

This matter involves the respondent's advertising for Thrive, CBD-EX, CBD-RX, and CBD-Max. The complaint alleges that respondent violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) Thrive treats, prevents, or reduces the risk of COVID-19; (2) CBD-EX, CBD, RX, and CBD-Max treat cancer; (3) Thrive is clinically or scientifically proven to treat, prevent, or reduce the risk of COVID-19; and (4) CBD-EX, CBD, RX, and CBD-Max are clinically or scientifically proven to treat cancer.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the respondent sells, markets, promotes, or advertises.

Part I prohibits respondent from making any representation about the efficacy of any covered product, including that such product will: (1) Treat, prevent or reduce the risk of COVID-19; (2) treat cancer; or (3) cure, mitigate or treat any disease in humans, unless the representation is non-misleading, including that, at the time such representation is made, he possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Provision, "competent and reliable scientific evidence" means human clinical testing of the covered product or of an essentially equivalent product that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Part II prohibits respondent from making any representation, other than representations covered under the Provision titled Prohibited Disease Claims, expressly or by implication, about the health benefits, performance, or efficacy of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, he possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is

true. For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that with regard to any human clinical test or study ("test") upon which the respondent relies to substantiate any claim covered by the order, the respondent must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research or that any benefit of any covered product is scientifically or clinically proven. Part V provides respondent a safe harbor for making claims approved by the Food and Drug Administration ("FDA").

Part VI requires respondent to send notices to consumers who purchased Thrive, CBD-EX, CBD-RX, and CBD-Max informing them about the settlement. Part VII requires respondent to send notices to resellers and retailers informing them about the settlement.

Part VIII requires respondent to submit an acknowledgement of receipt of the order, to serve the order on certain individuals, including all officers or directors of any business respondent controls and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which respondent has delivered a copy of the order.

Part IX requires respondent to file compliance reports with the Commission, and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part X contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records

necessary to demonstrate compliance or non-compliance with the order. Part XI contains other requirements related to the Commission's monitoring of the respondent's order compliance. Part XII provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission,
Commissioner Chopra dissenting,
Commissioner Slaughter not participating.

April J. Tabor,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve proposed updates to the approved information collection project "Safety Program in Perinatal Care (SPPC)-II Demonstration Project."

DATES: Comments on this notice must be received by 60 days after date of publication of this notice.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by emails at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Safety Program in Perinatal Care (SPPC)-II Demonstration Project

The SPPC-II Demonstration Project has the following goals:

(1) To implement the integrated AIM-SPPC II program in birthing hospitals in

OK and TX in coordination with the Alliance for Innovation on Maternal Health program (AIM) and the respective state PQC (Perinatal Quality Collaborative);

(2) To assess the implementation of the integrated AIM–SPPC II program in these hospitals; and

(3) To ascertain the short- and medium-term impact of the integrated AIM–SPPC II program on hospital (*i.e.*, perinatal unit) teamwork and communication, patient safety, and key maternal health outcomes.

The information collected for this Demonstration Project will be used to evaluate the implementation and impact of the SPPC–II program overlaid with AIM patient safety bundles in birthing hospitals in OK and TX. More specifically, the project will:

(a) Provide information on whether the proposed integration of AIM and SPPC–II programs can be implemented as intended, *i.e.*, through the use of a two-tier approach for training all clinical staff in all hospitals, coordination by the AIM Team Lead of the rollout of training clinical staff using e-modules on teamwork and communication, facilitation by AIM Team Leads of in-person sessions to practice teamwork and communication tools and strategies; or, what changes are needed to better facilitate program implementation;

(b) provide information regarding the impact of the integrated AIM–SPPC II program on use of teamwork and communication tools and strategies, teamwork and communication metrics, patient safety culture changes, AIM

bundle implementation, and key maternal health outcomes; and

(c) provide information regarding the sustainability of the integrated AIM–SPPC II program 18 months after implementation.

Due to pandemic-related impacts on the SPPC–II study population, we propose updating the SPPC–II data collection by (1) adding questions to the approved qualitative interview guide at 3–4 months to include pandemic-related questions to better understand the implementation context, (2) adding an additional qualitative interview collection at 15–16 months with a new interview guide to better understand the implementation context, and (3) increasing the total number of qualitative interview participants from 25 to 30 participants to account for the two qualitative interview collections at 3–4 months and 15–16 months. The total estimated annual burden hours for SPPC–II will increase from 54,654 hours in the previous clearance request, an increase of 5 hours.

