TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.22(b)(2) [3]—Other Updates of Registration	3673	2,687	1	2,687	0.5	1,344
807.22(b)(3) [3]—Annual Update of Listing Information	3673	22,607	1	22,607	0.5	11,304
807.26(e) [3]—Labeling and Advertisement Submitted at FDA Request	.....	71	1	71	1	71
807.34(a) [2]—Initial Registration and Listing when Electronic Filing Waiver Granted	.....	1	1	1	1	1
807.34(a) [3]—Annual Registration and Listing when Electronic Filing Waiver Granted	.....	1	1	1	1	1
807.40(b)(2) [3]—Annual Update of US Agent Information	3673	1,615	1	1,615	0.5	808
807.40(b)(3) [3]—US Agent Responses to FDA Requests for Information	3673	1,535	1	1,535	0.25	384
807.41(a) [3]—Identification of Initial Importers by Foreign Establishments	3673	12,983	1	12,983	0.5	6,492
807.41(b) [3]—Identification of Other Parties that Facilitate Import by Foreign Establishments	3673	12,983	1	12,983	0.5	6,492
Total One Time Burden	.....	.....	.....	.....	.....	14,975
Total Recurring Burden	.....	.....	.....	.....	.....	39,173

[1] Totals are rounded to the nearest whole number.
[2] One-Time Burden—Firm only provides initially.
[3] Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	Number of respondents	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
807.25(d) [2]—List of Officers, Directors, and Partners	22,338	1	22,338	.25 (15 minutes)	5,585
807.26 [2]—Labeling and Advertisements Available for Review	17,032	4	68,128	.5 (30 minutes)	34,064
Total	.....	.....	.....	.....	39,649

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden—Firm is required to keep records.

The following adjustments and program changes resulted in a 5,672-hour decrease to the overall total hour burden estimate for this information collection request.

- We adjusted the number of respondents based on updated registration and listing data.
- In the reporting burden table, we corrected the table footnotes to accurately indicate whether the information collection (IC) is a one-time or reoccurring burden.
- We also adjusted some of the IC descriptions in the table for increased clarity.
- We updated our estimate of Hours per Response for ''807.22(a) Initial Registration and Listing'' (+ 0.5 hours), ''807.22(b)(1) Annual Registration'' (− 0.25 hours), and ''807.22(b)(3) Annual Update of Listing Information'' (− 0.25 hours). Based on our review of the program, we believe these changes to the burden estimate will more accurately reflect the current preparation time for these ICs.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26303 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

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: Identification of Suspect Product and Notification

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.

DATES: Fax written comments on the collection of information by January 3, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0806. 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.

Guidance for Industry: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

OMB Control Number 0910–0806—Extension

This information collection supports the previously captioned Agency guidance and associated Form FDA 3911. The Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) added new section 582(h)(2) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1(h)(2)), requiring FDA to issue guidance to aid trading partners in identifying a suspect product and terminating a notification regarding an illegitimate product and, for a manufacturer, a product with a high risk of illegitimacy. *Suspect product* is defined in section 581(21) of the FD&C Act (21 U.S.C. 360eee(21)), as a product for which there is reason to believe it: (1) Is potentially counterfeit, diverted, or stolen; (2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) is potentially the subject of a fraudulent transaction; or (4) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Beginning January 1, 2015, section 582 of the FD&C Act requires certain trading partners, upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. *Illegitimate product* is defined in section 581(8) of the FD&C Act as a product for which credible evidence shows that it: (1) Is counterfeit, diverted, or stolen; (2) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) is the subject of a fraudulent transaction; or (4) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans. Also beginning January 1, 2015, trading partners must, upon determining that a product in their possession or control is illegitimate, notify FDA and all immediate trading partners that they have reason to believe they may have received the illegitimate product not later than 24 hours after making the determination. Under section 582(b)(4)(B)(ii)(II) of the FD&C Act, manufacturers are additionally required to notify FDA and any immediate trading partners that they believe may possess a product manufactured by or purportedly manufactured by the manufacturer not later than 24 hours after the determination is made or being notified by FDA or a trading partner that the product has a high risk of illegitimacy.

Under section 202 of the DSCSA, manufacturers, repackagers, wholesale distributors, and dispensers (*e.g.,* pharmacies) must: (1) Notify FDA when they have determined that a product in their possession or control is illegitimate (and, for manufacturers, when they have determined or been notified by FDA or a trading partner that a product has a high risk of illegitimacy); (2) notify certain immediate trading partners about an illegitimate product that they may have received (and, for manufacturers, that a product has a high risk of illegitimacy); (3) terminate notifications regarding illegitimate products (and, for manufacturers, a product with a high risk of illegitimacy), in consultation with FDA, when the notifications are no longer necessary; and (4) notify immediate trading partners when the notifications are terminated. Trading partners should use Form FDA 3911 to submit notifications and requests for terminations of notifications to FDA. Form FDA 3911 is available on FDA's web page (*https://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm*).

A. Notifications to FDA

Under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, as amended by the DSCSA, and beginning not later than January 1, 2015, a manufacturer, repackager, wholesale distributor, or dispenser who determines that a product in its possession or control is illegitimate must notify FDA of that determination not later than 24 hours after the determination is made. In addition, section 582(b)(4)(B)(ii)(II) of the FD&C Act requires manufacturers to notify FDA when a manufacturer determines that a product poses a high risk of illegitimacy.

We originally estimated that all manufacturers, repackagers, wholesale distributors, and dispensers would collectively submit 5,000 notifications per year. This estimate included the notifications by trading partners that have determined that illegitimate product is in their possession or control, as well as notifications by manufacturers that have determined a product poses a high risk of illegitimacy. As discussed in our **Federal Register** notice of June 11, 2014 (79 FR 33564), the estimate was based on our experience with field alert reports (Form FDA 3331) that holders of approved drug applications are required to submit for certain drug quality issues (21 CFR 314.81(b)(1)) and with reports of the falsification of drug sample records, diversion, loss, and known theft of prescription drug samples as currently required under § 203.37 (21 CFR 203.37). Upon evaluation of the number of notifications we received for fiscal years 2016 and 2017, however, we are lowering our estimate to 150 notifications.

We are also combining the estimates for manufacturers and repackagers because FDA's establishment and drug product listing database indicates that many companies perform activities of both manufacturers and repackagers. Although the DSCSA specifically defines dispensers, for estimation purposes, we are using estimates for pharmacies in general terms based on those that must comply with the new requirements under section 582(d) of the FD&C Act.

Because manufacturers, repackagers, and wholesale distributors are collectively responsible for prescription drugs from the point of manufacturing through distribution in the drug supply chain, we assume that most notifications of illegitimate products are

submitted by these three trading partners. The total number of respondents is comprised of 80 percent manufacturers (120), 15 percent wholesale distributors (22), and 5 percent pharmacies (8).

We estimate that the number of annual notifications will vary from 0 to 2 for manufacturers/repackagers, as well as from pharmacies, with the vast majority of companies making no notifications. Although FDA's establishment and drug product listing database currently contains registrations for approximately 6,500 manufacturers and repackagers, we estimate that approximately 120 manufacturers/repackagers will notify us of illegitimate products an average of one time per year. Although we estimate approximately 69,000 pharmacy sites in the United States, based on data from the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Hospital Association, we estimate that approximately 8 pharmacies will notify FDA of illegitimate product an average of one time per year. According to the Healthcare Distribution Alliance (formerly known as Healthcare Distribution Management Association), approximately 30 wholesale distributors are responsible for over 90 percent of drug distributions; based on sales and because FDA is estimating that over 2,200 small wholesale distributors might be responsible for the remaining 10 percent of drug sales, we estimate that wholesale distributors will be responsible for making about an average of 1 notification per year to account for the estimated 22 notifications that FDA will receive regarding illegitimate product. Each notification should include information about the person or entity initiating the notification, the product determined to be illegitimate or having a high risk of illegitimacy, and a description of the circumstances surrounding the event that prompted the notification. We estimate that each notification will take about 1 hour, as reflected in table 1.

B. Notifications to Trading Partners of an Illegitimate Product or Product With a High Risk of Illegitimacy

Under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, a trading partner who determines that a product in its possession is illegitimate must also notify all immediate trading partners that they believe may have received such illegitimate product not later than 24 hours after the determination is made. In addition, under section 582(b)(4)(B)(ii)(II) of the FD&C Act, a manufacturer is required to notify all immediate trading partners that the manufacturer believes may possess a product manufactured by or purported to be manufactured by the manufacturer not later than 24 hours after the determination is made or being notified by FDA or a trading partner that the product has a high risk of illegitimacy.

Because the extent of distribution of any illegitimate product is likely to vary from one situation to another, we assume a wide distribution of each illegitimate product. We estimate that, for each notification made by a manufacturer or repackager to FDA, approximately 30 trading partners (based on the number of distributors) will also be notified. This results in approximately 3,600 notifications annually to trading partners of manufacturers/repackagers. This estimate includes the notifications by manufacturers and repackagers who have determined that illegitimate product is in their possession or control, as well as notifications by manufacturers that have determined that a product poses a high risk of illegitimacy.

We estimate that a large wholesale distributor may have up to 4,500 trading partners, but a small wholesale distributor may have 200 trading partners, for an average of approximately 2,350. We originally estimated that a wholesale distributor would notify all 2,350 trading partners for each of the illegitimate products identified. However, we are lowering our estimate as a result of our experience with the collection and informal feedback from industry to reflect that 22 respondents will make 1,175 disclosures for a total of 25,850 disclosures annually; and that each disclosure will require approximately 12 minutes, for a total of 5,170 hours annually.

