experimental designs in order to capture how different questions function in a field setting. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations.

In 2021–2024, NCHS/CCQDER staff plan to continue research on methods evaluation and general questionnaire design research. We envision that over the next three years, NCHS/CCQDER will work collaboratively with survey researchers from universities and other Federal agencies to define and examine several research areas, including, but not limited to: (1) Differences between face-to-face, telephone, and virtual/video over internet cognitive interviewing, (2) effectiveness of different approaches to cognitive interviewing, such as concurrent and retrospective probing, (3) reactions of both survey respondents and survey interviewers to the use of Computer-Assisted Personal Interviewing (CAPI), Audio Computer-Assisted Self-Interview (ACASI), video over internet/virtual, (4) social, cultural and linguistic factors in the question response process, and (5) recruitment and respondent participation at varying levels of incentive in an effort to establish empirical evidence regarding remuneration and coercion. Procedures for each of these studies will be similar to those applied in the usual testing of survey questions. For example, questionnaires that are of current interest (such as RANDS and NIOSH) may be evaluated using several of the techniques described above. In addition, different versions of a survey question will be developed, and the variants then administered to separate groups of respondents in order to study the cognitive processes that account for the differences in responses obtained across different versions.

These studies will be conducted either by CCQDER staff, DHHS staff, or NCHS contractors who are trained in cognitive interviewing techniques. The results of these studies will be applied to our specific questionnaire development activities in order to improve the methods that we use to conduct questionnaire testing, and to guide questionnaire design in general.

OMB approval is requested for three years. Participation is voluntary. We are requesting 9,455 annualized hours, totaling 28,365 over three years. This is an increase of 1,672 hours per year or 5,016 hours over three years. The requested increases are due to an anticipated increase in the number and size of projects being undertaken.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals or households	Eligibility Screeners	4,400	1	5/60
Individuals or households	Developmental Questionnaires	8,750	1	55/60
Individuals or households	Respondent Data Collection Sheet	8,750	1	5/60
Individuals or households	Focus Group Documents	225	1	90/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17349 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–1880 and CMS–1856]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 13, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Request for Certification as Supplier of Portable X-Ray Services under the Medicare/Medicaid Program; *Use:* CMS–1880 is initially completed by suppliers of portable X-ray services, expressing an interest in and requesting participation in the Medicare program. The CMS–1880 form initiates the process of obtaining a decision as to whether the conditions of coverage are met by the portable X-ray supplier seeking Medicare participation. It also promotes data reduction or introduction to, and retrieval from, the Certification and Survey Provider Enhanced Reporting (CASPER) by the CMS Regional Offices (ROs). The CMS–1880 form is also completed by current Medicare participating portable x-ray supplier during each recertification survey. *Form Numbers:* CMS–1880 (OMB control number: 0938–0027); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 104; *Total Annual Responses:* 104; *Total Annual Hours:* 26. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Certification in the Medicare/Medicaid Program for Provides of Outpatient Physical Therapy and/or Speech-Language Pathology; *Use:* The form is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process of obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy and/or speech-language pathology services. The form is used by the State Agencies (SAs) to enter the new prospective provider into the national surveyor database. The form is also used for recertification of the provider. Surveyors are no longer required to use form CMS–1856. Surveyors are now able to access survey resources electronically from the national surveyor database, as a result, the need for surveyors to carry printed copies of the survey information data is no longer efficient. *Form Number:* CMS–1856 (OMB control number: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 195; *Total Annual Responses:* 195; *Total Annual Hours:* 49. (For policy questions regarding this collection contact Caecilia Blondiaux at 410–786–2190.)

Dated: August 10, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–17374 Filed 8–12–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1245]

Drug Products Approved in Abbreviated New Drug Applications Before the Enactment of the Hatch-Waxman Amendments; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to solicit comments on several issues related to FDA's post-approval regulation of certain drug products approved in abbreviated applications before the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish the current abbreviated new drug application (ANDA) process. Because these pre-Hatch-Waxman abbreviated new drug applications (referred to in this notice as ''PANDAs'') were submitted and approved under the provisions of the FD&C Act that apply to 505(b) new drug applications, they can serve as a reference listed drug (RLD) for ANDAs and can also be a listed drug relied on by 505(b)(2) applications. PANDAs have historically been overseen by FDA's Office of Generic Drugs, and FDA is aware that there may be some confusion about the applicability of certain statutory and regulatory provisions to PANDAs. FDA is seeking input from holders of PANDAs and other interested persons regarding whether there are regulatory or policy rationales for treating PANDAs differently from other 505(b) applications in certain respects.

DATES: Submit either electronic or written comments by December 13, 2021.

ADDRESSES: FDA is establishing a docket for public comments on this document. The docket number is FDA–2020–N–1245. The docket will close on December 13, 2021. Submit either electronic or written comments by that date. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 13, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows: