Pulmonary Hypertension (CTEPH) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class; and treatment of pulmonary arterial hypertension to improve exercise capacity, improve WHO functional class, and to delay clinical worsening. Subsequent to this approval, the USPTO received a patent term restoration application for ADEMPAS (U.S. Patent No. 7,173,037) from Bayer Intellectual Property GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ADEMPAS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ADEMPAS is 2,394 days. Of this time, 2,151 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* March 22, 2007. FDA has verified the Bayer Intellectual Property GmbH claim that March 22, 2007, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* February 8, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for ADEMPAS (NDA 204819) was initially submitted on February 8, 2013.

3. *The date the application was approved:* October 8, 2013. FDA has verified the applicant's claim that NDA 204819 was approved on October 8, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,317 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08337 Filed 4–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1904]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 May 12, 2016.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title ''Comparing Food Safety 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

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

I. Background

We conduct research and educational and public information programs relating to food safety and nutrition issued in our broad statutory authority, set forth in section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (the 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 1003(d)(2)(C) of the FD&C Act (21 U.S.C. 393(d)(2)(C)), to conduct research relating to foods, drugs, cosmetics, devices and tobacco products.

Our current food safety education and outreach programs and materials generally are developed and provided for the English-speaking population in the United States (U.S.) (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 (CDC) 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 (Listeria*), *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 development of 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 initial 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 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 1,000 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 plan to use the results of the study to develop follow-up 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 plan to use the results of the follow-up 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.

In the **Federal Register** of November 28, 2014 (79 FR 70875), 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 minutes)	6
Cognitive interview	9	1	9	1.5 (90 minutes)	14
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					1,655

[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 90 minutes to complete the interview, for a total of 13.5 hours, rounded to 14 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 1,655 hours; this estimate is 9 hours higher than that shown in the 60-day notice due to revised hours for cognitive interviews, from 30 minutes (0.5 hours) to 90 minutes (1.5 hours) each interview.

II. References

1. U.S. Food and Drug Administration. ''Foodborne Illness & Contaminants.'' June 9, 2014. (*http://www.fda.gov/Food/FoodborneIllnessContaminants/default.htm*).

2. Passel, J.S. and C. D'Vera. ''U.S. Population Projections: 2005–2050.'' Pew

Research Center. February 11, 2008. (*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. April 4, 2012. (*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: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08332 Filed 4–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1101]

EMD Serono; Withdrawal of Approval of a New Drug Application for LUVERIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of a new drug application (NDA) for LUVERIS (lutropin alpha for injection) held by EMD Serono, One Technology Place, Rockland, MA 02370. EMD Serono has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective April 12, 2016.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3381.

SUPPLEMENTARY INFORMATION: FDA approved LUVERIS (lutropin alpha for injection) on October 8, 2004, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. LUVERIS is indicated for concomitant administration with GONAL–F (follitropin alfa for injection) for stimulation of follicular development in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency. In a letter dated April 30, 2012, EMD Serono requested that FDA withdraw approval of NDA 021322 for LUVERIS under § 314.150(c). In that letter, EMD Serono noted that, as had been previously discussed with the Agency, it was not feasible to complete a trial that the company had agreed to at the time of approval under subpart H. By letter dated December 8, 2014, FDA notified EMD Serono that, when studies that are required as a condition of approval under the Agency's accelerated approval regulations are not completed, the approval of an application is withdrawn according to the procedures set forth in §§ 314.530 and 314.150(d) rather than under § 314.150(c). FDA requested that EMD Serono submit a new withdrawal request under § 314.150(d).

Following additional correspondence, by letter dated July 23, 2015, EMD Serono requested that FDA withdraw approval of NDA 021322 for LUVERIS under § 314.150(d) because a postmarketing study that was required as a condition of approval under subpart H was not completed. Because that study was required to verify and describe the clinical benefit of the drug product, the clinical benefit of LUVERIS has not been confirmed, and it has not been established to be safe and effective. In its July 23, 2015, letter, EMD Serono waived any opportunity for a hearing otherwise provided under §§ 314.150 and 314.530. FDA responded by letter dated September 2, 2015, acknowledging EMD Serono's request that FDA withdraw approval of LUVERIS under § 314.150(d). FDA also acknowledged that EMD Serono waived its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 021322, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08336 Filed 4–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0560]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens

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 May 12, 2016.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0582. Also include the FDA 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, *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.

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—OMB Control Number 0910–0582—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and compliant with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product