

CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and will conduct special analyses for

publication in peer-reviewed scientific journals to further describe and interpret these data.

In this extension request, CDC is requesting approval for approximately

60 burden hours annually. There is no cost to respondents.

Estimated Annualized Burden Hours

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Physician	NSSAE	10	1	1
Nurse	NSSAE	10	1	4
Medical Clerk	NSSAE	10	1	1

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National and Tribal Evaluation of the 2nd Generation of the Health Profession Opportunity Grants.

OMB NO.: 0970-0462.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of the Health Profession Opportunity Grants (HPOG) to serve TANF and Other Low Income Individuals. ACF has developed a multi-pronged research and evaluation approach for the HPOG Program to better understand and assess the activities conducted and their results. Two rounds of HPOG grants have been awarded—the first in 2010 (HPOG 1.0) and the second in 2015 (HPOG 2.0). There are federal evaluations associated with each round of grants. HPOG grants provide funding to government agencies, community-based organizations, post-secondary educational institutions, and tribal-affiliated organizations to provide education and training services to

Temporary Assistance for Needy Families (TANF) recipients and other low-income individuals, including tribal members. Under HPOG 2.0, ACF provided grants to five tribal-affiliated organizations and 27 non-tribal entities.

OMB previously approved data collection under OMB Control Number 0970-0462 for: the HPOG 2.0 National and Tribal Evaluation (Approved August 2015); and the National Evaluation impact study; the National Evaluation descriptive study; and the Tribal Evaluation (All approved June 2017). The proposed data collection activities described in this **Federal Register** Notice will provide data for the impact and cost benefit studies of the 27 non-tribal grantees participating in the National Evaluation of HPOG 2.0.

National Evaluation: The National Evaluation pertains only to the 27 non-tribal grantees that received HPOG 2.0 funding. The design for the National Evaluation features an implementation study, a systems change analysis, and cost benefit analysis. In addition, the National Evaluation is using an experimental design to measure and analyze key participant outcomes including completion of education and training, receipt of certificates and/or degrees, earnings, and employment in a healthcare career. The impact evaluation will assess the outcomes for study participants that were offered HPOG 2.0 training, financial assistance, and support services, compared to what their outcomes would have been if they had not been offered HPOG 2.0 services. This Notice provides the opportunity to comment on a proposed new information collection activity for the HPOG 2.0 National Evaluation’s impact study—the HPOG 2.0 Impact Evaluation

first follow-up survey, referred to as the Short-Term Follow-up Survey. The first follow-up survey of both treatment and control group members will be administered approximately 15 months after baseline data collection and random assignment. The survey will collect data about key outcomes of interest, including participants’ tenure and experience in HPOG programming; certifications and educational achievements; job placement; and receipt of benefits. These are the key outcomes of interest for which data are not otherwise available through existing data sources. Previously approved collection activities under 0970-0462 will continue under this new request for the National Evaluation of the non-tribal grantees.

In subsequent requests for clearance, we will submit (1) additional data collection instruments to support the descriptive study of the 27 non-tribal grantees participating in the HPOG 2.0 National Evaluation, including grantee interview guides and participant interview guides; and (2) the second follow-up survey—the Intermediate Follow-up Survey—for the HPOG 2.0 National Evaluation impact study. The second follow-up survey is for collecting data from both treatment and control group members at the 27 non-tribal grantees, approximately 36 months after baseline data collection and random assignment. This submission will also include data collection necessary for the National Evaluation’s cost benefit analysis.

Respondents: For the National Evaluation impact study: HPOG 2.0 study participants at the 27 non-tribal grantees.

ANNUAL BURDEN ESTIMATES

[This information collection request is for 3 years]

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
1. National Evaluation 15-Month Follow-up Survey	10,400	3,467	1	1	3,467

Estimated Total Annual Burden Hours: 3,467.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2016-E-1276; FDA-2016-E-1277; and FDA-2016-E-1278]

Determination of Regulatory Review Period for Purposes of Patent Extension; VIBERZI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VIBERZI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the

Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 6, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 6, 2018. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 6, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 Nos. FDA-2016-E-1276; FDA-2016-E-1277 and FDA-2016-E-1278 for "Determination of Regulatory Review Period for Purposes of Patent Extension; VIBERZI." 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.

- **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