

received the proposal and notice of opportunity for a hearing on November 8, 2021. Mr. Kuiper failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. George Kuiper has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Kuiper is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Kuiper is a prohibited act.

Any application by Mr. Kuiper for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0665 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-04484 Filed 3-2-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2021-N-0918; FDA-2018-N-1967; FDA-2009-D-0268; and FDA-2019-N-3077]

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 or Agency) 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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 |
|--|-----------------|-----------------------|
| Labeling Requirements for Human Prescription Drug and Biological Products | 0910-0572 | 1/31/2025 |
| Biosimilar User Fee Program | 0910-0718 | 1/31/2025 |
| Labeling of Certain Beers Subject to the Labeling Jurisdiction of the FDA | 0910-0728 | 1/31/2025 |
| Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities | 0910-0883 | 2/28/2025 |

Dated: February 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-04409 Filed 3-2-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Authorization for Medical Products for Use in Emergencies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, 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 information collection associated with FDA Authorization for Medical Products for Use in Emergencies.

DATES: Submit either electronic or written comments on the collection of information by May 2, 2022.

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 May 2, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 2, 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").

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-2022-N-0117 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Authorization for Medical Products for Use in Emergencies." 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, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@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.

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 requirements to

disseminate or disclose information to healthcare providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; specific recordkeeping and records access; restrictions on product advertising, distribution, and administration; and 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.

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 | 2,724 | 2 | 5,448 | 45 | 245,160 |
| Pre-EUA submissions or amendments | 2,001 | 1 | 2,001 | 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 | | | 7,560 | | 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. 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 |

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

| Records associated with conditions of authorization | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| 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 | 1,270 | 5 | 6,350 |

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: February 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-04496 Filed 3-2-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357-6400. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443-6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each

condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register.**” Set forth below is a list of petitions received by HRSA on January 1, 2022, through January 31, 2022. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and

2. Any allegation in a petition that the petitioner either:

a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury