for the Approval of Respirators (SAF), currently Version 9.

Respirator manufacturers are the respondents (estimated to average 73 each year over the years 2017–2020). Upon submission of the SAF, NIOSH evaluates their applications for approval. Respirator manufacturers submit applications according to their business needs, which depends upon market conditions, technical advances, and other factors that are not easy to forecast. The best estimate for the annual number of respondents is the number from the most recent year for which data exists, 73 in 2016, an increase from 63 in 2014. Those 73 applicants submitted 542 applications in 2016, providing the current best estimate. A $200 fee is required for each application. Respondents requesting respirator approval or certain extensions of approval are required to submit additional fees for necessary testing and evaluation as specified in 42 CFR parts 84.20–22, 84.66, 84.258 and 84.1102. In 2016, $2,662,329.00 was accepted.

Applicants are required to provide test data that shows that the manufacturer is capable of ensuring that the respirator is capable of meeting the specified requirements in 42 CFR part 84. The requirement for submitted test data is likely to be satisfied by standard testing performed by the manufacturer, and is not required to follow the relevant NIOSH Standard Test Procedures. As additional testing is not required, providing proof that an adequate test has been performed is limited to providing existing paperwork.

Manufacturers with current approvals are subject to site audits by the Institute or its agents. Audits may occur periodically, typically every second year, or because of a reported issue. NIOSH completed 59 site audits from 92 respirator approval holders for the 2016 fiscal year. There is an average fee of $8,833 for each audit to align with fee collection provisions of the Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701), and OMB Circular A–25 Revised. There is no cost to respondents other than the time to participate. The total estimated burden hours are 118,435. Burden hours have increased due to a moderate increase in the estimated number of annual responses per respondent.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Business or other for-profit	Standard Application for the Approval of Respirators.	73	7	229
Business or other for-profit	Audit	59	1	24

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. 2018–03385 Filed 2–16–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Redesign of Existing Data Collection; National Longitudinal Survey of Older Americans Act Participants (NLSOAAP)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995 (the PRA). This 30-Day notice collects comments on a proposed revision to an existing data collection related to the National Survey of Older Americans Act Participants (NSOAAP).

DATES: Submit written comments on the collection of information by March 22, 2018.

ADDRESSES: Submit written comments on the collection of information by fax 202–395–5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Heather Menne at 202–795–7733 or *Heather.Menne@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with Section 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

ACL is requesting approval for three years for a redesign of an existing data collection (OMB Control Number: 0985–0023).

The National Longitudinal Survey of Older Americans Act (OAA) Participants (NLSOAAP) information collection will include consumer assessment surveys for the Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services; and the National Family Caregiver Support Program. This survey builds on earlier national pilot studies and surveys, as well as performance measurement tools developed by ACL grantees in the Performance Outcomes Measures Project (POMP). Changes identified as a result of these initiatives, public comment, and the input from an expert panel (*i.e.,* comprised of gerontologists, survey methodologists, and OAA program experts), are included in this proposed redesign of an existing data collection. This information will be used by ACL to track performance outcome measures; support budget requests; comply with the GPRA Modernization Act of 2010 (GPRAMA) reporting requirements; provide national benchmark information; and inform program development and management initiatives.

This proposed collection is a revision that will replace the currently approved version (OMB Control Number: 0985–0023) by transitioning from a cross-sectional survey to a longitudinal survey. The current National Survey of Older Americans Act Participants (NSOAAP), an exclusively cross-sectional survey, can transition to a longitudinal information collection component by establishing a baseline cohort and conducting follow-up interviews with that cohort at specified time intervals. A baseline cohort can be selected in the same manner as in prior cycles of the cross-sectional NSOAAP.

Area Agencies on Aging (AAAs) would be selected with a probability proportional to their size, with some large AAAs sampled with certainty.

