DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3675]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collections applicable to the Pharmaceutical Distribution Supply Chain, provided for in Subchapter H of Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on the collection of information must be submitted by November 5, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 5, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–3675 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security.'' Received comments, those filed in a timely manner (*see* **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance

the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security

OMB Control Number 0910–0806—Revision

This information collection helps support implementation of sections 581 and 582 (21 U.S.C. 360eee and U.S.C. 360eee–1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which govern the pharmaceutical distribution supply chain. Definitions set forth in section 581 of the FD&C Act prescribe specific activities that apply to the individuals identified in section 582, including recordkeeping requirements intended to effectuate the tracing of certain pharmaceutical drugs as they are distributed within the United States. The recordkeeping provisions expressly provided for in sections 582(b) through (e) of the FD&C Act cover tasks associated with product identification, product tracing, transaction data, record verification, and disclosures (exchange) of information. Submissions to FDA, as provided for in section 582, include making specific product notifications, requesting exemption and/or waiver from any of the statutory requirements, and requesting termination of a notification in consultation with FDA.

The requirements of section 582 of the FD&C Act included in the information collection are self-executing. We regard most of the information collection activities required by the statute to be usual and customary recordkeeping activities by respondents and have therefore excluded from our estimated burden the time, effort, and financial resources attributable to those activities consistent with 5 CFR 1320.3(b)(2). Additionally, we note that some respondents are also subject to related reporting, recordkeeping, and disclosure requirements applicable under the Controlled Substances Act, for which currently active information collection approvals are maintained by the Department of Justice's Drug Enforcement Administration. At the same time, we account for notifications submitted to FDA, and estimate recordkeeping burden attributable to activities corresponding with illegitimate product notifications, including coordination of investigations of suspect products, among trading partners, as required by the statute.

To assist respondents with submitting specific product notifications to FDA regarding illegitimate product and product with a high-risk of illegitimacy, we have developed and utilize Form FDA 3911 entitled ''Drug Notification'' and the corresponding instructional document ''INSTRUCTIONS FOR COMPLETION OF FORM FDA 3911—DRUG NOTIFICATION.'' Instruction regarding the submission of Form FDA 3911 using the Center for Drug Evaluation and Research ''NextGen'' portal is available from our website at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products.* Form FDA 3911 is intended to provide a uniform format for initial notifications, followup notifications, and requests for the termination of a notification. We believe followup activities regarding suspect and/or illegitimate drug products includes information obtained during the conduct of an official Agency investigation and thus not covered by the PRA. Please see 5 CFR 1320.4(a)(2) and FDA ''General Enforcement Regulations'' in 21 CFR part 1. We have revised Form FDA 3911, and the instructions for completing the form, to add a new field requesting information about the geographic location of the incident that is the subject of the notification.

We have also published guidance documents, as provided for in section 582 of the FD&C Act, developed specifically to facilitate the efficient adoption of secure interoperable product tracing at the package level by respondents. The guidance documents discuss the recordkeeping activities expressly provided for in section 582 of the FD&C Act. To date we have developed and issued the following guidance documents:

- ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs'' guidance (2023 Standards for Interoperable Exchange Guidance) (September 6, 2023).
- ''Standardization of Data and Documentation Practices for Product Tracing'' draft guidance (Standardization of Data Guidance) (February 28, 2018).
- ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act'' guidance (Enhanced Drug Distribution Security Guidance) (August 31, 2023).
- ''Verification Systems Under the Drug Supply Chain Security [DSCSA] Act for Certain Prescription Drugs'' guidance (Verification Guidance) (December 7, 2023).
- ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' guidance (Definitions Guidance) (March 16, 2023).
- ''Product Identifiers Under the Drug Supply Chain Security Act—Questions and Answers'' guidance (Product Identifier Guidance) (June 3, 2021).
- ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' guidance (Suspect Product Guidance) (June 6, 2021).
- ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act'' guidance (Waivers Guidance) (August 4, 2023).

All Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* that utilizes topic specific search terms.

We also maintain a web page at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/fdas-implementation-drug-supply-chain-security-act-dscsa-requirements* that communicates FDA's ongoing implementation of the DSCSA requirements. Since DSCSA enactment on November 27, 2013, FDA has established a public docket to receive information and comments on DSCSA standards for the electronic tracking system, including comments regarding paper and electronic formats of information. In 2018, we initiated a pilot project, consistent with section 582(j) of the FD&C Act and approved in OMB control number 0910–0859, focusing on system attributes and demonstrating interoperability. Since completion of the pilot project, we continue to focus on the interoperability of the electronic systems described in section 582 of the FD&C Act and have revised this information collection to capture standardized transaction information.

Respondents to the information collection are manufacturers, wholesale distributors, dispensers, and repackagers of pharmaceutical drug products, as defined in section 581 of the FD&C Act and identified in section 582(a)(1) of the FD&C Act. Based on Agency data, we assume 70,000 respondents: 1,230 manufacturers and 170 repackagers, (1,400 cumulatively); 1,600 distributors; and 67,000

dispensers (including online and chain pharmacies).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 U.S.C. 360eee–1(b)–(e); information collection	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Notifications of illegitimate product: Form FDA 3911	500	28.2	14,100	8	112,800
Consultation/Requests for termination of notification of illegitimate product (Suspect Product Guidance, sec. IV.B)	500	1	500	1	500
Requests for waiver, exception or exemption, including material changes and renewals (Waivers Guidance, sec. III)	20	1	20	81	1,620
Total			14,620		114,920

As reflected in table 1, reporting activities include the submission of notifications to FDA regarding illegitimate product and product with a high-risk of illegitimacy using Form FDA 3911. We believe the burden that may be incurred from providing FDA with followup information that may be necessary with regard to suspect and/or illegitimate products is excluded from our accounting in accordance with 5 CFR 1320.3(c) because such followup would entail reporting activities that are usual and customary, and we have therefore not included this activity in our estimate of burden. Reporting activities also include requests for termination of a notification in consultation with FDA, using Form FDA 3911. FDA may request any additional information it determines necessary to complete the consultation. Finally, an authorized trading partner or other stakeholder seeking a waiver, exception, or exemption from requirements of section 582 of the FD&C Act may submit a request to FDA, or a request for material changes to or renewal of an approved initial request. These requests are also included in the scope of reporting activities.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 U.S.C. 360eee–1(b)–(e); information collection activity	Number of respondents	Number of records per respondent	Total annual records	Average burden per record (in hours)	Total hours
Documenting transaction (T3) information	70,000	1M	70,000,000,000	0.0000017	119,000
Disclosing illegitimate product notifications and terminations to trading partners	500	620	310,000	6	1,860,000
Product identification & information exchange: encoding packages and homogeneous cases with product identifier; exchange of information only w/authorized trading partners.	1,400	3,125,000	4,300,000,000	0.00007	301,000
Verification: identify and investigate suspect product, coordinate with other trading partners, quarantine product, notify FDA of suspect product that is not determined to be illegitimate product	30,125	8	241,000	0.62	149,420
Total			74,300,551,000 (~74.3B)		2,429,420

[1] The recordkeeping requirement includes the requirement to retain, notify third parties, the Federal government, or the public of the existence of such records; disclose such records to third parties, the Federal government, or the public; or report to third parties, the Federal government, or the public regarding such records. See 44 U.S.C. 3502(13); 5 CFR 1320.3(m).

[2] We regard activities established in section 582(b)–(e) of the FD&C Act (21 U.S.C. 360eee–1(b)–(e)) to be usual and customary for respondents to the information collection.

As reflected in table 2, the provisions in sections 582(b) through (e) require ongoing recordkeeping that documents product identification, tracing information, and verification activities. Records are to be produced to FDA within 24 hours of a request, consistent with section 582 of the FD&C Act. Each category of respondent (manufacturer, distributer, wholesaler, repackager) may expend varying degrees of time, effort, or financial resources to generate, maintain, retain, notify, or disclose such records commensurate with the corresponding tasks prescribed for that category. Data elements required to be documented and disclosed are defined in section 581 and set forth in section 582 of the FD&C Act. A significant portion of recordkeeping activity pertains to product identification and product tracing. Verification activities comprise another significant portion of activity, where respondents expend time, effort, or financial resources respective to their role. Although we have quantified what we believe to be the average amount of time, effort, or financial resources expended cumulatively by respondents, we regard these recordkeeping activities as usual and customary and exclude them from our burden estimate, consistent with 5 CFR 1320.3(b)(2).

Product Tracing and Product Identification

Information exchange activities with authorized trading partners as contemplated by section 582 of the

FD&C Act include: (1) providing the transaction information, the transaction history (when applicable), and transaction statement (T3) to the subsequent purchaser, providing relevant transaction information, transaction history, and transaction statement upon a request for information from FDA or other appropriate Federal or State officials if a recall or investigation of suspect or illegitimate product occurs, and, after the Statutory Date, facilitating the gathering of information necessary to produce the transaction information for each transaction [1] going back to the manufacturer at an authorized trading partner's request, or at the request of FDA or other appropriate Federal or State officials; and (2) capturing and maintaining transaction information, transaction history, and transaction statements for each transaction for not less than 6 years after the transaction. Product identification activities include the requirement that manufacturers and repackagers affix or imprint a product identifier to each package and homogeneous case of products that they intend to be introduced in a transaction into commerce and that they maintain product identifier information for each package and homogeneous case of product for not less than 6 years.

Verification Activities

Verification activities include: (1) coordinating with other trading partners during an investigation of a suspect product to determine whether the product is illegitimate; (2) for manufacturers and repackagers, responding to trading partners' requests for verification of product identifiers; (3) maintaining records of suspect product investigations and disposition of illegitimate product for not less than 6 years; (4) identifying suspect product; (5) quarantining suspect and illegitimate product; (6) investigating suspect product; (7) notifying FDA of suspect product that is determined not to be illegitimate product (when applicable); (8) processing saleable returns; and (9) establishing systems and processes to comply with all of these requirements.

We assume manufacturers, repackagers and wholesale distributors will already have systems and processes to comply with many of these requirements. Such systems will therefore only need to be updated to ensure full compliance with the DSCSA. We also anticipate that a chain pharmacy will develop the required systems and processes centrally at its headquarters or at its distribution centers and then distribute to each pharmacy.

Our estimated burden for the information collection as revised reflects a significant decrease in the burden estimates for annual responses and hours. We have excluded from our estimated burden the time, effort, and financial resources attributable to those activities we consider usual and customary by respondents, consistent with 5 CFR 1320.3(b)(2). We invite comment on our assumption.

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20064 Filed 9–5–24; 8:45 am]

BILLING CODE 4164–01–P

[1] Transaction is defined in section 581(24) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1150]

Determination of Regulatory Review Period for Purposes of Patent Extension; STEGLATRO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for STEGLATRO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by November 5, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 5, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 5, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2019–E–1150 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; STEGLATRO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.