The confidentiality of client data will be strictly protected as part of the project. LIHEAP application client waivers allow grantees to share information with OCS and its contractors.

### ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Total number of respondents</th>
<th>Total number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
<th>Annual burden hours</th>
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<tr>
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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Rare Pediatric Disease Priority Review Vouchers.” This draft guidance is a revision of the guidance of the same title that published in 2014. This draft guidance provides information on the rare pediatric disease priority review voucher program under the Federal Food, Drug, and Cosmetic Act (FD&C Act), under which FDA will award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the relevant statutory criteria. These priority review vouchers can be used when submitting future human drug marketing applications that would not otherwise qualify for priority review. Because there exists a need for products for rare pediatric diseases, this program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.

**DATES:** Submit either electronic or written comments on the draft guidance by September 30, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the information collection burden by September 30, 2019.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

**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–2014–D–1461 for “Rare Pediatric Disease Priority Review Vouchers.” Received comments 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.

**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
The draft guidance is intended to assist developers of rare pediatric disease products in assessing whether their product may be eligible for rare pediatric disease designation and a rare pediatric disease priority review voucher. It also clarifies the process for requesting such designations and vouchers, describes the information to include in the designation request and the voucher request, and describes sponsor responsibilities upon approval of a rare pediatric disease product application. Additionally, it describes how FDA will respond to requests for rare pediatric disease designation and vouchers.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Rare Pediatric Disease Priority Review Vouchers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), 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 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.

**Title:** Rare Pediatric Disease Priority Review Vouchers, Draft Guidance for Industry.

**Description of Respondents:**
Respondents to this collection of information are sponsors that develop drugs and biological products.

**Burden Estimate:**
This draft guidance on Rare Pediatric Disease Priority Review Vouchers is intended to assist developers of rare pediatric disease products in assessing whether their product may be eligible for rare pediatric disease designation and a rare pediatric disease priority review voucher.

The draft guidance clarifies the process for requesting such designations and vouchers, sponsor responsibilities upon approval of a rare pediatric disease product application, and the parameters for using and transferring a rare pediatric disease priority review voucher.

This draft guidance also refers to previously approved collections of information found in FDA regulations and guidance. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338, the collections of information in 21 CFR part 316 have been approved under OMB control number 0910–0167, and the collections of information in the guidance for industry entitled “ Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910–0765.

The draft guidance describes five collections of information that are not currently approved by OMB under the PRA: (1) The request for a rare pediatric disease designation, (2) the request for a rare pediatric disease priority review voucher, (3) the notification of intent to use a voucher, (4) the notification to transfer a voucher, and (5) the post-approval report. These collections of information will be used by the Agency to issue rare pediatric disease designations and vouchers, prepare for an incoming priority review, and maintain awareness about which sponsors currently hold vouchers.

**A. Request for Rare Pediatric Disease Designation**
Under the draft guidance, a stakeholder interested in obtaining a rare pediatric disease designation should include information about the drug and its proposed mechanism of action, a description of the rare pediatric disease for which the drug is being or will be investigated, whether or not the sponsor is requesting orphan drug designation or fast track designation at the same time, and documentation that the disease or condition for which the drug is proposed is a “rare pediatric disease” as defined in section 529(a)(3) of the FD&C Act (including evidence supporting whether the serious or life-threatening manifestations of the disease or condition primarily affect children or adults).

FDA estimates that annually a total of approximately 51 respondents will complete one rare pediatric disease designation request as described in question 9 of the draft guidance. FDA estimates that preparing these designation requests will take approximately 51 respondents will complete one rare pediatric disease designation request as described in question 9 of the draft guidance. FDA estimates that preparing these designation requests will take approximately 75 hours for each designation request. This includes the time that may be needed to respond to FDA actions and requests.

**B. Request for Rare Pediatric Disease Priority Review Voucher**
As described more fully in the draft guidance, the information to be provided in a request for a priority review voucher will depend on whether the sponsor has previously requested rare pediatric disease designation. Sponsors who have requested rare pediatric disease designation should include the latest designation correspondence from FDA (e.g., designation letter, deficiency letter, etc.) with the voucher request. Sponsors who have not requested rare pediatric disease designation should include in a voucher request prevalence estimates as of the time of new drug application/biologics license application submission, with supporting documentation. All sponsors requesting a voucher should explain how the application meets each of the eligibility criteria described in question 2 of the draft guidance.

We estimate that annually a total of approximately 20 respondents will complete one rare pediatric disease priority review voucher request as described in response to question 15 of the draft guidance. We estimate that preparing these designation requests will take approximately 40 hours for each rare pediatric disease priority review voucher request. This includes the time that may be needed to respond to FDA actions and requests.

**C. Notification of Intent To Use Voucher**
The sponsor redeeming a rare pediatric disease voucher must notify FDA of its intent to submit an application with a priority review voucher at least 90 days before submission of the application and must include the date the sponsor intends to submit the application (section 529(b)(4)(B)(i) of the FD&C Act).

FDA estimates that annually a total of approximately three respondents will complete one Notification of Intent to Use a Voucher as described in response to question 19 of the draft guidance. We estimate that preparing each of these Notifications of Intent to Use a Voucher will take approximately 8 hours.

**D. Transfer Notification**
Each person to whom a voucher is transferred must notify FDA of the change of voucher ownership within 30 days after the transfer. This notification should include a letter from the previous owner to the current owner and a letter from the current owner to the previous owner, each acknowledging the transfer. Any sponsor redeeming a voucher should include these transfer letters in the application submitted to FDA. A complete record of transfer must be made available to FDA to redeem a transferred voucher.

FDA estimates that annually a total of approximately two respondents will complete Transfer Notifications as described in response to question 21 of the draft guidance. We estimate that preparing each of these Transfer Notifications will take approximately 8 hours.

**E. Post-Approval Report**
The sponsor of an approved rare pediatric disease product application must submit a report to FDA no later than 5 years after approval that addresses the following, for each of the first 4 post-approval years: (1) The estimated population in the United States with the rare pediatric disease for which the product was approved (both the entire population and the population aged 0 through 18 years), (2) the estimated demand in the United States for the product, and (3) the actual amount of product distributed in the United States (section 529(e)(2) of the FD&C Act).

FDA estimates that annually a total of approximately two respondents will complete post-approval reports, as described in response to question 7 of the draft guidance. We estimate that each of these post-approval reports will take about 20 hours to complete.
FDA estimates the annual reporting burden for the draft guidance as follows:

<table>
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<th>Activity</th>
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<th>Average burden per response</th>
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<td>Transfer notification</td>
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<td></td>
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<td></td>
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</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access


Dated: July 24, 2019.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2019–16262 Filed 7–29–19; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information: Ensuring Patient Access and Effective Drug Enforcement

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Request for Information.

SUMMARY: This Request for Information (RFI) seeks comment on ensuring legitimate access to controlled substances, including opioids, while also preventing diversion and abuse, as well as how federal, state, local, and tribal entities can collaborate to address these issues.

DATES: Comments must be received at one of the addresses provided below, no later than 5 p.m. on August 29, 2019.

ADDRESSES: Written comments can be provided by email, fax or U.S. mail.
Email: EPADEAReport@hhs.gov.
Fax: (202) 690–5882.

FOR FURTHER INFORMATION CONTACT:
Office of the Assistant Secretary for Planning and Evaluation, 202–690–7100.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3 of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (EPADEA), Public Law 114–145, called for the Department of Health and Human Services, acting through the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Agency for Healthcare Research and Quality, and the Director of the Centers for Disease Control and Prevention, and in coordination with the Administrator of the Drug Enforcement Administration and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, to submit a report to Congress that identifies:

- Obstacles to legitimate patient access to controlled substances;
- Issues with diversion of controlled substances;
- How collaboration between Federal, State, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances;
- The availability of medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed;
- Beneficial enhancements to State prescription drug monitoring programs, including enhancements to require comprehensive prescriber input and to expand access to the programs for appropriate authorized users;
- Steps to improve reporting requirements so that the public and Congress have more information regarding prescription opioids, such as the volume and formulation of prescription opioids prescribed annually, the dispensing of such prescription opioids, and outliers and trends within large data sets.

II. Solicitation of Comments

EPADEA requires that the report incorporate feedback and recommendations from the following:

(1) Patient groups; (2) pharmacies; (3) drug manufacturers; (4) common or contract carriers and warehousing; (5) hospitals, physicians, and other health care providers; (6) State attorneys general; (7) Federal, State, local, and tribal law enforcement agencies; (8) health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; (9) wholesale drug distributors; (10) veterinarians; (11) professional medical societies and boards; (12) State and local public health authorities; and (13) health services research organizations.

This RFI is seeking comment from these stakeholders on the aforementioned issue areas to be covered by the report.

III. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble.