appropriate for use in the development of RELs? What is the utility of a standard ''action level'' (*i.e.,* an exposure limit set below the REL typically used to trigger risk management actions) and how should it be set? How should NIOSH address worker exposure to complex mixtures?

SUPPLEMENTARY INFORMATION: NIOSH and stakeholders have expressed concerns recently about limitations in the NIOSH Carcinogen Policy, prompting NIOSH to initiate a review of the carcinogen policy in 2010. A major limitation in the policy is the use of the term ''Potential Occupational Carcinogen'' which dates to the 1980 OSHA hazard classification for carcinogens outlined in 29 CFR 1990.103 and is defined as *''* * * any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals.''* A major limitation of this definition is that the policy allows for only one cancer category, which is ''potential occupational carcinogen.'' The adjective ''potential'' conveys uncertainty that is not warranted with many carcinogens such as asbestos, benzene, and others. This policy does not allow for classification on the basis of the magnitude and sufficiency of the scientific evidence. In contrast, other organizations, such as the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) allow for a more differential classification.

The revision of the NIOSH Carcinogen Policy also coincides with the international realization that there is a need for more efficient and quicker means of classifying chemicals. Qualitative and semi-quantitative approaches such as hazard banding are increasingly being investigated as a means of addressing the vast numbers of unregulated chemicals. NIOSH has been in collaboration with various organizations to consider utilizing hazard banding approaches to control chemicals. This will also be reflected in the review of the carcinogen and RELs policies.

This **Federal Register** notice serves to provide stakeholders and the public an opportunity for input on the revision of the NIOSH Carcinogen and REL Policies. It is anticipated that NIOSH will develop a report on the revised NIOSH Carcinogen and REL Policies to be made available in the Spring of 2012. Additional information regarding NIOSH plans to assess and revise the Carcinogen and REL Policy can be found in the April 2011 NIOSH e-news at *http://www.cdc.gov/niosh/enews/enewsV8N12.html* and on the NIOSH Cancer and REL Policy Web Topic Page [see *http://www.cdc.gov/niosh/topics/cancer/policy.html*].

FOR FURTHER INFORMATION CONTACT: T.J. Lentz, telephone (513) 533–8260, or Faye Rice, telephone (513) 533–8335, NIOSH, MS–C32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: August 12, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011–21405 Filed 8–22–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Comparing Nutrition 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) 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.

DATES: Fax written comments on the collection of information by September 22, 2011.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–New and title ''Comparing Nutrition Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

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

I. Background

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. 1).

Data from the Centers for Disease Control and Prevention (CDC) indicate that, in 2005 and 2006, 34.3 percent and 32.7 percent of the U.S. adult population are obese and overweight, respectively (Ref. 2). According to CDC, Hispanics had 21 percent higher obesity prevalence than Whites in 2008 (Ref. 3). CDC data also indicate variations in prevalence of obesity among adults of different race-gender groups; for example, during 2006 through 2008, non-Hispanic Blacks had the greatest prevalence of obesity (35.7 percent), followed by Hispanics (28.7 percent), and non-Hispanic Whites (23.7 percent); non-Hispanic Black women had the greatest prevalence (39.2 percent), followed by non-Hispanic Black men (31.6 percent), Hispanic women (29.4 percent), Hispanic men (27.8 percent), non-Hispanic White men (25.4 percent), and non-Hispanic White women (21.8 percent) (Ref. 3).

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 are in English, Spanish-dominant Hispanics' understanding and use of food labels may differ from that of English-dominant Hispanics and of non-Hispanics who use English exclusively. In addition, both English-dominant Hispanics and Spanish-dominant Hispanics may have different awareness, perceptions, and behaviors than English-speaking non-Hispanics on issues of health, nutrition, and food consumption (Refs. 5 through 8).

Existing research suggests that, in addition to language and other demographic differences, acculturation is an important factor associated with individual differences in dietary and public health-related perceptions, attitudes, and behaviors among Hispanics. Acculturation is defined as the change in behavior and values by immigrants when they come in contact with a new group, nation, or culture (Ref. 9). Immigrants may possess different degrees of acculturation, depending on the time of migration and other factors, such as the dominant culture of the neighborhoods where they live and work and type of education received (Refs. 10 and 11). Hence, variation in the degree of acculturation can lead to differences in lifestyle and behaviors, including behaviors related to dietary choices and to use and understanding of nutrition information on food labels, because of English proficiency and degree of assimilation into the values, lifestyles, and diets prevalent in this country. The existing research has shown the influence of acculturation on Hispanics' perceptions, attitudes, and behaviors relating to public health factors including dietary practices, nutrition, the health practices of pregnant women, obesity, coronary heart disease, Type 2 diabetes, alcohol consumption, and smoking behavior (for example, Refs. 10 and 12 through 21).

FDA needs an understanding of how different population groups perceive and behave in terms of food label understanding and use, nutrition, and health to inform possible measures that the Agency may take to help consumers make informed dietary choices. FDA is aware of no consumer research on a nationwide level of the impact of language and acculturation on Hispanics' dietary choices and label use. 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 label use, nutrition, and health among three population groups and the role that demographic and other factors may play in any differences.

The proposed study will use a Web-based survey to collect information from 2,400 adult members in online consumer panels maintained by a contractor. The study plans to randomly select 800 members into each of three groups: Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics. Either an English or a Spanish questionnaire will be used, as appropriate. The study plans to include topics such as: (1) Nutrition and health; (2) use and understanding of food labels and labeling information; (3) degree of capacity to understand and use health information; and (4) levels of acculturation among Hispanic respondents as measured by a Hispanic acculturation scale that is widely used in social science research (Ref. 22). To help understand the data, the study will also collect information on participants' background, including, but not limited to, health status and demographic characteristics, such as age, gender, education, and income.

The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. The results of the study will not be used to develop population estimates. The results of the study will be used for informing possible measures that the Agency may take to help consumers make informed dietary choices.

To help design and refine the questionnaire, we plan to conduct cognitive interviews by screening 72 adult panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take 0.5 hour. The total for cognitive interview activities is 11 hours (6 hours + 5 hours). Subsequently, we plan to conduct two waves of pretests of the questionnaire before it is administered in the study. We expect that 360 invitations, each taking 2 minutes (0.033 hour), will need to be sent to adult members of the online consumer panels to have 180 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 57 hours (12 hours + 45 hours). For the survey, we estimate that 4,800 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to adult members of the online consumer panels to have 2,400 of them complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 758 hours (158 hours + 600 hours). Thus, the total estimated burden is 826 hours. This estimate is 496 hours lower than the 1,322 hours published in the 60-day notice and reflects 20 fewer hours for pretest invitation and 476 fewer hours for survey invitation. Recent evidence available to the Agency suggests the study will not need to send as many invitations as originally estimated to achieve its target sample sizes in pretest and survey. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

In the **Federal Register** of March 14, 2011 (76 FR 13626), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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 min.)	6
Cognitive interview	9	1	9	0.5 (30 min.) ..	5
Pretest invitation	360	1	360	0.033 (2 min.)	12
Pretest	180	1	180	0.25 (15 min.)	45
Survey invitation	4,800	1	4,800	0.033 (2 min.)	158
Survey	2,400	1	2,400	0.25 (15 min.)	600
Total					826

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

II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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2. CDC, ''Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, Trends 1976–80 Through 2005–2006,'' December 2008, (*http://www.cdc.gov/nchs/data/hestat/overweight/overweight_adult.pdf*).

3. CDC, ''Differences in Prevalence of Obesity Among Black, White, and Hispanic Adults—United States, 2006–2008,'' *Morbidity and Mortality Weekly Report,* 58(27):740–744, July 17, 2009, (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5827a2.htm*).

4. CDC, ''Health Disparities Experienced by Hispanics—United States,'' *Morbidity and Mortality Weekly Report,* 53(40):935–937, October 15, 2004, (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5340a1.htm*).

5. National Heart, Lung and Blood Institute, ''Epidemiologic Research in Hispanic Populations: Opportunities, Barriers and Solutions,'' December 3, 2003, (*http://www.nhlbi.nih.gov/meetings/workshops/hispanic.htm*).

6. Information Resources, Inc., ''Times & Trends: Hispanic Consumers—Capturing CPG Market Potential,'' April 2008, (*http://www.symphonyiri.com/portals/0/articlePdfs/TT_April_2008_Hispanic_Consumers.pdf*).

7. Yang, S., M.G. Leff, D. McTague, *et al.,* ''Multistate Surveillance for Food-Handling, Preparation, and Consumption Behaviors Associated With Foodborne Diseases: 1995 and 1996 Behavioral Risk Factor Surveillance Systems Food-Safety Questions,'' *Morbidity and Mortality Weekly Report,* 47(SS–4):33–54, September 11, 1998, (*http://www.cdc.gov/mmwr/preview/mmwrhtml/00054714.htm*).

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14. Winkleby, M.A., S.P. Fortmann, and B. Rockhill, ''Health-Related Risk Factors in a Sample of Hispanics and Whites Matched on Sociodemographic Characteristics: The Stanford Five-City Project,'' *American Journal of Epidemiology* 137(12):1365–1375, 1993.

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Dated: August 18, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0386]

International Conference on Harmonisation; Guidance on E2F Development Safety Update Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E2F Development Safety Update Report.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes the format, content, and timing of a development safety update report (DSUR) for an investigational drug. The DSUR will serve as a common standard for periodic reporting on drugs under development (including marketed drugs that are under further study) among the ICH regions. The DSUR can be submitted in the United States in place of an annual report for an investigational new drug application (IND). The harmonized DSUR is intended to promote a consistent approach to annual clinical safety reporting among the ICH regions and enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.*