

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Program director survey ( <i>Instrument 1</i> ) .....	60	1	0.17	10.2
ERSEA lead staff survey ( <i>Instrument 2</i> ) .....	60	1	0.75	45
Onsite coordination <sup>a</sup> .....	60	1	1.5	90
Head Start parent/caregiver survey ( <i>Instrument 3</i> ) .....	600	1	0.5	300
Community partner survey ( <i>Instrument 4</i> ) .....	180	1	0.25	45
ERSEA lead staff focus group guide ( <i>Instrument 5</i> ) .....	24	1	1.5	36
Estimated Total Annual Burden Hours .....				526.2

<sup>a</sup> There is no instrument associated with this activity. We will ask each program director to nominate a staff person who will help coordinate data collection activities. This line accounts for the time of the onsite coordinator.

*Authority:* Head Start Act Section 640 [42 U.S.C. 9835].

Mary C. Jones,  
ACF/OPRE Certifying Officer.  
[FR Doc. 2024-10578 Filed 5-14-24; 8:45 am]  
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**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; OJEMDA (tovorafenib)**

**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) 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 OJEMDA (tovorafenib), approved on April 23, 2024, manufactured by Day One Biopharmaceuticals, Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1394.

**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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that OJEMDA (tovorafenib), manufactured by Day One Biopharmaceuticals, Inc., meets the criteria for a priority review voucher. OJEMDA (tovorafenib) is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

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 <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about OJEMDA (tovorafenib), go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: May 9, 2024.

**Lauren K. Roth,**  
Associate Commissioner for Policy.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2024-N-2032]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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 export certificate applications for FDA-regulated human food and cosmetic products.

**DATES:** Either electronic or written comments on the collection of information must be submitted by July 15, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 15, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered