

Finally, the National Adult Protective Services Association (NAPSA) conducted a survey of State APS programs in 2012, and the National Association of State Units on Aging and Disability (NASUAD) fielded a survey to its members, which are not APS programs, in January 2018 intended to update findings from the NAPSA 2012 survey. Since the survey replicates the original NAPSA survey, the questions in it are not focused on APS practice and are not directed at the same respondents as the proposed survey. As noted, a few topics in the original survey overlap with the proposed instrument, but the wording and focus of the few questions on similar topics are different. From this analysis, we conclude the proposed APS Practice Survey will yield vital information on APS practice not available from other sources.

**Proposed Collection Efforts**

The APS Practice Survey will collect state- and territory-specific practices for

all aspects of APS casework practice, including staffing, intake, investigation, service planning and delivery, and quality assurance. Across these areas, the survey will collect information on practices such as community partnerships and use of assessment tools.

The APS Practice Survey will be administered online using SurveyMonkey or a similar commercial survey-programming tool. The online survey will include data validation routines to minimize errors or unintentional omissions and will include appropriate skip patterns to reduce burden. Respondents will be state and territory APS agencies, including APS agencies in the District of Columbia, Puerto Rico, Guam, Northern Marianas Islands, Virgin Islands, and American Samoa. No personally identifiable information will be collected.

A pilot version of The APS Practice Survey was tested in nine (9) diverse

states between July and September 2017. Following their pretest of the survey instrument, pilot respondents participated in focus groups in which they provided recommendations on data collection procedures, views on the availability of data being requested, and estimates of the burden to each state and territory for completion of the survey. It is assumed that nearly every state and territory will participate and that time to develop a response will be similar to the experience of states during the pilot test. ACL has calculated the following burden estimates based on the results of the survey pilot test.

To review and comment on the proposed data collection, please visit the ACL public input site at <https://www.acl.gov/about-acl/public-input>.

**Estimated Program Burden**

ACL estimates the annual burden associated with this collection of information as follows:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
APS Practice Survey .....	56	1	3.50	196

*Estimated Total Annual Burden Hours: 196.*

Dated: November 25, 2020.

**Lance Robertson,**

*Administrator and Assistant Secretary for Aging.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-N-1671]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice for Nonclinical Laboratory Studies**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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:** Submit written comments (including recommendations) on the collection of information by December 31, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0119. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRStaff@fda.hhs.gov](mailto:PRStaff@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.

**Good Laboratory Practice for Nonclinical Laboratory Studies—21 CFR Part 58**

*OMB Control Number 0910-0119—Extension*

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification,

and include information collection provisions.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall

interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

In the **Federal Register** of July 24, 2020 (85 FR 44900), FDA published a 60-day notice requesting public

comment on the proposed collection of information.

One comment was received that encouraged implementation of automated collection methods and analytical software to evaluate results. FDA appreciates this comment and continually seek ways to employ efficient collection methods using our limited resources. The comment suggested no revision to our burden estimate.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
58.35(b)(7); Quality assurance unit	300	60.25	18,075	1	18,075
58.185; Reporting of nonclinical laboratory study results	300	60.25	18,075	27.65	499,774
<b>Total</b>					<b>517,849</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
58.29(b); Personnel	300	20	6,000	.21 (13 minutes)	1,260
58.35(b)(1)–(6) and (c); Quality assurance unit	300	270.76	81,228	3.36	272,926
58.63(b) and (c); Maintenance and calibration of equipment.	300	60	18,000	.09 (5 minutes)	1,620
58.81(a)–(c); SOPs	300	301.80	90,540	.14 (8 minutes)	12,676
58.90(c) and (g); Animal care	300	62.70	18,810	.13 (8 minutes)	2,445
58.105(a) and (b); Test and control article characterization.	300	5	1,500	11.8	17,700
58.107(d); Test and control article handling	300	1	300	4.25	1,275
58.113(a); Mixtures of articles with carriers	300	15.33	4,599	6.8	31,273
58.120; Protocol	300	15.38	4,614	32.7	150,878
58.195; Retention of records	300	251.50	75,450	3.9	294,255
<b>Total</b>					<b>786,308</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, FDA has made no adjustments to our burden estimate.

Dated: November 24, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2019–N–1845]

**Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain; Establishment of a Public Docket; Request for Comments; Reopening of the Comment Period and Provision of Additional Information and Analysis**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is reopening the comment period for and providing additional information and analysis regarding the notice entitled “Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain; Establishment of a Public Docket; Request for Comments” that appeared in the **Federal Register** of May 31, 2019. The Agency is taking this action to provide additional information and to allow