ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	DSW/ Organization	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Healthcare Organization Representatives.	Nursing	Online Survey with Healthcare Organization Representatives.	67	1	30/60	33
Nurses and Nursing Students.	Nursing	Brief Online Questionnaire for Nursing Organization Memberships.	2,934	1	10/60	489
Physicians and students in allied health professions.	Obstetrics & Gynecology	Avatar Training Satisfaction Survey.	1,200	1	6/60	120
Students in allied health professions.	Obstetrics & Gynecology	Proficiency Ratings Scale—Standardized Patient Version.	600	1	6/60	60
Physicians	Obstetrics & Gynecology	Proficiency Ratings Scale—Provider—Baseline.	600	1	6/60	60
Physicians	Obstetrics & Gynecology	Proficiency Rating Scale—Provider—1 Month Follow-Up.	600	1	2/60	20
Physicians	Obstetrics & Gynecology	FASD Training Event Evaluation.	124	1	2/60	4
Residency Directors, Training Coordinators, Clinic Directors.	Obstetrics & Gynecology	Pre- Assessment of Training Implementation.	14	1	30/60	7
Residency Directors, Training Coordinators, Clinical Directors, Physicians.	Obstetrics & Gynecology	Post-Assessment of Training Implementation.	14	1	30/60	7
Physicians	Pediatrics	FASD Core Training Survey—Pediatrics 3 Month Follow-Up.	120	1	15/60	30
Physicians	Pediatrics	Pediatrics DSW Baseline Survey.	535	1	4/60	36
Physicians	Pediatrics	Pediatrics DSW Year 4 Survey.	535	1	4/60	36
Physicians	Pediatrics	FASD Toolkit User Survey	50	1	15/60	13
Physicians	Social Work & Family Physicians.	Family Medicine Comprehensive Practice Evaluation.	62	1	8/60	8
Medical and allied health professionals.	National Organization on Fetal Alcohol Syndrome.	NOFAS Webinar Survey—Post-Test.	400	1	5/60	33
Medical and allied health professionals.	National Organization on Fetal Alcohol Syndrome.	NOFAS Webinar Survey—3 Month Follow-Up.	400	1	5/60	33
General public	National Organization on Fetal Alcohol Syndrome.	NOFAS Outcomes Vignette.	50	1	10/60	8
TOTAL						4,524

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–23088 Filed 9–14–15; 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; Guidance for Industry on 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 (the PRA).

DATES: Fax written comments on the collection of information by October 15, 2015.

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–NEW and title ''Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (OMB Control Number 0910—NEW)

In the **Federal Register** of June 11, 2014 (79 FR 33564), FDA announced the availability of a draft guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' The draft guidance addressed new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Section 202 of the DSCSA adds section 582(h)(2) (21 U.S.C. 360eee–1(h)(2)) to the FD&C Act, which requires FDA to issue guidance to aid certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and terminating notifications. The draft of this guidance identified specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain and provided recommendations on how trading partners can identify the product and determine whether the product is a suspect product as soon as practicable.

Beginning January 1, 2015, section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify (1) FDA and (2) all immediate trading partners that they have reason to believe may have received the illegitimate product, not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) of the FD&C Act to notify FDA, and any immediate trading partners that the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer, not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that a product is illegitimate. The draft guidance addressed how trading partners should notify FDA using Form FDA 3911. In addition, in accordance with section 582(h)(2) of the FD&C Act, the draft guidance sets forth the process by which trading partners must terminate the notifications using Form FDA 3911, in consultation with FDA, regarding illegitimate product and, for a manufacturer, a product with a high risk of illegitimacy, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

Burden Estimates: 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 immediate trading partners about an illegitimate product that they may have received (and, for manufacturers, a product with a high risk of illegitimacy); (3) terminate notifications regarding illegitimate products (and, for manufacturers, products 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.

1. 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, 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.

