TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
801.150(a)(2)	57	1	57	0.50	29
801.410(e) and (f)	30	924,100	27,723,000	0.0008	22,178
801.421(d)	10,000	160	1,600,000	0.25	400,000
Total					422,207

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

The medical device labeling regulations also refer to previously approved collections of information found in FDA regulations. The collections of information under § 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231; and the collections of information under § 801.435(g) have been approved under OMB control number 0910–0073.

Further, FDA concludes that labeling statements under §§ 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g), and 809.30(d)(2), (d)(3), and (e) do not constitute a "collection of information" under the PRA. Rather, these labeling statements are "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

Reporting

These estimates are based on FDA's registration and listing database for medical device establishments and FDA's knowledge of and experience with device labeling.

Recordkeeping

These estimates are based on FDA's registration and listing database for medical device establishments, Agency communications with industry, and FDA's knowledge of and experience with device labeling.

The medical device labeling regulations also refer to previously approved collections of information. The collections of information under §§ 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; and the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231.

The information collection requirements under §§ 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g), and 809.30(d)(2), (d)(3), (e) are not considered information collection because the public information is originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Dated: March 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5739 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0129]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled "Comparing Nutrition 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 May 13, 2011.

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

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

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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 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. 1). According to CDC, Hispanics had 21 percent higher obesity prevalence than Whites in 2008 (Ref. 2). 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. 2).

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 9).

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. 10). 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. 11 and 12). 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. 11 and 13 through 22).

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. 23). 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 960 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 77 hours (32 hours + 45 hours). For the survey, we estimate that 19,200 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 2400 of them complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 1,234 hours (634 hours + 600 hours). Thus, the total estimated burden is 1,322 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Cognitive interview screener	72	1	72	0.083	6
Cognitive interview	9	1	9	0.5	5
Pretest invitation	960	1	960	0.033	32
Pretest	180	1	180	0.25	45
Survey invitation	19,200	1	19,200	0.033	634
Survey	2,400	1	2,400	0.25	600
Total					1,322

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

3. Passel, J.S. and C. D'Vera, "U.S. Population Projections: 2005–2050," Pew Research Center, Washington, DC, available at *http://pewhispanic.org/files/reports/85.pdf,* February 11, 2008.

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8. 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, available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/00054714.htm,* September 11, 1998.

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13. Otero-Sabogal, R., F. Sabogal, E.J. Pérez-Stable, et al., "Dietary Practices, Alcohol Consumption, and Smoking Behavior: Ethnic, Sex, and Acculturation Differences," *Journal of National Cancer Institute Monograph,* 18: 73–82, 1995.

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Dated: March 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5736 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0112]

Draft Guidance for Industry on Chemistry, Manufacturing, and Controls Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #216 entitled "Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use". The purpose of this document is to provide recommendations on what documentation to submit to support the CMC information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 30, 2011.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael J. Popek, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8269, *e-mail: michael.popek@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #216 entitled "Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use." This draft guidance provides recommendations on what documentation to submit to support the CMC information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use. This information is filed to CVM in a new animal drug application (NADA), conditional NADA, investigational new animal drug file, abbreviated NADA, generic investigational new animal drug file, drug master file, or veterinary master file.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this draft guidance have been approved under OMB control number 0910–0032 (expiration date April 30, 2011).

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: March 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5816 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0108]

Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "User Fee Waivers, Reductions, and Refunds for Drug and Biological Products." This revised draft guidance provides recommendations to applicants considering whether to request a waiver or reduction in user fees. This guidance is a revision of the draft guidance entitled "Draft Interim Guidance Document for Waivers of and Reductions in User Fees," issued July 16, 1993.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by June 13, 2011.

Submit written comments on the proposed collection of information by May 13, 2011.

ADDRESSES: Submit written requests for single copies of the revised draft 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,