

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/DevelopingProductsforRareDiseasesConditions/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]

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## 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