

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Child Support Portal Registration (Office of Management and Budget #: 0970-0370)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Office of Child Support Services (OCSS), Administration for Children and Families (ACF), is requesting the federal Office of Management and Budget (OMB) approve the “Child Support Portal Registration,” with minor revisions, for an additional three years. The OCSS Child Support Portal (“Portal”) contains applications to help state child support agencies administer their programs. Authorized Portal users must register with OCSS to access Portal applications and provide OCSS with certain Portal

application preferences. The current OMB approval expires on February 28, 2025.

DATES: *Comments due* September 16, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov*. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:
Description: The OCSS Division of Federal Systems (DFS) maintains the Portal, which contains various applications through which authorized users may view, update, upload, or download information for child support purposes. Authorized users must register to access the Portal. The DFS Portal team authenticates registrants and then creates secure profiles for authorized users for employers, insurers, and financial institutions based on information provided in the

Employer Services and Insurance Match Debt Inquiry Portal Agreement and Profile forms. Information provided in the electronic National Medical Support Notice (e-NMSN), the electronic Incoming Withholding Order (e-IWO), and Federally Assisted State Transmitted (FAST) Levy Financial Institution Profile form gives DFS the necessary information to set up the respective program user’s process and capture preferences. The information OCSS collects for the Portal registration and profiles remains the same but they underwent minor clarification revisions and edits to update “Office of Child Support Enforcement (OCSE)” to “Office of Child Support Services (OCSS).”

State child support agencies manage and authenticate authorization for individual users via the state proxy server; therefore, a Portal Registration form is not required. State users must, however, provide DFS with their respective Portal preferences.

Respondents: Employers, Financial Institutions, Insurers, and State Child Support Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total annual estimated number of respondents	Total annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Portal Registration Screens	52,284	1	0.15	7,842.60
Employer Services Agreement and Profile	20,040	1	0.08	1,603.20
Insurance Match Debt Inquiry Agreement and Profile	6	1	0.08	0.48
e-NMSN: Plan Administrator Profile	0	0	0.22	0.00
e-NMSN: Employer Profile	20	1	0.22	4.40
e-NMSN: State Profile	4	1	0.22	0.88
e-IWO Employer/Payroll Provider Profile	117	1	0.08	9.36
FAST Levy Financial Institution Profile	2	1	0.08	0.16

Estimated Total Annual Burden Hours: 9,461.08.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 653(m)(2) and 44 U.S.C. 3554.

Mary C. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; VYVGART HYTRULO (efgartigimod alfa and hyaluronidase-qvfc)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. 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 issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application (Supplement-5) for VYVGART HYTRULO (efgartigimod alfa and hyaluronidase-qvfc), approved June 21, 2024, meets the criteria for redeeming 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, email: Cathryn.Lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application (Supplement-5) for VYVGART HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) meets the redemption criteria.

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 VYVGART HYTRULO (efgartigimod alfa and hyaluronidase-qvfc), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: July 11, 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-D-1829]

Platform Technology Designation Program; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance for industry “Platform Technology Designation Program for Drug Development” that appeared in the **Federal Register** of May 29, 2024. In the notice of availability for the draft guidance, FDA requested comments on the proposed collection of information. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance for industry “Platform Technology Designation Program for Drug Development” published May 29, 2024, 89 FR 46406. Either electronic or written comments must be submitted by August 28, 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 August 28, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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-2024-D-1829 for “Platform Technology Designation Program for Drug Development.” 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