

material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at: <https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/general-and-plastic-surgery-devices-panel>. Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing on issues pending before the committee. Written submissions may be made to the contact person on or before March 9, 2021. Oral presentations from the public and organizations will be scheduled on March 23, 2021, between approximately 12:40 p.m. Eastern Time to 1:40 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 11, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by March 12, 2021.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at [artair.mallett@fda.hhs.gov](mailto:artair.mallett@fda.hhs.gov) or 301-796-9638 at least 7 days in advance of the meeting. FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-03066 Filed 2-12-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-0026]

#### Issuance of Priority Review Voucher; Rare Pediatric Disease Product

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that OXLUMO (lumasiran) injection, manufactured by Alnylam Pharmaceuticals Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that OXLUMO (lumasiran) injection, manufactured by Alnylam Pharmaceuticals Inc., meets the criteria for a priority review voucher. OXLUMO (lumasiran) injection is indicated for the treatment of primary hyperoxaluria type 1 to

lower urinary oxalate levels in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about OXLUMO (lumasiran) injection, go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: February 8, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-03012 Filed 2-12-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-5569]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking

**AGENCY:** Food and Drug Administration, 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:** Submit written comments (including recommendations) on the collection of information by March 18, 2021.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0442. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601

Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRASStaff@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.

**Medical Devices; Device Tracking—21 CFR Part 821**

*OMB Control Number 0910-0442—Extension*

Section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)), as amended by Food and Drug Administration Modernization Act (Pub. L. 105-115), provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a “tracked implant”), or (3) the device is life-sustaining or life-supporting (referred to as a “tracked l/s-l/s device”) and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2)

facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1 through 3 are based on the approximate number of device tracking orders, 12 annually. FDA estimates that approximately 22,000 respondents may be subject to tracking reporting requirements.

Under § 821.25(a) (21 CFR 821.25(a)), device manufacturers subject to FDA tracking orders must adopt a tracking method that can provide certain device, patient, and distributor information to FDA within 3 to 10 working days. Assuming one occurrence per year, FDA estimates it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under § 821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. Based on the number of audits manufacturers conduct annually, FDA estimates it would receive no more than one notice in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2) (21 CFR 821.30(c)(2)), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. FDA has not made such a request and is not aware of any manufacturer making a request. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, the Agency estimates a burden of 1 hour to comply.

Under § 821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. FDA’s estimate of the burden for distributor audit responses assumes that manufacturers audit database entries for 5 percent of tracked devices distributed. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, FDA estimates a burden of 1 hour to comply.

In the **Federal Register** of November 5, 2020 (85 FR 70634), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>**

Activity; 21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d) .....	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e) .....	1	1	1	1	1
Notification of failure to comply—821.25(d) .....	1	1	1	1	1
Multiple distributor data—821.30(c)(2) .....	1	1	1	1	1
Total .....	.....	.....	.....	.....	4

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>**

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a) .....	12	1	12	76	912
Record of tracking data—821.25(b) .....	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) <sup>2</sup> .....	12	1	12	63	756
Manufacturer data audit—821.25(c)(3) .....	12	1,124	13,488	1	13,488

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d) .....	22,000	1	22,000	1	22,000
Total .....					592,276

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity; 21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b) .....	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d) .....	1,100	1	1,100	1	1,100
Total .....					23,100

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this information collection has not changed since the last OMB approval.

Dated: February 9, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-03017 Filed 2-12-21; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19**

**ACTION:** Notice of amendment.

**SUMMARY:** The Acting Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

**DATES:** This amendment to the Declaration is effective as of February 16, 2021.

**FOR FURTHER INFORMATION CONTACT:** L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue

SW, Washington, DC 20201; 202-260-0365, *paige.ezernack@hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F-3, which addresses liability immunity, and section 319F-4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113-5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, enacted on March 27, 2020, to expand Countermeasures under the PREP Act.

On January 31, 2020, former Secretary, Alex M. Azar II, declared a

public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation’s health care community to the COVID-19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, and January 21, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID-19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID-19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary’s Declaration and