

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1904]

Agency Information Collection Activities; Proposed Collection; Comment Request; Comparing Food Safety Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish a notice in the **Federal Register** concerning each proposed collection of information and allow 60 days for public comment. This notice invites comments on the proposed data collection entitled “Comparing Food Safety Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers.”

DATES: Submit either electronic or written comments on the collection of information by January 27, 2015.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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 before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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.

Comparing Food Safety Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers—(OMB Control Number 0910—NEW)

We conduct research and educational and public information programs relating to food safety and nutrition under our broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(b)(2)), to protect the public health by ensuring that foods are “safe, wholesome, sanitary, and properly labeled,” and in section 903(d)(2)(C) of the FD&C Act (21 U.S.C. 393(d)(2)(C)), to conduct research relating to foods, drugs, cosmetics, and devices.

Our current food safety education and outreach programs and materials generally are developed and provided for the English-speaking population in the United States (Ref. 1). To better protect public health and to help consumers practice safe food handling, we need empirical data on how different population groups understand, perceive,

and practice food safety and food handling. An emerging and important demographic trend in the United States is the increase in Hispanics. Recent estimates suggest that Hispanics (defined as those who identify themselves as of Hispanic or Latino origin) are the largest and fastest growing minority group in the nation; the proportion of the U.S. population that was Hispanic was 14 percent in 2005 and is projected to increase to 29 percent in 2050 (Ref. 2).

Data from the Centers for Disease Control and Prevention indicate that, in the past two decades, Hispanics were one of the population groups that often experienced higher incidence rates (per 100,000 population) of bacterial causes of foodborne illness than Caucasians (Ref. 3). These bacterial causes include *Campylobacter*, *Listeria monocytogenes*, *Shigella*, and *Salmonella*. While some Hispanics living in the United States use the English language exclusively, or more often than Spanish (English-dominant Hispanics), other U.S. Hispanics predominantly use the Spanish language in their daily lives (Spanish-dominant Hispanics) (Ref. 4). Since most U.S. food labels, including safe food handling instructions, are in English, Spanish-dominant Hispanics’ understanding and use of safe food handling instructions may differ from that of English-dominant Hispanics and of non-Hispanics who use English exclusively. In addition, Hispanics may have certain food handling practices that may increase their risk of foodborne illness (Ref. 5).

FDA needs an understanding of how different population groups perceive and behave in terms of food safety and food handling to inform possible measures that we may take to better protect public health and to help consumers practice safe food handling. FDA is aware of no consumer research on a nationwide level on how different population groups understand, perceive, and practice food safety and food handling. This study is intended to provide answers to research questions such as whether and how much Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics differ in their knowledge, attitude, and behavior toward food safety and food handling among the three population groups, and the role that demographic and other factors may play in any differences.

The proposed study will use a Web-based instrument to collect information

from 3,000 adult members in online consumer panels maintained by a contractor. The study plans to randomly select 800 panel members in each of three groups: Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics. Both English and Spanish questionnaires will be used, as appropriate. The study plans to include topics such as: (1) Food safety knowledge and attitude and (2) food handling and consumption practice. To

help us understand the data, the study will also collect information on respondents' background, including, but not limited to, health status and demographic characteristics, such as age, gender, education, and income, and degree of acculturation among Hispanic respondents using a measure developed by Marin, et al. (Ref. 6).

The study is part of our continuing effort to protect the public health. We will not use the results of the study to develop population estimates. We will use the results of the study to develop

followup quantitative and qualitative research to gauge the prevalence and extent of differences in food safety knowledge and behaviors between the three mentioned population groups. We will use the results of the followup research to help inform the design of effective education and outreach initiatives aimed at helping reduce the risk of foodborne illness for the general U.S. population as well as Hispanics.

We estimate the burden of this collection of information 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
Cognitive interview screener	72	1	72	0.083 (5 minutes)	6
Cognitive interview	9	1	9	0.5 (30 minutes)	5
Pretest invitation	1,440	1	1,440	0.033 (2 minutes)	48
Pretest	180	1	180	0.25 (15 minutes)	45
Study invitation	24,000	1	24,000	0.033 (2 minutes)	792
Study	3,000	1	3,000	0.25 (15 minutes)	750
Total					1,646

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

We base our estimates on prior experience with research that is similar to this proposed study. We will use a cognitive interview screener with 72 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 5.976 hours, rounded to 6 hours. We will conduct cognitive interviews with nine participants. We estimate that it will take a participant approximately 30 minutes to complete the interview, for a total of 4.5 hours, rounded to 5 hours. We also plan to conduct a pretest to identify and resolve potential survey administration problems. We will send a pretest invitation to 1,440 prospective pretest participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 47.52 hours, rounded to 48 hours. We will administer the pretest with 180 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 45 hours. We will send a study invitation to 24,000 prospective participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 792 hours. We will administer the study with 3,000 participants and estimate that it will take a participant 15 minutes (0.25

hours) to complete the study, for a total of 750 hours. The total estimated burden for all the study activities is 1,646 hours.

II. References

1. FDA. "Foodborne Illness & Contaminants." June 9, 2014. Available at <http://www.fda.gov/Food/FoodborneIllnessContaminants/default.htm>.
2. Passel, J. S. and D'V. Cohn. "U.S. Population Projections: 2005–2050." Pew Research Center. Washington, DC February 11, 2008. Available at <http://pewhispanic.org/files/reports/85.pdf>.
3. Quinlan, J. J. "Foodborne Illness Incidence Rates and Food Safety Risks for Populations of Low Socioeconomic Status and Minority Race/Ethnicity: A Review of the Literature." *International Journal of Environmental Research and Public Health*, 10(8): 3634–3652. 2013.
4. Taylor, P., M. H. Lopez, J. Martínez, and G. Velasco. "Language Use Among Latinos." Pew Research Center. Washington, DC April 4, 2012. Available at <http://www.pewhispanic.org/2012/04/04/iv-language-use-among-latinos/>.
5. Henley, S. C., S. E. Stein, and J. J. Quinlan. "Identification of Unique Food Handling Practices That Could Represent Food Safety Risks for Minority Consumers." *Journal of Food Protection*, 75: 2050–2054. 2012.
6. Marin, G., F. Sabogal, B. V. Marin, et al. "Development of a Short Acculturation Scale for Hispanics." *Hispanic Journal of Behavioral Sciences*, 9(2): 183–205. 1987.

Dated: November 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1152]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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.