FDA originally estimated that a total of approximately 5,000 notifications per year would be made by all manufacturers, repackagers, wholesale distributors, and dispensers. This estimate included the notifications by trading partners who 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 the June 11, 2014, **Federal Register** notice, this estimate was based on FDA's experience with FARs (Form FDA 3331) required to be submitted by holders of approved drug applications for certain drug quality issues (§ 314.81(b)(1) (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). In response to the **Federal Register** notice, FDA received a comment from a trade association representing a primary stakeholder stating that the estimate of 5,000 notifications was too high based on experience of its members. In response to the comment, FDA reexamined the estimate of 5,000 notifications. We determined that the 5,000 FARs and 5,000 sample reports under § 203.37 received each year included initial, followup and final reports. While FDA does not know the exact number of notifications that will be submitted, we lowered the estimate to 1,000 notifications in response to the comment and our reexamination of the data, and adjusted the PRA accordingly.

FDA is 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. While the DSCSA specifically defines dispensers, for estimation purposes, FDA is 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, collectively, manufacturers, repackagers, and wholesale distributors are responsible for prescription drugs from the point of manufacturing through distribution in the drug supply chain, in the June 11, 2014, **Federal Register** notice, FDA assumed that most notifications of illegitimate products would be made by these three trading partners. FDA received a comment from a major stakeholder group stating that they believed that the number of notifications estimated for wholesale distributors was too high based on their past experience. The commenter speculated that most notifications would be made by manufacturers. In addition, manufacturers are the only stakeholder group required to submit notifications of high risk of illegitimacy. FDA originally estimated that approximately 50 percent of the notifications will be made by manufacturers and repackagers, 45

percent by wholesaler distributors, and 5 percent by pharmacies. In response to the comment and the fact that only manufacturers submit notifications of high risk of illegitimacy, FDA is changing the proportion that will be made by manufacturers and repackagers to 80 percent (800), 16 percent by wholesale distributors (160), and 4 percent by pharmacies (40).

FDA estimates that the number of annual notifications will vary from 0–2 for manufacturers/repackagers, wholesale distributors, and pharmacies, with the vast majority of companies making no notifications. While the FDA establishment and drug product listing database currently contains registrations for approximately 6,500 manufacturers and repackagers, we estimate that approximately 800 manufacturers/repackagers will notify FDA of illegitimate product or a product with a high risk of illegitimacy an average of one time per year. While FDA estimates 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 40 pharmacies will notify FDA of illegitimate product an average of one time per year. Because, according to 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 distributors will be responsible for making an estimated 160 notifications FDA will receive regarding illegitimate product.

FDA intends to make Form FDA 3911 available on its Web page for trading partners to use to notify FDA. Each notification should include information about the person or entity initiating the notification, the product determined to be illegitimate, or to have a high risk of illegitimacy, and a description of the circumstances surrounding the event that prompted the notification. FDA estimates that each notification will take about 1 hour. The estimated total annual burden hours for making notifications to FDA is approximately 1,000 hours annually (table 1).

2. 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 the trading partner has reason to believe may have received such illegitimate product of that determination not later than 24 hours after the determination is made. In addition, a manufacturer is required, under section 582(b)(4)(B)(ii)(II) of the FD&C Act, to notify all immediate trading partners that the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer not later than 24 hours after the manufacturer has determined or been 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, FDA assumed a wide distribution of each illegitimate product. FDA estimates 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 24,000 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.

FDA estimates 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. FDA originally estimated that a wholesale distributor would notify all 2,350 trading partners for each of the illegitimate products identified. However, comments received from a trade association indicated that they believed this number was too high based on past experience. FDA has reduced the number of trading partners that a wholesale distributor would notify to 50 percent resulting in the notification of 1,175 trading partners for each of the 160 notifications resulting in a total of 188,000 notifications to trading partners.

FDA estimates 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 40 illegitimate products identified, resulting in approximately 80 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, which might include, but is not limited to, posting of notifications on a company Web site, telephoning, sending an email, 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. FDA estimates that for all trading partners, each notification of immediate trading partners will take approximately 0.2 hours. The estimated total burden hours of making notifications to trading partners is approximately 42,416 hours annually (table 2).

3. Consultation 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 require 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 sets forth the process by which trading partners must consult with FDA to terminate notifications that are no longer necessary.

FDA is making Form FDA 3911 available to trading partners on its Web page to request a termination of notification. 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. FDA estimates 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 FDA assumes that each notification will eventually be terminated at some point. FDA assumes 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 approximately 1,000 hours annually (table 3).

4. 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 require 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. FDA estimates 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 of notifying trading partners that the notification is terminated is approximately 42,416 hours annually (table 4).

The total burden of drug notifications for all stakeholders is 86,832 hours.

In the **Federal Register** of June 11, 2014 (79 FR 33564), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments on the draft guidance from 20 different organizations, companies, and individuals. The draft guidance provided scenarios that could increase the risk of a suspect product entering the supply chain and recommendations on how trading partners may identify products that may be suspect. The draft guidance also provided the process for notifying FDA and immediate trading partners when a trading partner has determined that a product is an illegitimate product or a manufacturer has determined that a product has a high risk of illegitimacy and the process for terminating those notifications in consultation with FDA. Many of the comments requested information about parts of the DSCSA that were not specifically covered by, nor intended to be covered by, the draft guidance, such as cleared product notifications, suspect product investigation, illegitimate product determinations, quarantine, and verifications, which FDA intends to address in other guidance or by other public means.

Several commenters raised issues pertaining to the information collection provisions in the draft guidance and Form FDA 3911. FDA has clarified the process for making notifications and requests for termination to FDA in the final guidance. FDA also clarified several fields on Form FDA 3911 and the instructions for using Form FDA 3911 in response to comments received to the draft guidance. The issues raised by the commenters are addressed further in this document.

Scope-Related Issues

Issue 1: Several comments were received requesting clarification about the scope of what is considered to be an illegitimate product or what constitutes a high risk of illegitimacy. For example, commenters requested clarification that a product may be determined to be illegitimate only as a result of fraud and not due solely to quality issues. Commenters also asked for a definition of high risk of illegitimacy.

FDA Response to Issue 1: The purpose of this guidance is to provide a process for trading partners to submit notifications to FDA and immediate trading partners after the determination of illegitimacy or high risk of illegitimacy has been made and to submit requests for consultation to FDA to terminate a notification. To determine the scope of illegitimate products, trading partners should refer to the definition of illegitimate product in section 581(8) of the FD&C Act (21 U.S.C. 360eee(8)), which does not exempt quality issues. The current guidance has been amended to add scenarios to help manufacturers determine if a product has a high risk of illegitimacy. Please refer to *Issue 14* for more information on ''high risk of illegitimacy.''

Issue 2: Is it necessary to send a notification to FDA when an illegitimate product or product with high risk of illegitimacy can be dispositioned or contained quickly?

FDA Response to Issue 2: Yes. Provisions of the DSCSA require trading partners to notify FDA when a determination has been made that a product is illegitimate, or for manufacturers, that a product has a high risk of illegitimacy. The amount of time it takes for a firm to control the product or manage the situation is not a factor in determining when a notification to FDA and other trading partners is required, *i.e.* not later than 24 hours after the determination is made that a product is illegitimate or has a high risk of illegitimacy.

Issue 3: Many commenters asked if FDA was going to make either Form FDA 3911 or information about the notifications public.

FDA Response to Issue 3: The notifications and requests for termination will be handled according to Agency regulations, the Freedom of Information Act, and other applicable disclosure law. In some cases, FDA may coordinate with the notifying person or entity and issue Agency public health alerts to protect the public health based on information received through drug notifications received under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act.

Form FDA 3911 and Instruction-Related Issues

Several commenters requested clarification of the instructions for filling out existing fields on Form FDA 3911 or requested additional information be added to Form FDA 3911 including additional fields.

Issue 4: Commenters requested clarification about the fields on Form FDA 3911 to describe the product that is the subject of the notification. Specifically, commenters wanted clarification about the terms ''generic'' and ''trade'' names.

FDA Response to Issue 4: FDA has clarified the names of these fields on Form FDA 3911 and the associated instructions. The field called ''Generic Name'' was changed to ''Name of Product as it appears on the label''. The field called ''Trade Name (if applicable)'' was changed to ''Primary Ingredients'' and the instructions were amended to request that the notifying person or entity list the active pharmaceutical or biological ingredients, if known, and if the information is not already listed in the ''Name of Product as it appears on the label'' field. These changes will clarify how the notifying person or entity should describe the product that is the subject of the notification.

Issue 5: Several commenters wanted clarification about the fields on Form FDA 3911 for identification of company versus the reporter.