Random samples of clients within each selected AAA will be sampled from the agencies' client lists. However, in a change from current procedures, the target sample size would be increased from current standards (n = 6000) to account for attrition of individuals over time. For the duration of the longitudinal cohort analysis, the same sample of AAAs and clients should be maintained to preserve the longitudinal nature of the study. Three strategies are key for transforming the current survey into a longitudinal study, while preserving the ability to produce nationally representative cross-sectional estimates of client characteristics at each wave. The three strategies include: (1) A higher initial sample size (n = 6600), (2) an intensive operational campaign to keep track of respondents over time, and (3) limiting the number of waves for each cohort study (*e.g.,* three waves are proposed).

Comments in Response to the 60 Day Federal Register Notice

A 60-Day notice was published in the **Federal Register** in Vol. 82, No. 185, Pages 44800–44802, on September 26, 2017 announcing that ACL was requesting approval of a proposed redesign of an existing data collection extension with modifications of a currently approved data collection. ACL received comments from sixty-four (64) organizations and 15 individuals about the Redesigned National Survey of Older Americans Act Participants (NSOAAP). ACL reviewed all of the comments. Two (2) of the comments were deemed not relevant. The first referenced other data collections and not the NSOAAP (*i.e.,* Census), and the other was commentary without reference to the NSOAAP.

The majority of the comments that ACL received requested improved methodology for collecting gender identity (*e.g.,* adding questions to understand gender identity/transgender status). ACL plans to conduct cognitive testing of questions in the redesigned information collection tool, including the gender question, to determine whether the questions are interpreted as intended. Based on the cognitive testing of the information collection tool, ACL will determine whether additional changes are necessary. Other public comments supported the: (a) Longitudinal methodology; (b) collection of data on sexual orientation; (c) inclusion of a rotating module on discrimination; and (d) limiting of burden on the Area Agencies on Aging (AAAs). Because these comments were in support of the proposed information collection, no response is needed.

Burden Estimates

Descriptions of previous National Surveys of OAA Participants can be found under the section on Performance Outcomes on ACL's website at: *https://www.acl.gov/programs/performance-older-americans-act-programs.* Copies of the survey instruments and data from previous National Surveys of OAA Participants can be found and queried using the AGing Integrated Database (AGID) at *https://agid.acl.gov/.* The proposed revisions for the National Survey of Older Americans Act Participants may be found on the ACL website at: *https://www.acl.gov/about-acl/public-input.*

The estimated average hour burden per respondent for the Redesigned NSOAAP will change from the 0.80 hour estimate in 2017 to 0.71 hours. This decrease is due to the proposed change of Area Agencies on Aging only providing client lists once at the start of the three years of data collection (compared to annually in the current cross-sectional data collection). ACL estimates the burden of this revised collection of information as follows:

TABLE—ESTIMATED ANNUALIZED BURDEN HOURS

Respondent/data collection activity	Number of respondents	Responses per respondent	Average hours per response	Annual burden hours
Baseline				
Area Agency on Aging: Respondent selection process	250	1	4.0	1,000
Service Recipients (i.e., Case Management; Congregate Nutrition; Home-delivered Nutrition; Homemaker; Transportation).	4,400	1	.6667	2,933
National Family Caregiver Support Program Clients	2,200	1	.6667	1,467
Year 2				
Area Agency on Aging: Respondent selection process	0	0	0	0
Service Recipients (i.e., Case Management; Congregate Nutrition; Home-delivered Nutrition; Homemaker; Transportation).	4,200	1	.6667	2,800
National Family Caregiver Support Program Clients	2,100	1	.6667	1,400
Year 3				
Area Agency on Aging: Respondent selection process	0	0	0	0
Service Recipients (i.e., Case Management; Congregate Nutrition; Home-delivered Nutrition; Homemaker; Transportation).	4,000	1	.6667	2,667
National Family Caregiver Support Program Clients	2,000	1	.6667	1,333
Total	19,150	Varies	.710 (weighted mean).	13,600

Dated: February 13, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–03390 Filed 2–16–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–1891]

Determination of Regulatory Review Period for Purposes of Patent Extension; PORTRAZZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for PORTRAZZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 23, 2018. 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 by August 20, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 23, 2018. 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.

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:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–E–1891 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; PORTRAZZA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase