days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* November 10, 2016. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective November 10, 2016.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 30, 2018. FDA has verified the applicant's claim that the premarket approval application (PMA) for GORE CARDIOFORM ASD OCCLUDER (PMA 050006 S071) was initially submitted November 30, 2018.

3. *The date the application was approved:* May 28, 2019. FDA has verified the applicant's claim that PMA 050006 S071 was approved on May 28, 2019.

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 556 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, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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 *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13687 Filed 6–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0281]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 27, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0281–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Prevention Communication Formative Research.

Type of Collection: Revision.

OMB No.: 0990–0281.

Abstract: The Office of Disease Prevention and Health Promotion (ODPHP) is focused on developing and disseminating health information to the public. ODPHP faces an increasingly urgent interest in finding effective ways to communicate health information to America's diverse population. ODPHP strives to be responsive to the needs of America's diverse audiences while simultaneously serving all Americans across a range of channels, from print to new communication technologies. To carry out prevention information efforts, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of their communication and education efforts. The information collected will be used to improve communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, the Move Your Way Campaign and the President's Council on Sports, Fitness & Nutrition. ODPHP communicates through its website (*www.health.gov*) and through other channels including social media, print materials, interactive training modules, and reports. Data collection will be qualitative and quantitative and may include in-depth interviews, focus groups, web-based surveys, omnibus surveys, card sorting, and various forms of usability testing of materials and interactive tools to assess the public's understanding of disease prevention and health promotion content, responses to prototype materials, and barriers to effective use.

The program is requesting a 3-year extension of the clearance.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
In-depth interviews—Screener	1,500	1	10/60	250
In-depth interviews—Instrument	500	1	1.00	500
Focus groups—Screener	2,925	1	10/60	487.5

ANNUALIZED BURDEN HOUR TABLE—Continued

Forms (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Focus groups—Instrument	975	1	1.50	1,462.5
Intercept interviews	5,250	1	5/60	437.50
Cognitive testing of instruments—Screener	150	1	10/60	25
Cognitive testing of instruments—Cognitive test	50	1	2.00	100
Web-based surveys—Screener	30,000	1	5/60	2,500
Web-based surveys—Survey	10,000	1	15/60	2,500
Omnibus surveys	2,100	1	10/60	350
Gatekeeper reviews	325	1	30/60	162.5
Card sorting—Screener	600	1	10/60	100
Card sorting—Card sort	200	1	1.00	200
Usability and prototype testing of materials (print and web)—Screener	1,800	1	10/60	300
Usability and prototype testing of materials (print and web)—usability tests	600	1	1.00	600
Total	.....	.....	.....	9,975.00

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–13737 Filed 6–25–21; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Opportunity To Become a Healthy People 2030 Champion

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services' (HHS) Office of Disease Prevention and Health Promotion (ODPHP) invites public and private sector organizations that support Healthy People 2030 (HP2030), the nation's disease prevention and health promotion plan, to become a Healthy People 2030 Champion (HP2030 Champion).

Eligibility: Any organization may apply to be a HP2030 Champion. The selected HP2030 Champions will be recognized for their commitment and work toward achieving HP2030's vision of *a society in which all people can achieve their full potential for health and well-being across the lifespan.*

HP2030 Champions. HP2030 Champions can be public and private organizations such as those at the state, local, county, and tribal levels, non-governmental organizations, non-profit organizations, businesses, academic organizations, organizations that impact health outcomes, philanthropic organizations, and tribal organizations that identify themselves as being aligned with or promoting HP2030, HP2030's vision, and HP2030's overarching goals. All organizations may apply. Applicants for HP2030 Champions shall submit a letter of interest and identify how they address or support health promotion, disease prevention, social determinants of health (SDOH), health disparities, health equity, and/or well-being and work in alignment with HP2030 through activities, donations, or other means. Applicants for HP2030 Champions will be evaluated according to the organization's commitment to support the overarching goals of Healthy People 2030 and the Healthy People 2030 objectives. Individuals are not eligible to be HP2030 Champions.

HP2030 Champions will receive recognition from ODPHP on *Health.gov/healthypeople2030,* a digital HP2030 Champion badge for their website to highlight their support of HP2030, and HP2030 information, tools and resources for dissemination.

The following activities may be considered as an organization's demonstrated commitment to HP2030's overarching goals and objectives:

- Promoting and increasing access to disease prevention and health promotion activities;
- Providing access to training or certification programs for disease prevention and health promotion;
- Addressing SDOH, eliminating disparities, achieving health equity, and/or promoting well-being;
- Providing training and other necessary resources to adapt or modify disease prevention and health promotion activities to meet the needs of diverse populations, address SDOH, eliminate disparities, achieve health equity, and/or promote well-being;
- Developing partnerships across a variety of sectors, including business, community, academia, education, faith-based, government, health care, media, public health, and technology;
- Working across sectors to address SDOH, eliminate disparities, and achieve health equity;
- Evaluating health promotion and disease prevention programs or partnering with academic institutions or public health organizations to evaluate health promotion and disease prevention activities;
- Including information in their public facing materials about programs for disease prevention, health promotion, addressing SDOH, eliminating disparities, achieving health equity, and/or promoting well-being in community needs assessments;
- Adopting or implementing the HP2030 framework (*i.e.,* vision, mission, overarching goals, foundational principles), Leading Health Indicators (LHIs), Overall Health and Well-Being Measures (OHMs) and/or HP2030 objectives in their strategic plan;
- Promoting HP2030; providing opportunities and venues for disease prevention and health promotion activities;
- Partnering with national, state, tribal, or local volunteer organizations to provide education, training, or programs regarding health promotion, disease prevention, SDOH, health disparities, health equity, and well-being;
- Supporting an entity with the responsibility to organize and coordinate efforts within and across sectors to foster health promotion and well-being;
- Promoting collaboration across all levels, including neighborhoods, communities, tribes, cities, states, counties, and localities, to increase and expand participation in health