We estimate that a pharmacy purchases prescription drugs from an average of two wholesale distributors. Therefore, a pharmacy would notify 2 trading partners for each of the 8 illegitimate products identified, resulting in approximately 16 notifications annually to pharmacy trading partners.

Manufacturers/repackagers, wholesale distributors, and pharmacies may notify their trading partners using existing systems and processes used for similar types of communications. Such communications may include, but are not limited to, posting notifications on a company website, sending an email, telephoning, or mailing or faxing a letter or notification. The information contained in the notification to the immediate trading partner should be the same as or based on the notification that was already submitted to FDA. We estimate that, for all trading partners, each notification of immediate trading partners will take approximately 0.2 hour (12 minutes). The estimated total burden hours that manufacturers/repackagers, wholesale distributors, and pharmacies will take to notify trading partners is approximately 5,893 hours annually, as reflected in table 2.

C. Consultations With FDA and Termination of Notification

Section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act requires that a trading partner who determines, in consultation with FDA, that a notification made under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), or (e)(4)(B)(ii) is no longer necessary must terminate the notification. The guidance for industry sets forth the process by which trading partners should consult with FDA to terminate notifications that are no longer necessary.

Each request for termination of notification must include information about the person or entity initiating the request for termination, the illegitimate product or product with a high risk of illegitimacy, the notification that was issued, and an explanation about what actions have taken place or what information has become available that make the notification no longer necessary. Trading partners should also include the FDA-assigned incident number associated with the initial notification on the request for termination. The request for a termination will be viewed as a request for consultation with FDA. We estimate that the same amount of time will be required to provide the information necessary to request termination as is required to make the notification. The time required to investigate and resolve an illegitimate product notification will vary, but we assume that each notification will eventually be terminated. We assume that the number of requests for termination of a notification per year will be the same as the original number of notifications for a given year. The estimated total burden hours of making requests for termination of notifications to FDA is 150 hours annually, as reflected in table 3.

D. Notifications to Trading Partners That a Notification Has Been Terminated

Section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the

FD&C Act requires that a trading partner who, in consultation with FDA, terminates a notification made under section 582(b)(4)(B)(ii)(I) or (II), (c)(4)(B)(ii), (d)(4)(B)(ii), or (e)(4)(B)(ii) must also promptly inform previously-notified immediate trading partners that the notification has been terminated. We estimate that the burden for notifying trading partners of an illegitimate product and the number of trading partners notified will be the same as the estimates for notification of termination. The estimated total burden hours of notifying trading partners that the notification is terminated is approximately 5,893 hours annually, as reflected in table 4.

In the **Federal Register** of September 6, 2018 (83 FR 45254), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—NOTIFICATIONS TO FDA [1]

Respondent description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	120	1	120	1	120
Wholesale Distributors	22	1	22	1	22
Dispensers	8	1	8	1	8
Total					150

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT [1]

Respondent description	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	120	30	3,600	0.20 (12 minutes)	720
Wholesale Distributors	22	1,175	25,850	0.20 (12 minutes)	5,170
Dispensers	8	2	16	0.20 (12 minutes)	3
Total					5,893

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR CONSULTATION WITH FDA AND TERMINATION OF NOTIFICATION [1]

Respondent description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	120	1	120	1	120
Wholesale Distributors	22	1	22	1	22
Dispensers	8	1	8	1	8
Total					150

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

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT TERMINATION [1]

Respondent description	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	120	30	3,600	0.2 (12 minutes)	720
Wholesale Distributors	22	1,175	25,850	0.2 (12 minutes)	5,170
Dispensers	8	2	16	0.2 (12 minutes)	3
Total					5,893

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

Cumulatively, the total estimated burden is 12,086 annual hours, which reflects a significant decrease. We base this adjustment on our experience with the information collection since its establishment and implementation.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26295 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5928]

Post-Complete Response Letter Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants Under Generic Drug User Fee Amendments; 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 for industry entitled ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' This guidance is intended to clarify the criteria for granting post-complete response letter (CRL) meeting requests and the scope of discussions for granted meeting requests. This guidance provides procedures that will promote well-managed post-CRL meetings and help ensure that such meetings are scheduled and conducted in accordance with the commitments made by FDA in connection with the reauthorization of the Generic Drug User Fee Amendments for Fiscal Years 2018–2022 (GDUFA II).

DATES: The announcement of the guidance is published in the **Federal Register** on December 4, 2018.

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–2017–D–5928 for ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' 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.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–6902.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' GDUFA was reauthorized (GDUFA II) on August 18, 2017, in order to facilitate timely access to high quality, affordable generic medicines. In accordance with the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Goals or Commitment Letter) that accompanied the legislation, FDA committed to schedule and conduct 90 percent of post-CRL meetings within prescribed time frames.