutsakorn 74000 Thailand. All other conditions and terms of this permit remain the same.

Dated: April 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08762 Filed 4–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1423]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Imports and Electronic Import Entries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 26, 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 0910–0046. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Imports and Electronic Import Entries

OMB Control Number 0910–0046—Revision

This information collection supports Agency regulations found in 21 CFR part 1, subparts D (§§ 1.70 through 1.81 (21 CFR 1.70 through 1.81)) and E (§§ 1.83 through 1.101 (21 CFR 1.83 through 1.101)), governing FDA import activities and related Agency guidance. Specifically, the regulations prescribe the required data elements that respondents must submit when importing, or offering for import, an FDA-regulated article into the United States. Review of the data elements allows FDA to continue to meet its responsibilities pertaining to current submission requirements established by the U.S. Customs and Border Protection (CBP) related to the submission of entry information in using its Automated Commercial Environment (ACE) system, or any CBP-authorized electronic data interchange (EDI) system. Respondents (ACE filers) submit important and useful information about FDA-regulated products being imported or offered for import into the United States so that we may effectively and efficiently review products and determine their admissibility. In addition, and as set forth in the regulations, certain product types are subject to additional data elements (for example, 21 CFR 1.77 prescribes additional data elements for radiation-emitting products), as well as those data elements applicable to all products.

We are revising the information collection to provide for a weekly entry filing program (WEF). More detailed information on Foreign Trade Zones (FTZ)/WEF, is available at *https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing.* The WEF program, which is available for some FDA-regulated products, allows entry filers to file a single entry estimating the amount of merchandise anticipated to be removed from an FTZ and offered for U.S. consumption during a 7-day period. To participate, we recommend respondents who wish to file a weekly entry of FDA-regulated products with CBP to first request a preliminary assessment from FDA. As part of this assessment, we recommend submission of the following information:

- FDA Import Division(s) [1] with geographic oversight over the FTZ location;
- Identification of whether products are manufactured or stored in the FTZ;
- FTZ site/subzone number and address;
- Importer of Record (IOR) Facility Establishment Identifier (FEI), if known;
- Manufacturer FEI, if known; and
- Port of entry.

The division information is necessary so that we can appropriately route the submission within the Agency. Information on whether the product is stored or manufactured in the zone is necessary for FDA to determine the applicable admissibility requirements. The FTZ and port information is necessary to ensure that basic requirements in 19 CFR part 146 are met. The IOR and manufacturer FEI information is requested by FDA to expedite the admissibility review. Requests to participate in the WEF process are submitted to the FDA Import Division Office covering the intended port of entry.

We are also revising the information collection to include our Import Trade Auxiliary Communication System (ITACS), currently approved under OMB control number 0910–0842. The ITACS is used by the import trade community and was implemented to improve communication with FDA. By utilizing ITACS, respondents to the information collection have the ability to establish an account and electronically check the status of FDA-regulated entries and lines, submit entry documentation, submit the location of goods availability for those lines targeted for examination by FDA, and check the estimated laboratory analysis completion dates for lines that have been sampled. For further information regarding ITACS, please visit our website at *https://www.fda.gov/industry/import-systems/itacs.*

In the **Federal Register** of January 3, 2020 (85 FR 318), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Upon review of our active information collection inventory, however, and on our own initiative, we have decided to make additional revisions to the information collection to improve the efficiency of Agency operations. Specifically, we are including Form FDA 766 ''Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts'' (currently approved under OMB control number 0910–0025) as the collection instrument for 21 CFR 1.95. Form FDA 766 facilitates collection of information associated with certain general enforcement provisions for importing FDA-regulated articles into the United States. The form

[1] Some FTZs are covered by multiple Import Divisions.

is available on the internet at *https://www.fda.gov/industry/actions-enforcement/reconditioning.*

Relatedly, we also are revising the information collection to include reference to Agency guidance entitled ''Pre-Launch Activities Importation Requests (PLAIR).'' Historically, when applicants with a pending new drug application, abbreviated new drug application, or Center of Drug Evaluation and Research-regulated biologics licensing application (information collection associated with these submissions is currently approved under OMB control number 0910–0001) sought to import unapproved finished dosage form drug products into the United States in preparation for market launch, we considered such requests, informally referred to as ''PLAIRs,'' on a case-by-case basis. Since implementing the PLAIR program in 2013, interest continues to increase, so we continue to develop a more formalized process.

Accordingly, to facilitate submissions and improve our own efficiencies, we published a notice of availability in the **Federal Register** of July 24, 2013 (78 FR 44572), announcing a draft guidance document discussing our PLAIR program, including an analysis under the PRA of the burden we estimate is attributable to the applicable information collection activities. We ultimately intend to finalize the guidance document to further clarify our recommendations on what products are eligible for a PLAIR, what information should be included in a PLAIR submission, when and how a PLAIR can be submitted to FDA, and the circumstances under which the Agency intends to grant a PLAIR. We therefore are including this estimate to account for burden that may be associated with this information collection. The draft guidance is available from our website at: *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports* and is being issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment on Agency guidance documents at any time.

Description of Respondents: Respondents to the information collection are domestic and foreign importers of FDA-regulated articles being imported or offered for import into the United States and entry filers who submit import entries on behalf of these importers.

As a result of these revisions, we have adjusted our burden estimate for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 1, subpart D	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Importers submission of data elements (preparing the required information).	85,480	10.05	859,074	0.05576 hours (3.346 minutes)	47,902
Entry filers (unique lines only)	3,419	12,196	41,698,124	0.04466 hours (2.68 minutes)	1,862,238
WEF participants	15	1	15	0.87 hours (52 minutes)	13.05
ITACS; creation of new account	500	1	1	0.5 (30 minutes)	250
Form FDA 766	324	1	324	0.25 (15 minutes)	81
Submissions in accordance w/PLAIR	70	5	350	16	5,600
Total			42,557,888		1,916,084

[1] There are no capital or operational and maintenance costs associated with the information collection.

As reflected in table 1, rows 1 and 2, we estimate 85,480 importers and 3,419 entry filers will make submissions. An importer of record may be the owner or purchaser of the article being imported or offered for import, or a customs broker licensed by CBP under 19 U.S.C. 1641 who has been designated by the owner, purchaser, or consignee to file the import entry. There is only one importer of record per entry. We have updated the number of responses and respondents since last OMB review of the information collection to reflect the best data available to the Agency from January 1, 2018, to December 31, 2018. We retain our currently approved estimate of the number of responses per respondent and time per response as representative of the industry average.

As reflected in table 1, row 3, we estimate 15 respondents will submit WEFs. Persons wishing to file weekly entries of FDA regulated products are encouraged to provide the information identified so that FDA can conduct a preliminary admissibility assessment of the associated products and firms. This submission typically contains the information FDA requests for multiple products (*i.e.,* the respondent wishes to file weekly entries for multiple products and submits the information for each product together). Generally, submissions involving multiple products are significantly less burdensome on a per-product basis. We estimate that the burden for each product in a WEF submission is approximately 52.5 minutes, for a total of 13.125 hours annually. Depending on the product and scale of submission, this estimated burden can fall to as low as 15 minutes per product. The reason why this burden can be significantly higher than an ACE submission is that the WEF submission is done manually, typically through a spreadsheet. Filers submitting in ACE typically use software that is developed to specifically automate and expedite the entry submission process and allows filers to automatically upload entry information. While the WEF submission includes an initial one-time submission burden, we expect reduced burden over a long term because filers can subsequently submit one entry covering multiple withdrawals from the FTZ in any given 7-day period.

As reflected in table 1, row 4, we estimate that 500 new ITACS accounts will be created annually. Since developing and implementing ITACS, we believe that most users have already created an account and, therefore, we have adjusted this estimate downward since last OMB review and approval.

As reflected in table 1, row 5, we estimate the submission of 324 Forms FDA 766 in conjunction with FDA-regulated products. This figure is based on Agency import data and our experience with the information collection. We assume it takes respondents 15 minutes to complete and submit Form FDA 766. Although current instructions communicate that four copies be submitted (one copy to be returned to respondent), we plan to update the form to reduce this number.

As reflected in table 1, row 6, we estimate 70 submissions under the PLAIR program. Since implementation of PLAIR there has been significant interest. We have therefore doubled our original estimate of 35 to 70 respondents annually but retain the average burden per response of 16 hours to provide the information recommended in the draft guidance.

Cumulatively these changes and adjustments result in a reduction in annual responses by 40,111,035 and an increase in burden hours by 130,572. These changes and adjustments reflect the realization of one-time burden associated with conforming to new CBP electronic reporting requirements since last OMB approval of the information collection that we believe no longer applies. Finally, we consolidated related information collection activities associated with CFR part 1, subparts D (§§ 1.70 through 1.81) and E (§§ 1.83 through 1.101) governing FDA import activities.

Dated: April 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08763 Filed 4–23–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 26, 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 0910–0806. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Drug Supply Chain Security Act Implementation OMB Control Number 0910–0806—Revision

This information collection supports Agency implementation of section 582 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1) (FD&C Act) as revised by the Drug Supply Chain Security Act (DSCSA) (Pub. L. 113–54). For efficiency of Agency operations, we are revising information collection currently approved under OMB control number 0910–0806 pertaining to certain provisions of the DSCSA to also include information collection activity associated with waivers, exceptions, and exemptions from requirements. Finally, we are revising the title of the information collection from ''Identification of Suspect Product and Notification'' to ''Drug Supply Chain Security Act Implementation'' to reflect the broadening scope of this information collection request. As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources. We have developed guidance to assist respondents to the information collection with this topic and are including it in the information collection accordingly.

In the **Federal Register** of May 9, 2018 (83 FR 21297), we published a notice announcing the availability of a draft guidance for industry entitled ''Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act,'' including an analysis and inviting public comment under the PRA regarding the proposed information collection.

The draft guidance was issued consistent with FDA's good guidance practice regulation (21 CFR 10.115) which provides for public comment at any time. We intend to finalize the guidance document and are seeking OMB approval of the attendant information collection discussed in the document.

The most recent version of the draft guidance is available at: *https://www.fda.gov/media/113342/download.*

In the 2018 NOA, we estimated that annually 20 trading partners or stakeholders would submit approximately 20 requests for a waiver, exception, or exemption. This estimate was based on communications we had with trading partners and stakeholders since the 2013 enactment of the DSCSA. We also estimated that it would require an average of 40 hours for respondents to prepare and submit each request and to submit any additional followup information that we may request, for a total burden of approximately 800 hours.

As described in the draft guidance, a recipient of a waiver, exception, or exemption should notify us whenever there is a material change in the circumstances that is the basis for the relief. In addition, we intend to biennially review waivers, exceptions, and exemptions that extend longer than 2 years in duration and may ask the recipient to submit information to determine whether a material change in the circumstances has occurred. We estimated that annually we would receive approximately 1 notification or other information from approximately 1 respondent that there has or has not been a material change in the circumstances that warranted the waiver, exception, or exemption and that each notification will require approximately 16 hours to prepare and submit to us, for a total of approximately 16 hours.

A trading partner may request that we renew a waiver, exception, or exemption that is of limited duration. This request should include a detailed statement justifying the continuance of the relief and the desired length of the extension. We estimated that annually we would receive approximately 1 renewal request from approximately 1 respondent and that each request would require approximately 16 hours to prepare and submit to us, for a total of approximately 16 hours.

To address the comment that that it will require more than 40 hours to prepare and submit requests for a waiver, exception, or exemption from the requirements of section 582 of the FD&C Act and to submit any additional follow up information that we may request, we increased the estimate to 80 hours. Therefore, we now estimate that the total annual burden hours for submitting these requests is