information collection plan is designed to allow CDC to conduct formative research information collection activities for developing new tools and methodologies to support agency research, surveillance, program evaluation, communications, health promotion, and research project development. It helps researchers identify and understand the characteristics of target populations that influence their decisions and actions.

Formative research is integral in developing programs as well as improving existing and ongoing programs. Formative research looks at the community in which a public health intervention is planned or will be implemented and helps the project staff understand the interests, attributes and needs of different populations and persons in that community. Formative research occurs before a program is designed and implemented, or while a program is being conducted.

CDC conducts formative research to develop public-sensitive and effective communication messages and data collection tools. To develop scientifically valid and appropriate methods, interventions, and instruments, cycles of interviews and focus groups are designed to inform the development of a product.

Products from these formative research studies will be used for prevention of illness and disease. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC's health communication takes place within campaigns that have fairly lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development process.

This request may include studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced.

This request may include the collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to the identified needs.

Overall, these development activities are intended to provide information that will increase the success of surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: (1) Structured and qualitative interviewing for surveillance, research, interventions and material development, (2) cognitive interviewing for development of specific data collection instruments, (3) methodological research (4) usability testing of technology-based instruments and materials, (5) field testing of new methodologies and materials, (6) investigation of mental models for health decision-making, to inform health communication messages, and (7) organizational needs assessments to support development of capacity. Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements.

In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation of respondents is voluntary. There is no cost to participants other than their time. Annual estimated burden is 18,750 hours.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (Hrs.)
General public and health care providers.	Screener	5,000	1	15/60	1,250
	Interview	5,000	1	1	5,000
	Focus Group Interview	5,000	1	2	10,000
	Survey	5,000	1	30/60	2,500

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–25601 Filed 10–21–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3180–N4]

Food and Drug Administration

[Docket No. FDA–2010–N–0308]

Program for Parallel Review of Medical Devices

AGENCY: Food and Drug Administration; Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) (the Agencies) are informing the public that the Parallel Review of medical devices pilot program will be fully implemented and extended indefinitely. The Agencies are soliciting nominations from manufacturers of innovative medical devices to participate in the ''Program for Parallel Review of Medical Devices.'' The Parallel Review program is a collaborative effort that is intended to reduce the time between FDA marketing approval or FDA's granting of a de novo request and Medicare coverage decisions through CMS's National Coverage Determination (NCD)

process. This program is intended to ensure prompt and efficient patient access to safe and effective and appropriate medical devices for the Medicare population.

DATES: The program described in this document for parallel review for medical devices is effective October 24, 2016. The program will be fully implemented as of the date of the publication of this document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: *For device manufacturers interested in Parallel Review and for general questions:* Murray Sheldon, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5443, *Parallel-Review@fda.hhs.gov. For questions related to devices reviewed by Center for Biologics Evaluation and Research:* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911. *For general questions about the NCD process:* Tamara Syrek Jensen, Centers for Medicare and Medicaid Services, 410–786–3529, *Tamara.SyrekJensen@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Parallel Review Pilot Program's History

As discussed in the September 17, 2010, **Federal Register** notice (75 FR 57045), the Agencies announced their intention to initiate a Parallel Review pilot program that would establish a process for overlapping evaluation of clinical evidence for premarket, FDA-regulated medical devices in order to reduce the time between FDA marketing approval or FDA's granting of a de novo request and a Medicare NCD. The Agencies piloted the program in an effort to increase quality of patient health care by facilitating earlier access to innovative medical technologies for Medicare beneficiaries.

In the October 11, 2011, **Federal Register** notice (76 FR 62808), the Agencies provided notice of the procedures for voluntary participation in the pilot program as well as the guiding principles they intended to follow during the program. In the December 18, 2013, **Federal Register** notice (78 FR 76628), the Agencies extended the duration of the pilot program for an additional 2 years.

Currently, the Agencies appreciate the full potential of the parallel review program and realize the positive impact of the pilot, and have now decided to transition into a permanent program.

B. Purpose of Parallel Review

Parallel Review allows both Agencies to review information about a medical device concurrently, rather than sequentially, while continuing to make their premarket review and coverage decisions consistent with their respective statutory authority. FDA works to ensure that only safe and effective medical devices are marketed in the United States. CMS makes coverage decisions for medical technologies, which are reasonable and necessary for the Medicare population. Neither FDA's premarket review criteria nor CMS's coverage processes criteria change when a medical device is accepted into the parallel review program.

C. Lessons Learned From the Parallel Review Pilot Program

The Agencies learned two primary lessons from the Parallel Review pilot program. First, they found that manufacturers benefit from engaging both Agencies at the pivotal clinical trial design phase. The feedback that manufacturers receive from both Agencies at the pivotal clinical trial design stage can assist manufacturers in designing pivotal trials that can answer both Agencies' evidentiary questions. Thus, it is more likely that manufacturers will only need to conduct a single pivotal clinical study rather than several pivotal clinical studies to satisfy both Agencies.

Second, concurrent review by the Agencies of clinical evidence can reduce the time from FDA premarket approval or the granting of a de novo request to an NCD. For example, on August 11, 2014, FDA approved a medical device that was part of the Parallel Review Pilot Program. On the same day, CMS initiated its national coverage analysis (NCA). CMS published a favorable final NCD on October 9, 2014, less than 2 months after the medical device received its premarket approval and 7 months before the NCD statutory due date.

II. Parallel Review Program

Based on the positive experience from the Parallel Review Pilot Program, both Agencies have decided to extend the Parallel Review program indefinitely.

A. Parallel Review Process

The program has two stages: (1) The pivotal clinical trial design development stage, and (2) the concurrent evidentiary review stage. The manufacturer should submit a request for parallel review prior to the start of the first stage by sending an email to *Parallel-Review@fda.hhs.gov,* which indicates their interest in the program and includes the following information:

1. Nomination of manufacturer:
- Name of the manufacturer and relevant contact information;
- name of the product;
- succinct description of the technology and disease or condition the device is intended to diagnose or treat; and
- state of development of the technology (that is, in pre-clinical testing, in clinical trials, currently undergoing premarket review by FDA)

2. A statement that the manufacturer intends to meet jointly with FDA and CMS using FDA's Pre-Submission program (Ref. 1), or other mechanisms that allow for meetings of the three parties to gather and incorporate feedback from both Agencies about the design and analysis of their pivotal clinical trial, to support a marketing application and a National Coverage Determination.

3. A statement that the medical device will require an original or supplemental application for premarket approval (PMA) or the granting of an FDA de novo request;

4. The medical device is not excluded by statute from Part A and/or Part B Medicare coverage (and the request for parallel review includes a list of Part A and/or Part B Medicare benefit categories, as applicable, into which the manufacturer believes the medical device falls); and

5. A statement that the medical device addresses the public health needs of the Medicare population (and the request for parallel review includes an explanation of how).

Upon completion of the pivotal trial and submission of an original or supplemental PMA, or a de novo request, the Agencies intend to review the pivotal clinical trial evidence concurrently (''in parallel''). Both Agencies will independently review the data to determine whether it meets their respective Agency's standards and communicate with the manufacturer during their respective reviews.

Manufacturers and each Agency have the option to withdraw from the Parallel Review Program until CMS opens the NCD by posting a tracking sheet. For example, if the manufacturer would like to withdraw from the program after the pivotal trial, but before the NCA tracking sheet is posted, that would be acceptable. More information on the NCD process is set forth in the August 7, 2013 **Federal Register** notice (78 FR 48164). Once a tracking sheet is posted, CMS must complete the statutorily defined NCD process.

B. Candidate Prioritization

The Agencies intend to review Parallel Review requests and respond within 30 days after receipt of the email. The Agencies intend to prioritize innovative medical devices that will benefit from the efficiencies of the Parallel Review. Priority will also be given to medical devices expected to have the most impact on the Medicare population. An FDA marketing approval does not guarantee a favorable coverage decision.

III. Paperwork Reduction Act of 1995

As stated in previous **Federal Register** notices related to the Parallel Review pilot, due to FDA and CMS resource issues, the permanent program will follow the same capacity limit by accepting no more than five candidates per year. As such, like the pilot program, this collection of information does not meet the definition of an information collection, as defined under 44 U.S.C. 3501–3520.

IV. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff.'' Available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.*

Dated: October 18, 2016.

Leslie Kux,

Associate Commissioner for Policy, Food and Drug Administration.

Dated: October 5, 2016.

Andy Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–25659 Filed 10–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0663]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 (the PRA).

DATES: Fax written comments on the collection of information by November 23, 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 0910–0672. Also include the FDA docket number found in brackets in the heading of this document.

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans; OMB Control Number 0910–0672—Extension

In the **Federal Register** of October 31, 2013 (78 FR 65338), FDA published a document entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.'' The document clarified the Agency's expectations for timely review, evaluation, and submission of relevant and useful safety information and implemented internationally harmonized definitions and reporting standards for IND safety reports. The document also required safety reporting for bioavailability and bioequivalence studies. The document was intended to improve the utility of Investigational New Drug (IND) safety reports, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, and harmonize safety reporting requirements internationally.

The rulemaking included the following information collection under the PRA that was not already included in 21 CFR 312.32 and approved under OMB control number 0910–0014.

Section 312.32(c)(1)(ii) and (c)(1)(iii) requires reporting to FDA, in an IND safety report, of potential serious risks from clinical trials within 15 calendar days for findings from epidemiological studies, pooled analyses of multiple studies, or other clinical studies that suggest a significant risk in humans exposed to the drug.

Section 312.32(c)(1)(iii) specifies the requirements for reporting to FDA in an IND safety report potential serious risks from clinical trials within 15 calendar days for findings from in vitro testing that suggest a significant risk to humans.

Section 312.32(c)(1)(iv) requires reporting to FDA in an IND safety report within 15 calendar days of any clinically important increase in the rate of occurrence of serious suspected adverse reactions over that listed in the protocol or investigator brochure.

The rulemaking also included new information collection under the PRA by requiring safety reporting for bioavailability and bioequivalence studies (21 CFR 320.31(d)).

In tables 1 and 2 of this document, the estimates for ''No. of Respondents,'' ''No. of Responses per Respondent,'' and ''Total Annual Responses'' were obtained from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) reports and data management systems for submissions received in 2013, 2014, and 2015, and from other sources familiar with the number of submissions received under the noted 21 CFR section. The estimates the ''Hours per Response'' are unchanged based on information from CDER and CBER individuals familiar with the burden associated with these reports and from prior estimates received from the pharmaceutical industry.

In the **Federal Register** of March 18, 2016 (81 FR 14860), we published a 60-day notice requesting public comment on the proposed extension of this