FDA Response to Issue 5: FDA modified Form FDA 3911 to make it clearer that we want information about the company who is responsible for making the notification. The ''reporter'' is the person whom the FDA may contact for additional information about the notification. FDA considers the company with the illegitimate product in its possession or control, or a manufacturer that has made a determination that a product has a high risk of illegitimacy, to be the company that is responsible for making and terminating the notification, even if that company contracts with another person or entity to submit the notification on its behalf.

Issue 6: Commenters asked about the term ''unique facility identifier'' since the D-U-N-S number is a corporate identifier not a facility identifier. The commenter requested that FDA clarify that it is asking for the unique ''Corporate'' and not ''Facility'' identifier.

FDA Response to Issue 6: FDA uses a site specific identifier called the unique facility identifier (UFI) as a useful resource in identifying and confirming certain business information for the company responsible for making the notification. FDA currently prefers the D-U-N-S number as the UFI. Since the commenters were confused about the term ''facility'', we clarified in the instructions to Form FDA 3911 that the UFI for the company making the notification is the number being requested.

Issue 7: Several commenters requested a notification reference number for identification purposes.

FDA Response to Issue 7: FDA agrees with the commenters and has added a field for an incident number. FDA plans to assign an incident number when the initial notification is received. FDA will send the incident number in the response that confirms the receipt of the initial notification to the notifying person or entity. This incident number should be used in all future correspondence about the specific incident/event that is the subject of the initial notification, including any request for termination. The form, instructions, and process in the guidance have been amended to include the incident number. There is no additional burden to the company making the notification to include this number on any additional correspondence with FDA including the request for termination.

Issue 8: Commenters requested the addition of an FDA contact be added to Form FDA 3911 for questions about the form.

FDA Response to Issue 8: FDA has added a contact telephone number in addition to the email address previously provided on the Drug Notification Web page referenced in the guidance.

Issue 9: Commenters requested a field to indicate that the company making the notification (wholesale distributor, repackager, or dispenser) has consulted with the manufacturer when determining whether a product is illegitimate.

FDA Response to Issue 9: The DSCSA, section 582(c)(4)(B), (d)(4)(B), and (e)(4)(B), requires that wholesale drug distributors, dispensers, and repackagers coordinate with the manufacturer when determining whether a product is illegitimate. Form FDA 3911 should be used to submit a notification after the determination that a product is illegitimate is made. A separate field was not designated for this topic because the company making the notification may identify the manufacturer they coordinated within the ''For Notification, Description of Event/Issue'' Field. This option has been added to the instructions.

Issue 10: Commenters requested a field on Form FDA 3911 to list all trading partners that they believe may possess the illegitimate product.

FDA Response to Issue 10: FDA did not add a specific field to Form FDA 3911 for companies to list the names of trading partners that may have illegitimate product. While not required, a company may identify all trading partners that they believe may possess the illegitimate product in the ''Description of Event/Issue'' Field. Under the DSCSA, trading partners are responsible for making notifications to all immediate trading partners that they have reason to believe may have received such product.

Issue 11: Commenters requested a space or field to list a case or report number associated with a Medwatch report or other report submitted to FDA.

FDA Response to Issue 11: FDA agrees with commenters that it may be useful to know the report or case number for other required or voluntary submissions made to FDA about the same issue. This information may be included in the ''For Notification: Description of Event/Issue'' or ''For Request for Termination of Notification: Description of Why Notification is No Longer Necessary'' fields. FDA amended the instructions on Form FDA 3911 for notifying parties to provide this information if known.

Issue 12: Commenters requested a check box to indicate that testing of the drug product was completed.

FDA Response to Issue 12: FDA did not add a check box to indicate if testing was completed. However, the company making the notification or request for termination should provide this type of information in the fields, ''For Notification, Description of Event/Issue'' or ''For Request for Termination of Notification: Description of Why Notification is No Longer Necessary.''

Issue 13: Commenters asked for clarification about the purpose of the ''drug use'' and ''drug description'' fields.

