expiry dating extensions under section 564A of the FDC&C Act. We attribute greater burden to those requests for FDA to review pre-EUA packages submitted by product sponsors than burden we attribute to those submitted by Federal agencies (*e.g.,* Centers for Disease Control and Prevention, the Department of Defense), and have considered other factors that contribute to variability in burden for reporting, including the type of product and whether there is a previously reviewed pre-EUA package or investigational application.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Records associated with conditions of authorization	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
EUA Holders	648	2	1,296	25	32,400
State and local Public Health Authorities	1	1	1	3	3
Total			1,297		32,403

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

We provide a conservative estimate for respondent recordkeeping, recognizing that the Federal Government performs much of this activity in conjunction with submissions. We do not include burden for public health authorities who may need to submit emergency dispensing orders or expiration date extension requests, assuming covered entities already maintain these records for the products they stockpile.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Dissemination of required information by EUA Holder or Authorized Stakeholder	635	2	1270	5	6350

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

Our third-party disclosure estimate is based on the number of EUA holders and authorized stakeholders disseminating information, including fact sheets, advertising, and promotional materials.

We have increased our burden estimate for the information collection to reflect the increase in submissions we have received over the last 3 years.

Dated: June 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14347 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1956]

Identifying Trading Partners Under the Drug Supply Chain Security Act; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). The revised draft guidance explains how to determine when certain statutory requirements will apply to entities that are considered trading partners in the drug supply chain. It also discusses the activities of private-label distributors, salvagers, and returns processors and reverse logistics providers. Additionally, the revised draft guidance discusses the distribution of drugs for emergency medical reasons, office use, non-human research purposes, and research purposes in humans under an investigational new drug application. This guidance revises the August 2017 draft guidance entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act.''

DATES: Submit either electronic or written comments on the draft guidance by September 6, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2017–D–1956 for ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' 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, 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.

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *Aaron.Weisbuch@fda.hhs.gov* or *drugtrackandtrace@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' The DSCSA (Title II of Pub. L. 113–54) establishes new requirements to develop and enhance drug distribution security by 2023. It does this, in part, by defining different types of entities in the drug supply chain as *trading partners* (manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers). Among other things, the DSCSA requires that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers meet the applicable requirements for being ''authorized trading partners.''

In addition, the DSCSA outlines requirements for specific trading partners, including drug product tracing, verification, and licensure requirements (where applicable). This revised draft guidance describes the activities and requirements for entities that are considered to be a manufacturer, repackager, wholesale drug distributor, third-party logistics provider, and/or dispenser and therefore considered a trading partner under the DSCSA. This guidance revises the draft guidance entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act'' that was published on August 24, 2017 (82 FR 40159).

In response to public comments received and policy considerations, FDA has added or revised its current thinking on the status of some entities as trading partners, including private-label distributors, salvagers, and returns processors and reverse logistics providers. The Agency has also provided clarification on certain drug distribution scenarios, including distribution for emergency medical use, office use, non-human research purposes, and research in humans under an investigational new drug application. FDA also addresses the interpretation of section 582(a)(7) of the Federal Food, Drug, and Cosmetic Act, which discusses third-party logistics providers licensure status prior to the effective date of the forthcoming regulations establishing licensure standards.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this revised draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-*

information-biologics/biologics-guidances, or https://www.regulations.gov.

Dated: June 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14345 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0559; FDA–2018–N–4206; FDA–2017–D–5225; FDA–2018–N–3758; FDA–2018–D–4533]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
PHS Guideline on Infectious Disease Issues in Xenotransplantation	0910–0456	6/30/2025
MDUFMA Small Business Qualification Certification	0910–0508	6/30/2025
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	0910–0752	6/30/2025
Expanded Access to Investigational Drugs for Treatment Use	0910–0814	6/30/2025
Compounding Animal Drugs from Bulk Drug Substances	0910–0904	6/30/2025

Dated: June 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14348 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–E–0450]

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

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MARGENZA 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 6, 2022. 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 January 3, 2023. 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. Electronic comments must be submitted on or before September 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2022. 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'').