

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-3037]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

**DATES:** Fax written comments on the collection of information by January 28, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title “Generic Clearance for Quantitative Testing for the Development of FDA Communications.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD

20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control Number 0910—NEW

This notice announces the FDA information collection request from OMB for a generic clearance that will allow FDA to use quantitative social/behavioral science data collection techniques (*i.e.*, surveys and experimental studies) to test consumers’ reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, it is important to assess communications while they are under development. Understanding consumers’ attitudes, motivations, and behaviors in response to potential communications and education messaging plays an important role in improving FDA’s communications.

If the following conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;

- The collections are noncontroversial;
- Personally identifiable information (PII) is collected only to the extent necessary<sup>1</sup> and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;<sup>2</sup> and
- Information gathered will yield qualitative findings; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.*, a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA’s Research Involving Human Subjects Committee, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

In the **Federal Register** of September 4, 2018 (83 FR 44888), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN, BY ANTICIPATED DATA COLLECTION METHODS

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive Interviews Screener .....	720	1	720	0.083 (5 minutes)	60
Cognitive Interviews .....	144	1	144	1	144
Pre-test study screener .....	2,400	1	2,400	0.083 (5 minutes)	199
Pre-testing study .....	480	1	480	.25 (15 minutes)	120
Self-administered surveys/experimental Studies Screener .....	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys/Experimental Studies ...	15,000	1	15,000	.25 (15 minutes)	3,750

<sup>1</sup> For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

<sup>2</sup> As defined in OMB and agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important

public policies or important private sector decisions.”

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN, BY ANTICIPATED DATA COLLECTION METHODS—Continued

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total .....	.....	.....	.....	.....	10,498

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The total estimated annual burden is 10,498 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: December 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–28252 Filed 12–27–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Meeting of the National Advisory Council on Nurse Education and Practice

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** National Advisory Council on Nurse Education and Practice (NACNEP) has scheduled a public meeting. Information about NACNEP and the agenda for this meeting can be found on the NACNEP website at <https://www.hrsa.gov/advisory-committees/nursing/index.html>.

**DATES:** January 28, 2019, 8:30 a.m.–4:30 p.m. and January 29, 2019, 8:30 a.m.–2:30 p.m. ET.

**ADDRESSES:** This meeting will be held in-person and by teleconference and webinar. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

- Conference call-in number: 1–888–455–0640; passcode: HRSA COUNCIL.

- Webinar link: <https://hrsa.connectsolutions.com/nacnep/>.

**FOR FURTHER INFORMATION CONTACT:** Deitra W. Scott, MSN, RN, Nurse Consultant, Division of Nursing and Public Health, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 11N112, Rockville, Maryland 20857; 301–945–3113; or [DScott1@hrsa.gov](mailto:DScott1@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** NACNEP provides advice and recommendations to the Secretary of HHS (Secretary) and Congress on policy issues related to the activities carried out under Title VIII of the Public Health Service (PHS) Act, including issues related to the nurse workforce, education, and practice improvement. NACNEP also prepares and submits an annual report to the Secretary and Congress describing its activities, including NACNEP's findings and recommendations concerning activities under Title VIII, as required by the PHS Act.

During the January 28–29, 2019, meeting, NACNEP will finalize the 15th Report (topic is Promoting Nursing Leadership in the Transition to Value-Based Care) and continue discussions on potential topics for its 16th Report. Agenda items are subject to change as priorities dictate. The meeting agenda will be available at the NACNEP website at least 14 days prior to the meeting. Refer to the NACNEP website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACNEP should be sent to Deitra W. Scott, Nurse Consultant, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Deitra W. Scott at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 10 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present

government-issued identification prior to entry.

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

[FR Doc. 2018–28292 Filed 12–27–18; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with