FDA Response to Issue 13: The DSCSA applies to prescription drugs for human use. Including these fields helps FDA confirm that the DSCSA requirement applies to the product(s) subject to the notification. The fields also provide flexibility for future use of this form in other contexts. FDA included an ''other'' option under the ''drug use'' field to choose if a drug has multiple approvals for use. An instruction to explain ''other'' when selected by a notifying person or entity was added. We have also included more choices under the ''drug description'' field to help FDA distinguish between products regulated by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

High Risk of Illegitimacy-Related Issues

Issue 14: Several manufacturers requested clarification and specific information about how to document that a notification is for a product with ''a high risk of illegitimacy.'' Commenters also requested clarification on FDA's interpretation of ''high risk of illegitimacy.''

FDA Response to Issue 14: In the draft guidance, FDA did not distinguish between illegitimate product notifications and high risk of illegitimacy notifications because the timing and process for these submissions is the same. However, because we received several comments, FDA has revised the guidance to specify the process for notifications for products with a ''high risk of illegitimacy'' that are required by the DSCSA to be submitted by manufacturers. The guidance provides direction for manufacturers on how to submit notifications for products with a high risk of illegitimacy. It also clarifies when products may have a high risk of illegitimacy. These clarifications do not affect our expected numbers of notifications or terminations, since the PRA estimates in the draft guidance already included products with a high risk of illegitimacy. FDA also amended the instructions for Form FDA 3911 to indicate that manufacturers document a notification for product with a ''high risk of Illegitimacy'' in the ''For Notification, Description of Event/Issue'' field. FDA clarified the instructions for several other fields on Form FDA 3911 to indicate more clearly that they apply to both notifications for illegitimate products and for products with a high risk of illegitimacy.

Timing-Related Issues

Issue 15: Commenters asked for clarification regarding the requirement to submit a notification within 24 hours of making the determination that a product is illegitimate or has a high risk of illegitimacy.

FDA Response to Issue 15: The DSCSA specifies that notifications are to

be submitted no later than 24 hours after making the determination that a product in the possession or control of the trading partner is illegitimate. This same timeframe also applies to manufacturers notifying FDA and other trading partners when they determine that a product has a high risk of illegitimacy. This timeframe will help prevent or limit illegitimate product or product with a high risk of illegitimacy from entering or being further distributed in the U.S. supply chain.

Issue 16: Several commenters indicated that a 10-day timeframe for FDA to provide a consultation in response to a request for termination is too long and could result in drug shortages. Commenters stated that the process for requesting expedited consultation was unclear.

FDA Response to Issue 16: FDA will review and consult with notifying parties regarding requests for termination as soon as possible. The timing of FDA's review and consultation will depend on the number of requests and the circumstances surrounding the requests for termination that are received. Since notifications under the DSCSA are submitted to FDA when it has been determined by trading partners that a product is illegitimate or by manufacturers that a product has a high risk of illegitimacy, in many cases, these products would be counterfeit, intentionally adulterated, diverted, stolen, or otherwise unfit for further distribution and would likely not be further distributed. As FDA indicated in the draft guidance, FDA will consider requests for expedited review when included with a request for termination. We have clarified the process for requesting expedited review by adding an instruction to Form FDA 3911 directing the company that is requesting termination to also request and justify the need for expedited review when explaining why the notification is no longer necessary.

Duplication of Submission-Related Issues

Issue 17: Comments were received requesting an explanation of why the development of Form FDA 3911 was necessary instead of using the standard FAR for notifications under the DSCSA.

FDA Response to Issue 17: The FAR is a required postmarketing report made by an application holder (new drug or generic drug) when there is a problem, generally a quality problem, associated with a drug as outlined in § 314.81(b)(1). FDA developed Form FDA 3911 because the FAR form was inadequate for making notifications required under the DSCSA for a product that is illegitimate or has a high risk of illegitimacy for a reason not necessarily related to product quality or otherwise described in § 314.81(b)(1) (*e.g.,* diverted, stolen, etc.). In addition, only applicant holders are required to submit the FAR to FDA. Illegitimate product notifications are required to be sent to FDA by manufacturers, repackagers, distributors, and dispensers. Notifications of products with a high risk of illegitimacy are also required to be submitted by manufacturers. It is not known how frequently the same incident will generate submission of a FAR and Form FDA 3911 notifications. FDA is collecting information on FDA Form 3911 that will enable us to quantify duplication of submissions.

Issue 18: Commenters requested clarification about whether every trading partner should submit a separate notification to FDA about the same illegitimate product.

FDA Response to Issue 18: The DSCSA (section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii)) requires that certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) with illegitimate product in their possession or control submit a notification. Trading partners should submit notifications as required by the relevant statutory provisions.

Issue 19: Commenters requested clarification about whether they are required to submit a notification to FDA if they are notified of a suspect or illegitimate product by FDA and determine that they have it in their possession or control.

FDA Response to Issue 19: The DSCSA (section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii)) requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to submit an illegitimate product notification to FDA if a trading partner determines that it has illegitimate product in its possession or control.

Notifying Trading Partners-Related Issues

Issue 20: Several comments asked for clarification about the process for notifying trading partners of an illegitimate product. Commenters stated that FDA should clarify that existing systems and processes can be used to make notifications to trading partners as well as informing them of terminations of such notifications.

FDA Response to Issue 20: In the draft guidance, FDA specified that existing processes and systems can be used to inform trading partners that a notification has been terminated. FDA agrees with the comments received and has added to the final guidance that trading partners can use existing systems and processes to provide notification to trading partners that they believe may have received the illegitimate product or a product with high risk of illegitimacy.

Issue 21: A commenter requested that FDA develop a system that would allow for notification of FDA and other trading partners at the same time.

FDA Response to Issue 21: Manufacturers, repackagers, wholesale distributors, and dispensers with illegitimate product or manufacturers that determine that a product has a high risk of illegitimacy are responsible for notifying their trading partners in addition to FDA. FDA developed a process for trading partners to use to notify FDA using Form FDA 3911. As clarified in the guidance and *Issue 20,* the notifying person or entity can use its existing systems and processes to provide the necessary notification to trading partners. If preferred, the notifying person or entity may provide a copy of Form FDA 3911 to other trading partners in addition to FDA to meet that requirement.

Issue 22: A commenter asked for clarification if dispensers' immediate trading partners include other pharmacies in the same group of chain pharmacies as well as the wholesale distributor or manufacturer from whom the dispenser purchased drug.

FDA Response to Issue 22: The intent of the notification provisions in the DSCSA is to prevent illegitimate product entering or being further distributed into the supply chain to protect public health. FDA expects that a dispenser that has illegitimate product in its possession or control would let the other trading partners know about such illegitimate product if the dispenser has reason to believe that they might have possession or control of the same product. This analysis will be situation-specific. FDA refers the commenter to the definition of ''trading partner'' in section 581(23) of the FD&C Act and the definition of ''dispenser'' in section 581(3) of the FD&C Act.

Termination Process-Related Issues

Issue 23: One commenter stated that FDA should publish guidance on criteria to terminate a notification so that the FDA does not have to play ''gatekeeper'' for the termination of a notification.

FDA Response to Issue 23: The DSCSA (section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of FD&C Act) requires that a notification be terminated in

consultation with FDA. This guidance addresses the process by which trading partners should use Form FDA 3911 to make requests for termination, and the form will serve as a request to consult with FDA.

Issue 24: Comments were received asking for clarification about which entities could request to terminate a notification. Several commenters thought that FDA should be able to self-initiate a termination. Other commenters suggested that the request for termination could be made by any involved trading partner and not limited to the trading partner making the initial notification.

FDA Response to Issue 24: FDA believes that the trading partner making the notification should be responsible for making the request for termination because it knows if the illegitimate product in its possession or control has been satisfactorily dispositioned and if the notification is no longer necessary. The process in the guidance has been amended to clarify this point. The guidance does not specify a process for trading partners to terminate notifications submitted by other trading partners.

PRA Analysis Related Issues

Issue 25: One commenter stated that the estimates in the PRA analysis did not take into account the time it takes to investigate and make the determination that a product is illegitimate. It only included the time to fill out the form and notify trading partners.

FDA Response to Issue 25: While the commenter's assessment is correct, the PRA analysis in this guidance was calculated for the process for making and terminating notifications to FDA and notifying immediate trading partners who are believed to have the drug. This guidance assumes that the determination has already been made that the drug is illegitimate or has a high risk of illegitimacy. FDA intends to publish additional guidance that will address the investigation of suspect product to determine whether the product is illegitimate. The PRA analysis for those activities will be covered at that time.