This study is being conducted by AHRQ through its contractor, Johns Hopkins University (JHU), and through JHU's subcontractor, AIM, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project the following updates to the data collections will be implemented:

(a) Qualitative, semi-structured interviews with AIM Team Leads will be conducted by phone about 3–4 months and 15–16 months after the SPPC–II implementation start date to assess the perceived utility of the training and assistance needed with the rollout of training to all frontline clinical staff using the e-modules and facilitation sessions to consolidate the information, and to better understand the implementation context (including barriers, facilitators, and strategies). An interview guide developed based on the Consolidated Framework for Implementation Research framework will be used to conduct the interviews, together with a corresponding consent form.

Estimated Annual Respondent Burden

Exhibit 1 shows only the estimated annualized burden hours for the respondents' time to participate in updates to the information collection of the SPPC–II Demonstration Project.

One-hour qualitative interviews will be conducted with a total of 30 AIM Team Leads in the 2 states about 3–4 months and 15–16 months after the SPPC–II implementation start date.

The total annual burden hours are estimated to be 54,659 hours, an increase of 5 hours from the previous clearance request.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Qualitative semi-structured interviews with AIM Team Leads at 3–4 months and 15–16 months	30	1	1.00	30
Total	30	NA	NA	30

Exhibit 2 shows only the hours and cost of updates to the collection. The

cost burden of the updated collection is estimated to be \$1,494.90 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Qualitative semi-structured interviews with AIM Team Leads at 3–4 months and 15–16 months	30	30	\$49.83	\$1,494.90
Total	30	30	1,494.90

* National Compensation Survey: Occupational wages in the United States May 2017 “U.S. Department of Labor, Bureau of Labor Statistics.”

^a Hourly wage for nurse-midwives (\$48.36; occupation code 29–1161).

^b Weighted mean hourly wage for obstetrician-gynecologists (\$113.10; occupation code 29–1064; 30%); nurse-midwives (\$49.83; occupation code 29–1161; 30%); registered nurses (\$35.36; occupation code 29–1161; 20%); and nurse practitioners (\$51.86; occupation code 29–1171; 20%).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 13, 2020.

Virginia L. Mackay-Smith,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Alzheimer's and Dementia Program Data Reporting Tool (ADP–DRT) OMB #0985–0022

AGENCY: Administration for Community Living, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a 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 the Proposed Revision and solicits comments on the information collection requirements related to Alzheimer's and Dementia Program Data Reporting Tool (ADP–DRT).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 14, 2020.

ADDRESSES: Submit electronic comments on the collection of information to: Erin Long (Erin.Long@acl.gov). Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Erin Long.

FOR FURTHER INFORMATION CONTACT: Erin Long, Administration for Community Living, Washington, DC 20201, Erin.Long@acl.gov, 202–795–7389.

SUPPLEMENTARY INFORMATION: Under the 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions,

including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates; (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.

The Older American's Act requires ACL to evaluate “demonstration projects that support the objectives of this Act, including activities to bring effective demonstration projects to scale with a prioritization of projects that address the needs of underserved populations, and promote partnerships among aging services, community-based organizations, and Medicare and Medicaid providers, plans, and health (including public health) systems. (Section 201 (42 U.S.C. 3011) Sec. 127. Research and Evaluation).

To fulfill the evaluation requirements and allow for optimal federal and state-level management of ACL's Alzheimer's Disease Program, specific information must be collected from grantees.

The current reporting tool is set to expire June 22, 2020. The Alzheimer's and Dementia Program (ADP) Project Officer has reviewed the current data collection procedures to ensure the acceptability of these items as appropriate and thorough evaluation of the program, while minimizing burden for grantees.

The result of this process is the proposed modifications to the existing data collection tool. ACL is aware that different grantees have different data collection capabilities. It is understood that, following the approval of the modified data collection tool, ACL will work with its grantees to offer regular training to ensure minimal burden.

The proposed data collection tools may be found on the ACL website for review at <https://nadrc.acl.gov/node/226>.

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows: