product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product MONJUVI (tafasitamab-cxix). MONJUVI is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received patent term restoration applications for MONJUVI (U.S. Patent Nos. 8,524,867; 9,803,020) from Xenocor, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of MONJUVI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MONJUVI is 3,806 days. Of this time, 3,590 days occurred during the testing phase of the regulatory review period, while 216 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 3, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 3, 2010.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 30, 2019. FDA has verified the applicant's claim that the biologics license application (BLA) for MONJUVI (BLA 761163) was initially submitted on December 30, 2019.

3. *The date the application was approved:* July 31, 2020. FDA has verified the applicant's claim that BLA 761163 was approved on July 31, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 610 days or 1,370 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14357 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–2022–N–0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Use Authorization of Medical Products

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 5, 2022.

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 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Emergency Use Authorization of Medical Products

OMB Control Number 0910–0595—Extension

This information collection helps support implementation of Agency policies applicable to the authorization for medical products for use in emergencies under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b). For more information regarding emergency use authorization (EUA), visit our website at *https://www.fda.gov/*

emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. The FD&C Act permits the Commissioner of Food and Drugs (the Commissioner) to authorize the use of unapproved medical products, or unapproved uses of approved medical products, during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)).

Also under section 564 of the FD&C Act, the Commissioner may establish conditions on issuing an authorization that may be necessary or appropriate to protect the public health. These conditions can include: (1) requirements to disseminate or disclose information to healthcare providers or authorized dispensers and product recipients; (2) adverse event monitoring and reporting; (3) data collection and analysis; (4) specific recordkeeping and records access; (5) restrictions on product advertising, distribution, and administration; and (6) limitations on good manufacturing practice requirements. As governed by statute, some conditions are mandatory to the extent practicable for authorizations of unapproved products, and discretionary for authorizations of unapproved uses of approved products. Some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out an activity for which the authorization is issued. Sections 564A and 564B of the FD&C Act establish streamlined mechanisms intended to facilitate preparedness and response activities involving certain FDA approved products without requiring FDA to issue an EUA, and set forth emergency dispensing order and expiration date extension authority.

The guidance document entitled, ''Emergency Use Authorization of Medical Products and Related Authorities'' (January 2017), available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities,* discusses FDA issuance of Emergency Use Authorizations (EUAs) under section 564 of the FD&C Act; implementation of the emergency use authorities set forth in section 564A of the FD&C Act; reliance on the governmental pre-positioning authority set forth in section 564B of the FD&C Act; and related FDA regulations. As discussed in the guidance document, the specific type and amount of data needed to support an EUA will vary depending on the nature of the declared emergency and the nature of the candidate product. The guidance document encourages early engagement with FDA, explains mechanisms for communication, and makes content and format recommendations on submitting information to the Agency. The guidance document also recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

In the **Federal Register** of March 3, 2022 (87 FR 12175), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. One comment communicated that the information collection has proven useful in expediting the availability of vaccines during the pandemic, and also suggested potential modifications. The second comment was not responsive to the information collection topics solicited in our 60-day notice. Neither comment offered alternative burden estimates.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for a substantive amendment to an existing EUA	2724	2	5448	45	245,160
Pre-EUA submissions or amendments	2001	1	2001	34	68,034
Submitting information required under conditions of authorization	36	3	108	8	864
State and local public health authority submissions required under conditions of authorization for unapproved EUA product	1	1	1	2	2
State and local public health authority requests for Emergency Dispensing Order	1	1	1	2	2
State and local public health authority requests for expiration date extension	1	1	1	20	20
Total			7560		314,082

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

Although we have averaged burden across all respondents, we categorize reporting activity by the type of EUA-related submission: (1) those who file a request for FDA to issue an EUA and/or a substantive amendment to an EUA that has previously been issued; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) those who must report on activities related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must report to FDA regarding such activity; (4) public health authorities (*e.g.,* State, local) who must report on certain activities (*e.g.,* administering product, disseminating information) related to an unapproved EUA, and public health authorities who submit an expiration date extension request for an approved product; (5) those who request an emergency dispensing order under section 564A; and (6) those who request

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'').