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.

Respondents: 51 (State Governments and the District of Columbia)

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Action Transmittal LIHEAP–AT–2020–04 Extension of the FY 2015 RECS LIHEAP Administrative Data Matching to FY 2020	51	1	24	1,224	408

Estimated Total Annual Burden Hours: 408.

As LIHEAP is a block grant, there is varying capacity to collect and report data among grantees. The estimated burden hours displayed above are for the average LIHEAP grantee. All LIHEAP grantees have existing data systems to collect, maintain, and analyze this data to complete annual reporting requirements.

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. 8629(a).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–16162 Filed 7–29–19; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1461]

Rare Pediatric Disease Pediatric Priority Review Vouchers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Rare Pediatric Disease Priority Review Vouchers.'' This draft guidance is a revision of the guidance of the same title that published in 2014. This draft guidance provides information on the rare pediatric disease priority review voucher program under the Federal Food, Drug, and Cosmetic Act (FD&C Act), under which FDA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

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 except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Orphan Products Development, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5126, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Friedman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5209, Silver Spring, MD 20993, 301–796–2989; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–4061; or Terrie Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5126, Silver Spring, MD 20993, 301–796–8646.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Rare Pediatric Disease Priority Review Vouchers.'' This draft guidance provides information on implementation of section 529 of the FD&C Act (21 U.S.C. 360ff) regarding the awarding of priority review vouchers to sponsors of certain rare pediatric disease product applications. Under section 529 of the FD&C Act, a sponsor who receives an approval for a drug or biological product to treat or prevent a rare pediatric disease (as defined by statute) may, if the statutory criteria are met, qualify for a voucher that can be used to receive a priority review for a subsequent marketing application for a different product.

This draft guidance is a revision of the draft guidance of the same title that published November 17, 2014 (79 FR 68451). The revisions address updates to the statutory provision on rare pediatric disease priority review vouchers made by the Advancing Hope Act of 2016 (Pub. L. 114–229) and the 21st Century Cures Act (Pub. L. 114–255), including changes made to the definition of rare pediatric disease. When final, this draft guidance will provide FDA's thinking regarding the new definition of rare pediatric disease and explain the new statutory requirement to request a rare pediatric disease priority review voucher. This draft guidance also includes revisions based on FDA's experience with implementing the rare pediatric disease priority review voucher program, including voucher request procedures.

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 (PRA) (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 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 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rare pediatric disease designation request	51	1	51	75	3,825
Rare pediatric disease priority review voucher request	20	1	20	40	800
Notification of intent to use a voucher	3	1	3	8	24
Transfer notification	2	1	2	8	16
Post-approval report	2	1	2	20	40
Total					4,705

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

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

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: EPAEDEAreport@hhs.gov.

Fax: (202) 690–5882.

Mail: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy, Attn: EPAEDEA Report Feedback, 200 Independence Avenue SW, Room 434E, Washington, DC 20201.

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 (EPAEDEA), 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

EPAEDEA 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 warehousemen; (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.