the securities transactions conducted by or on behalf of the account were undertaken by the bank in the exercise of its trust or fiduciary responsibilities with respect to the account.

Section 741. Section 741(a)(2)(ii)(A) requires a bank relying on this exemption, which permits banks to effect transactions in the shares of a money market fund, to provide customers with a prospectus for the money market fund securities, not later than the time the customer authorizes the bank to effect the transaction in such securities, if the class or series of securities are not no-load. In situations where a bank effects transactions under the exemption as part of a program for the investment or reinvestment of deposit funds of, or collected by, another bank, the Section permits either the effecting bank or the deposit-taking bank to provide the customer a prospectus for the money market fund securities.

Legal authorization and confidentiality: The Board's Legal Division has determined that section 3(a)(4)(F) of the Exchange Act (15 U.S.C. 78c(a)(4)(F)) authorizes the Board and the SEC to require the information collection. The FR 4025 is required to obtain a benefit because banks wishing to utilize exemptions provided by the rules 701, 723, and 741 are required to comply with the recordkeeping and disclosure requirements. If an institution considers the information to be trade secrets and/or privileged, such information could be withheld from the public under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)). Additionally, to the extent that such information may be contained in an examination report, such information maybe also be withheld from the public under section (b)(8) of the Freedom of Information Act (5 U.S.C. 552 (b)(8)).

Current Actions: On April 3, 2017, the Board published a notice in the **Federal Register** (82 FR 16210) requesting public comment for 60 days on the extension, without revision, of the Recordkeeping and Disclosure Requirements Associated with Regulation R. The comment period for this notice expired on June 2, 2017. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, July 17, 2017.

Ann E. Misback

Secretary of the Board.

[FR Doc. 2017–15263 Filed 7–19–17; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0407]

Pilot Project Program Under the Drug Supply Chain Security Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intent to establish a pilot project program under the Drug Supply Chain Security Act (the DSCSA Pilot Project Program) to assist in development of the electronic, interoperable system that will identify and trace certain prescription drugs as these are distributed within the United States. Under this program, FDA will work with stakeholders to establish one or more pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Participation in the DSCSA Pilot Project Program will be voluntary and will be open to pharmaceutical distribution supply chain members. FDA will be particularly interested in participation reflecting the diversity of the supply chain, including large and small entities from all industry sectors. This notice describes the proposed DSCSA Pilot Project Program, including proposed instructions for submitting a request to participate. FDA is soliciting comments on the proposed collection of information associated with establishment of the DSCSA Pilot Project Program before submitting the proposed collection to the Office of Management and Budget (OMB) for approval. FDA does not intend to begin the proposed DSCSA Pilot Project Program or accept requests to participate in the program until OMB has approved the proposed collection of information.

DATES: Submit written or electronic comments on this pilot project program by *September 18, 2017.*

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before *September 18, 2017.* The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of *September 18, 2017.* Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–0407 for ''Pilot Project Program under the Drug Supply Chain Security Act; Request for Comments.'' 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.

FOR FURTHER INFORMATION CONTACT: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 50, Rm. 4285, Silver Spring, MD 20993–0002, 301–796–3130, *DSCSAPilotProjects@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added the new sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360eee and 360eee–1, respectively). Under section 582(j) of the FD&C Act, FDA is required to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

FDA will be establishing the DSCSA Pilot Project Program to implement section 582(j) of the FD&C Act. This program will assist the development of the interoperable electronic system to be established by 2023. The new system has the potential to reduce diversion of drugs distributed domestically as well as help reduce the influx of counterfeit drugs from foreign sources. The program will be designed to explore issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, identifying the system attributes that are necessary to implement the requirements established under the DSCSA, and any other issues identified by FDA (see section 582(j)(2)(B) of the FD&C Act). Particular program goals include assessing the ability of supply chain members to: Satisfy the requirements of section 582 of the FD&C Act; identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and 581(8) of the FD&C Act, respectively; and demonstrate the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain, in addition to identifying the system attributes needed to implement the requirements of section 582, particularly the requirement to utilize a product identifier for product tracing and verification purposes. FDA plans to coordinate with stakeholders who reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors. The pilot project is designed to allow industry to identify and evaluate the most efficient systems for their unique operational systems.

II. The Proposed DSCSA Pilot Project Program

FDA will be seeking pilot project participants from the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders. FDA expects that participants will propose the design and execution of their pilot project in their submission to FDA; however, FDA intends to meet with all pilot project participants to ensure that the learnings from the pilot project(s) will be complementary in informing the direction of the development of the electronic, interoperable system that will go into effect in 2023. FDA encourages supply chain members to focus their proposed pilot project(s) on the DSCSA requirements related to the interoperable, electronic tracing of products at the *package level.* Specifically, the pilot project(s) should focus on the requirements for package-level tracing and verification that go into effect in 2023. Such pilot projects will be more useful than pilot projects dedicated to lot-level tracing. If there are adequate pilot project submissions, FDA may establish more than one pilot project to accomplish the goals of the DSCSA Pilot Project Program.

A. Products Eligible for Proposed Pilot Projects

Proposed pilot projects may include any prescription drug that is a ''product'' within the meaning of section 581(13) of the FD&C Act. At its discretion, FDA may also consider proposed pilot projects involving product types outside the scope of section 581(13) of the FD&C Act (*e.g.,* over-the-counter medicines) that could further the objectives of the DSCSA Pilot Project Program. Each package and homogenous case of product that is part of a pilot project should bear a ''product identifier'' as described in sections 581(14) and 582(a)(9) of the FD&C Act.

B. Potential Issues To Examine and Evaluation Methods To Use in Proposed Pilot Projects

On April 5 and 6, 2016, FDA held a public workshop entitled ''Proposed Pilot Project(s) under the Drug Supply Chain Security Act (DSCSA).'' This public workshop provided a forum for members of the pharmaceutical distribution supply chain to discuss the design objectives of pilot projects established by FDA under section 582(j) of the FD&C Act. Based on the information gathered at that workshop and from the comments submitted to the public docket for the workshop (Docket No. FDA–2016–N–0407), FDA has identified several potential issues to examine, and evaluation methods to use, in pilot projects established under the DSCSA Pilot Project Program. These potential issues and evaluation methods are summarized in table 1. This table is intended only to assist in the design of potential pilot projects; it does not represent FDA's views or policies regarding the issues described in the table. For ease of reference, the potential issues to examine and evaluation methods have been grouped by focus areas for the pilot projects.

TABLE 1—POTENTIAL ISSUES TO EXAMINE AND EVALUATION METHODS TO USE IN PROPOSED PILOT PROJECTS

Pilot project focus area	Potential issues to examine	Potential evaluation methods
Product Identifier	• Processes related to the requirement for manufacturers to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce. • Methods used to issue and manage serial numbers (*e.g.*, including a contract manufacturer's role if applicable or how a repackager associates its product identifier with the product identifier assigned by the original manufacturer). • Different representations for the product identifier (*e.g.*, different formats of NDC or serial number).	• Impacts of different representations of the product identifier on systems or processes. —Number of errors. —Time to process. —Time to reconcile these differences.
Barcode Quality	• Readability of barcode printed or affixed including impact of environmental and human factors. • Application of linear and 2D barcodes on product • Distinguishing which barcode to read/use and when.	• Barcode read error rates. —Number of items unnecessarily quarantined or held up. —Time and resource impacts.
Interoperability	• Process and technical challenges due to variety of solutions expected (*e.g.*, type of database used and system architecture for exchanging information among trading partners). • Maintaining the integrity of information contained in the barcode of serialized product throughout the distribution supply chain (e.g., a trading partner goes out of business or one acquires another business). • Different methods for exchanging information (*e.g.*, the use of Electronic Data Interchange, Electronic Product Code Information Services, and other solutions separately).	• For both decentralized and centralized models, time implications. —To investigate suspect and illegitimate products. —For notifications required within the statutory timelines. —Related to scaling up from pilot to full production. • Product tracing information (across multiple partners). —Capability to retrieve the information. —Accuracy of the information (within and between systems). • Security and access. —Evaluate and document access levels for trading partners.
Data/Database/System Issues.	• Data quality from beginning to end of the product lifecycle and vice versa. • System performance when full or partially loaded with data. • Data format or processes for data transfer —Use of technical standards for defining data attributes to enable interoperable transfers. —Methods to handle the ''master data'' (product-specific data) and transaction data separately to minimize ''master data'' redundancy. • Integration into individual/company data systems • Control and access to data by trading partners, FDA or other Federal or State officials (data governance). • Ability of the system to record product status (*e.g.*, to indicate expired, illegitimate, in error, quarantined) at all packaging levels.	• System Performance and Effectiveness. —Time to access and use product tracing information, once that data is received into a system. —Quality of product tracing information. —Number of breaches to system. —Number of attempts to breach the system that were prevented or minimized. • Data and product flow. —Number of unsuccessful attempts to access data and operational impacts. —Number of system interactions within one, and amongst multiple, trading partners. —Time and resource changes on operations when data and product not moving at same time (e.g., product arrives before data arrives). —Time for location/ownership/status changes to be reflected in the system. —Time of product flow delays and associated costs due to system or data problems.
Aggregation/Disaggregation	• Multiple levels of adoption of inference, by different trading partners.. —Impact of inference gaps, changes or errors in data, particularly downstream when searching or examining the data; how can errors be corrected.	• Number of system and product interactions within one, and amongst multiple, trading partners. • Time required to conduct aggregate/disaggregate operations and transactions. • Accuracy of aggregation data (measure error counts). • Time to gather aggregation/disaggregation data for investigations and notifications. • Time to resolve errors in data.
Verification/Notification	• Process for investigation of suspect or illegitimate product, including any communication or coordination. —Making and responding to verification requests —Making, responding, and terminating notifications —Responding to requests for information —Testing boundaries of the system	• Response times: Current vs. future process. • Time needed to obtain product tracing information to respond to a request for verification. • Time needed to make, respond to, or terminate a notification. • Time to gather product tracing information to support an investigation for a suspect or illegitimate product, or a recall.

TABLE 1—POTENTIAL ISSUES TO EXAMINE AND EVALUATION METHODS TO USE IN PROPOSED PILOT PROJECTS—Continued

Pilot project focus area	Potential issues to examine	Potential evaluation methods
Exception Handling/Errors/ Inconsistencies.	• Identify 'honest errors' (*e.g.*, over/under shipments, clerical errors or aggregation errors). • Correcting 'honest errors'	• Percentage of items that are successfully verified vs. those that were targeted for verification. • Number of connections/queries needed to gather product tracing information in response to a verification or notification request. • Percent errors detected: compare exceptions introduced vs. exceptions detected. —Identify the first step in the process where error detected. • Number of new or changed processes needed to accomplish DSCSA goals. —Time and resource impacts. • 'Honest Errors'. —Number of items unnecessarily quarantined and held up. —Time required to detect and correct errors. —Impact on trading partners to correct errors. • Barcode read error rates. —Number of items unnecessarily quarantined or held-up. —Time and resource impacts.
Special Scenarios	• Situations when data and product do not move together. • Situations when serialized product are sold and distributed along with non-serialized product.	• Error rates for special processes. —Number of items unnecessarily quarantined or held-up. —Time and resource impacts. • Accuracy of linkage between original manufacturer product identifier and repackager-issued product identifier.

FDA also received input from the workshop participants and in the comments submitted to the public docket on factors that the Agency should take into consideration when establishing pilot projects. These factors described in the comments include the extent to which the pilot projects:

- Represent the mix of products and levels of packaging in the supply chain.
- Include a diverse set of supply chain stakeholders (types and sizes) and transaction types.
- Use adaptive design to make the pilot projects more efficient.
- Target known weaknesses in the supply chain.
- Can be completed in time to provide useful information for trading partners.
- Evaluate human factors that could present implementation challenges.
- Simulate illegitimate products/transactions to test a process or system.
- Document costs to implement, use, and maintain piloted solutions.

Although the Agency intends to take these factors into consideration when establishing pilot projects, FDA also recognizes that a single pilot project is unlikely to satisfy every factor. Accordingly, FDA may establish a pilot project based on a request to participate in the program that does not satisfy one or more of the factors listed in this document.

C. Proposed Instructions for Submitting a Request To Participate in the Proposed DSCSA Pilot Project Program

Once the DSCSA Pilot Project Program is established, volunteers interested in participating in the DSCSA Pilot Project Program will be able to submit a request to participate by email to a designated FDA email address for the program. For a group of entities that partner to participate in a pilot project, only one submission and one point-of-contact for the proposed pilot project should be provided in the request to participate. Requests to participate may also consider other ideas for a pilot project that are not included in this notice.

D. Proposed Content of the Submission for a Request To Participate in the Proposed DSCSA Pilot Project Program

The following information should be included in the request:

- Contact information for the submitter or point of contact, if different from the submitter (name, mailing address, phone number, email address).
- Names of all partnering entities that would participate in such pilot project (name of company and name of company representative).
- Type(s) of each partnering entity participating in the pilot project (partnering entities include authorized trading partners or other supply chain stakeholders).
- Number of employees for each partnering entity that would participate in such pilot project.
- Proposed start and finish dates of the pilot project.
- Commitment to start the pilot project within 4 months of receiving a letter of acceptance from FDA.
- Product(s) that will be used in the pilot project.
- Location(s) where pilot project will be performed (facility address).
- Description of the proposed pilot project, including, but not limited to, the goals, objectives, processes that will be studied, and evaluation methods.

E. Initiation and Duration of Proposed Pilot Projects

The selected participants should be ready to start their pilot project within 4 months of receiving a letter of acceptance from FDA into the program. The duration of a pilot project should not exceed 6 months. FDA may consider a pilot project with a later start date or longer duration depending on the proposed goal(s) and objective(s). Each pilot project is expected to be completed within the proposed duration time period. This time period does not include an additional 30-days for completion of a final report (see section G. Proposed Reports).

F. Participation in Proposed Pilot Projects

Prior to launching a pilot project, FDA will hold a design strategy meeting with the selected pilot participant(s) to review the goal(s) and objective(s) for the pilot project and discuss the plans and other pertinent details. The participant(s) will be responsible for conducting their pilot project. A group of entities (members of the pharmaceutical distribution supply chain and other stakeholders, including trade associations) that partner to conduct a pilot project may be considered a single participant for purposes of the DSCSA Pilot Project Program. The partners in any pilot project that is selected into the program will be responsible for the funding and resources necessary to conduct the pilot project, and for determining each partner's role and responsibility in their pilot project. Pilot project participants will also be expected to submit reports on the progress of their pilot projects to FDA (see section G. Proposed Reports). Participants should evaluate their pilot project using the evaluation methods they identified during the pilot project design process.

G. Proposed Reports

Each pilot project is expected to be completed within the proposed duration time period, and participants will be expected to report progress to FDA while the pilot project is being conducted, in addition to a final report within 30 days of completing the pilot project. These reports will provide insight into the systems and process needed to comply with certain DSCSA requirements for enhance drug distribution security.

1. Progress Report(s)

Each pilot project program participant is expected to provide reports on the progress of their pilot project to FDA. The progress reports are intended to capture the ongoing work during the pilot project, including but not limited to, current status or results, changes, challenges, and/or lessons learned. FDA will work with participants to develop an appropriate schedule for the submission of progress reports based on the design and duration of the pilot project. Because the duration of a pilot project should not exceed 6 months, the frequency of progress reports will vary based on the length of the individual pilot project. Pilot projects of relatively shorter duration may result in shorter time intervals between progress reports. For example, FDA may ask for monthly progress reports for a 6-month pilot project, however for a one-month pilot project, FDA may ask for weekly progress reports.

2. Final Report

Within 30 business days of completing a pilot project, each participant is expected to provide a final report to FDA that captures the description, objectives, methods, evaluation, costs and key findings and lessons learned from the project. Timely completion of pilot project and the final report will support FDA's DSCSA implementation, including the statutory requirements under section 582(j) to consider information from pilot projects in the development of guidances for unit-level tracing and standards for the interoperable data exchange in section 582(h)(3) and (4) of the FD&C Act. FDA may also request that the participants meet with the Agency upon the completion of their pilot project or the final report.

H. Proposed Final DSCSA Pilot Project Program Report

To ensure that all supply chain members benefit from the information generated by the DSCSA Pilot Project Program, FDA intends to make the following information about each of the program's pilot projects available to the public in a final program report: (1) The names and industry sector(s) of the pilot project participant(s); (2) the pilot project's objectives and evaluation methods; (3) the duration of the pilot project; and (4) the key findings and lessons learned from the pilot project. The information related to the DSCSA Pilot Project Program and the final program report will be posted on FDA's Web site.

I. Proposed Recordkeeping

Any records generated by a participant for conducting a pilot project should be maintained as an entity would as in a normal course of business. For participants that involve partnering entities, the partnering entities can decide who is responsible for the records generated by conducting a pilot project. FDA recommends that the progress reports and the final report that participants create and submit to FDA for a pilot project should be maintained for at least 1 year after completion of the pilot project.

J. Initiation of FDA's DSCSA Pilot Project Program

FDA does not intend to begin the proposed DSCSA Pilot Project Program or accept requests to participate in the program until OMB has approved the proposed collection of information described in this notice.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the **Federal Register** to solicit comment for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

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

The estimated burden for the information collection associated with the DSCSA Pilot Project Program consists of the following:

Submitting a request to participate and reporting activities. FDA estimates that no more than 10 respondents (*i.e.,* the submitter or point of contact identified on the request to participate) will submit a request to participate, and that it will take approximately 80 hours to complete a request and submit the request to FDA. FDA estimates that certain respondents will coordinate with partnering entities to submit a request to participate; the burden estimate associated with that coordination follows. FDA estimates that it will select no more than eight participants for the pilot program. The estimated total time for respondents to submit a request to participate in the program is 800 hours. Once the request

to participate is accepted, the submitter is now a participant of the DSCSA Pilot Project Program. FDA estimates that the eight respondents (*i.e.,* participants) will submit an average of five progress reports to FDA. Because the duration of a pilot project should not exceed 6 months, the frequency of progress reports will vary based on the length of the individual pilot project. Pilot projects of relatively shorter duration may result in shorter time intervals between progress reports so that the reports will be sufficient to capture progress while the pilot project is ongoing. FDA estimates that it will take approximately 8 hours to compile and submit each progress report. The estimated total number of hours for submitting progress reports would be 320 hours. After completion of their pilot project, each respondent will provide one final report to FDA. FDA estimates that it will take the eight respondents approximately 40 hours to submit a final report. The estimated total number of hours for submitting the final report is 320 hours. The total hours for the estimated reporting burden are 1,440 hours (table 2).

Recordkeeping activities. Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the program and compiling reports. Respondents can use current record retention capabilities for electronic or paper storage to achieve these activities. FDA estimates that no more than 10 respondents will have recordkeeping activities related to program participation. FDA believes that it will take 0.5 hour/year to ensure that the documents related to submitting a request to participate in the program are retained properly for a minimum of 1 year after the pilot project is completed (as recommended by FDA). The resulting total to maintain the records related to submitting a request is 5 hours annually. For retaining records related to progress reports and the final report properly for a minimum of 1 year after the pilot project is completed (as recommended by FDA), FDA estimates that it will take approximately 0.5 hour/year. As noted previously, FDA estimates that the eight respondents will submit an average of five progress reports and one final report to FDA. The estimated total for maintaining progress reports and the final report is 20 and 4 hours, respectively. The total recordkeeping burden is estimated to be 29 hours (table 3).