Issue 26: One commenter stated that, based on its experience, FDA estimates for notifications are high.

FDA Response to Issue 26: FDA reexamined the estimate of notifications in response to this comment. FDA originally estimated that a total of approximately 5,000 notifications per year would be made by all manufacturers, repackagers, wholesale distributors, and dispensers based on FDA's experience with FARs (Form FDA 3331) required to be submitted by holders of approved drug applications for certain issues specified by § 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. We determined that the 5,000 FARs and 5,000 sample reporting under § 203.37 received each year included initial, followup, and final reports. While FDA does not know the exact number of notifications that will be submitted, we lowered the estimate to 1,000 notifications in response to the comment and our reexamination of the data and adjusted the PRA analysis accordingly.

Issue 27: Commenters stated that the FDA estimated number of trading partners that would likely have the illegitimate product and have to be notified was high.

FDA Response to Issue 27: FDA recognizes that not every trading partner will possess illegitimate product. However, until serialization is required and implemented, the initial notifying person or entity may not be able to identify which specific immediate trading partners may possess or control illegitimate product. FDA assumed that the initial notifying person or entity would notify all trading partners and we have chosen not to amend the number of trading partners that are notified at this time.

Issue 28: A major stakeholder association stated that it did not believe, based on past experience, that wholesale distributors would be making as many notifications as FDA estimated both to FDA and to trading partners.

FDA Response to Issue 28: In the original estimates, FDA assumed that most notifications will be made by three trading partners, manufacturers, repackagers, and wholesale distributors. FDA reexamined the proportion of notification expected from each of the regulated groups. The commenter had speculated that it believed that manufacturers would be making most notifications. In addition, manufacturers are required to submit notifications of high risk of illegitimacy. In response to the comment and the fact that only manufacturers submit notifications of high risk of illegitimacy, FDA is changing the proportion of notifications that will be made by manufacturers and repackagers from 50 percent to 80 percent (800), from 45 percent to 16 percent by wholesale distributors (160), and 5 percent to 4 percent by pharmacies (40). FDA had also originally assumed that wholesale distributors would have to notify an average of 2,350 trading partners for each notification. We agree with the commenters that this was an overestimation and have lowered the number of trading partners to be notified by wholesale distributors to 1,175 (50 percent) for each notification.

Description of Respondents: Respondents are drug manufacturers, repackagers, wholesale distributors, and dispensers and might include small businesses in these categories.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Notifications to FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	800	1	800	1	800
Wholesale Distributors	160	1	160	1	160
Dispensers	40	1	40	1	40
Total					1,000

[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 [1]

Notifications to trading partners of an illegitimate product	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	800	30	24,000	0.20 (12 minutes)	4800
Wholesale Distributors	160	1,175	188,000	0.20 (12 minutes)	37,600
Dispensers	40	2	80	0.20 (12 minutes)	16
Total	.....	.....	.....	.....	42,416

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Consultation with FDA and termination of notification	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	800	1	800	1	800
Wholesale Distributors	160	1	160	1	160
Dispensers	40	1	40	1	40
Total	.....	.....	.....	.....	1,000

[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 [1]

Notifications to trading partners of an illegitimate product termination	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	800	30	24,000	0.20 (12 minutes)	4800
Wholesale Distributors	160	1,175	188,000	0.20 (12 minutes)	37,600
Dispensers	40	2	80	0.20 (12 minutes)	16
Total	.....	.....	.....	.....	42,416

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

Dated: September 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23203 Filed 9–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 15, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 594–4306.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Childhood Home Visiting (Home Visiting) Program Fiscal Year (FY) 2015, FY2016, FY2017 Non-Competing Continuation Progress Report for Formula Grant OMB No. 0915–0355—Extension.

A 30-day notice was previously published on July 8, 2015, for this information collection request but it contained incorrect burden figures.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA) in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The purpose of this formula grant program is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices. All fifty states, the District of Columbia, and five territories and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible for formula grants and submit non-competing continuation progress reports annually. There are 56 jurisdictions eligible for formula awards and 56 formula awards are issued annually.

Need and Proposed Use of the Information: This information collection