In developing its burden estimate for records associated with the proposed pilot projects, FDA has taken account of existing industry practices for keeping records in the normal course of their business. In particular, FDA is aware of various supply chain stakeholders that have conducted pilot projects over the past few years, including some pilot projects that occurred before the DSCSA was enacted. These pilot projects covered topics related to serialization, movement of product data, aggregation of data, and verification of product identifiers of returned products. Members of the supply chain who conduct pilot projects of their own accord created associated records as a matter of usual and customary business practice. Therefore, the burden estimates for like records associated with the proposed FDA pilot project program are not included in the calculation of the recordkeeping burden (see 5 CFR 1320.3(b)(2)). FDA welcomes comments on the activities identified for conducting a pilot project that FDA considers to be usual and customary business practice.

Third-party disclosure activities. For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. For the initial request to participate, FDA estimates that eight respondents will work with their respective partnering entities, and the average number of partnering entities will be two. FDA estimates that each respondent will spend 8 hours coordinating with each partnering entity. Thus, for eight respondents with an average of two partnering entities, the estimated total burden for coordinating with partnering entities related to the submission of the request to participate in the program is 128 hours. FDA estimates that seven respondents will need to coordinate with an average of two partnering entities to create progress reports and the final report to submit to FDA. Earlier, FDA estimated that an average of five progress reports will be submitted to FDA per respondent. If a respondent has an average of 2 partners, it will coordinate 10 times with those partners on the progress reports. FDA estimates that for each progress report, it will take 4 hours to coordinate with each partner, resulting in a total of 280 hours. FDA estimates that for each final report, it will take approximately 20 hours to coordinate with each partner, resulting in a total of 280 hours. The total estimation for third-party disclosure burden is 688 hours (table 4).

TABLE 2—ESTIMATED REPORTING BURDEN [1]

DSCSA pilot project program	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Requests to participate	10	1	10	80	800
Progress reports	8	5	40	8	320
Final report to FDA	8	1	8	40	320
Total					1,440

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

TABLE 3—RECORDKEEPING BURDEN [1]

DSCSA Pilot project program	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per record	Total hours
Records related to requests to participate	10	1	10	0.5 (30 minutes)	5
Records related to progress reports	8	5	40	0.5 (30 minutes)	20
Records related to the final report to FDA	8	1	8	0.5 (30 minutes)	4

TABLE 3—RECORDKEEPING BURDEN [1]—Continued

DSCSA Pilot project program	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per record	Total hours
Total					29

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

TABLE 4—THIRD-PARTY DISCLOSURE BURDEN [1]

DSCSA pilot project program	Number of respondents	Number of disclosures per respondent	Total disclosures	Hours per disclosure	Total hours
Coordination with partnering entities related to requests to participate	8	2	16	8	128
Coordination with partnering entities related to progress reports	7	10	70	4	280
Coordination with partnering entities related to final reports	7	2	14	20	280
Total					688

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

Dated: July 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15203 Filed 7–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3068]

Patient-Focused Drug Development for Hereditary Angioedema; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting and an opportunity for public comment on ''Patient-Focused Drug Development for Hereditary Angioedema.'' Patient-Focused Drug Development is part of FDA's performance commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of hereditary angioedema (HAE) on daily life. FDA also is seeking patients' views on treatment approaches for HAE.

DATES: The public meeting will be held on September 25, 2017, from 9 a.m. to 3 p.m. Registration to attend must be received by August 10, 2017. Submit either electronic or written comments on the public meeting by November 20, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Since 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–N–3068 for ''Patient-Focused Drug