

review and clearance. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on March 22, 2016.

**Authority:** This data collection effort is in response to the Elder Justice Act of 2009, which amended title XX of the Social Security Act (42.U.S.C. 13976 *et seq.*). These provisions require that the Secretary of HHS “collects and disseminates data annually relating to the abuse, exploitation, and neglect of elders in coordination with the Department of Justice” (Sec. 2041(a)(1)(B)), and “conducts research related to the provision of adult protective services” (Sec. 2041(a)(1)(D)). Furthermore, the Elder Justice Coordinating Council (EJCC) included as its third recommendation for increasing federal involvement in addressing elder abuse, neglect, and exploitation: Develop a national adult protective services (APS) system based upon standardized data collection and a core set of service provision standards and best practices.

**Background:** From 2013–2015, ACL, in partnership with the U.S. Department of Health & Human Services’ Office of the Assistant Secretary for Planning and Evaluation (ASPE), developed and pilot

tested NAMRS. When implemented, NAMRS will be the first comprehensive, national reporting system for APS programs. NAMRS is intended to collect quantitative and qualitative data on the practices and policies of adult protective services (APS) agencies, as well as the outcomes of investigations into the maltreatment of older adults and adults with disabilities. In developing NAMRS, ACL and ASPE convened key stakeholders to identify data elements that are the most critical for a national system. More than 40 state administrators, researchers, service providers, and other stakeholders provided input in focus group conference calls. Additionally, more than 30 state representatives from 25 different states met in three in-person working sessions to discuss the uses of collected data and the key functionalities. A pilot version of NAMRS was tested in nine (9) diverse states, and refined based on feedback from the pilot and additional stakeholder engagement. A full discussion on the background of NAMRS, including the development of the system, the public engagement process, and the pilot testing can be found in the NAMRS section of the ACL Web site.

**Proposed Collection Effort:** NAMRS has been developed as a voluntary system to collect annually both summary and de-identified case-level data on APS investigations. NAMRS consists of three components:

- (1) ACL proposes to collect descriptive data on state agency policies and practices from all states through the “Agency Component,” and
- (2) Case-level, non-identifiable data on persons who receive an investigation by APS in response to an allegation of abuse, neglect, or exploitation through the “Case Component.”
- (3) For states that are unable to submit a case-level file through the “Case Component,” a “Key Indicators Component” will be available for them to submit data on a smaller set of core items.

ACL will provide technical assistance to states to assist in the preparation of their data submissions. Respondents will be state APS agencies and 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. ACL has calculated the following burden estimates (information on how the estimates were calculated is available in the NAMRS section of the ACL Web site):

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Agency Component .....	56	1	13	728
Key Indicators Component .....	31	1	40	1,240
Case Component .....	25	1	150	3,750
Estimated Total Annual Burden Hours .....	.....	.....	.....	5,718

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication of this announcement. Written comments and recommendations for the proposed information collection should be sent directly to the following address: Office of Management and Budget, Paperwork Reduction Project, email: [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV); Attention: Desk Officer for the Administration for Community Living.

With respect to the collection of information via NAMRS, ACL specifically requests comments on:

- (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency,

including whether the information shall have practical utility;

- (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information;

- (c) the quality, utility, and clarity of the information to be collected; and

- (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Consideration will be given to comments and suggestions submitted within 30 days of this publication. The proposed collection of information tools may be found in the NAMRS section of the ACL Web site.

Dated: August 2, 2016.  
**Edwin L. Walker,**  
*Acting Assistant Secretary for Aging.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–N–0566]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Alumni Commissioner’s Fellowship Program Fellows**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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:** Fax written comments on the collection of information by September 7, 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 title Outcomes Evaluation Survey for Graduates of the FDA Commissioner's Fellowship Program. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@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.

**Survey of Alumni Commissioner's Fellowship Program Fellows—OMB Control Number 0910-NEW**

FDA is requesting approval from the Office of Management and Budget to gather information from Alumni Commissioner's Fellowship Program (CFP) Fellows. The information from Alumni CFP Fellows will allow FDA's Office of the Commissioner (OC) to easily and efficiently elicit and review program feedback. The online survey will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their experience with the FDA while a Commissioner's Fellow. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of

surveys being misrouted within the Agency mail system. The information gathered by the survey will be used to gain insights into, and to document, impacts that the CFP has had and is having on former CFP fellows and contributions and impacts that the former fellows are making in their current work. The surveys include questions to assess the following measures: Post-fellowship employment (*e.g.*, employment type); number of awards; number of contributions while a CFP fellow (*e.g.*, number of publications, guidances authored or co-authored); and contributions in their field (*e.g.*, list of publications).

In the **Federal Register** of February 24, 2016 (81 FR 9202), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Fellowship Program Survey .....	35	1	35	0.50 (30 minutes) .....	17.5

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

FDA based these estimates on the number of fellows that have graduated and left the Agency over the past 5 years.

Dated: August 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-2062]

**Determination That BENTYL (Dicyclomine Hydrochloride) Syrup and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or

effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:**

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993-0002, 301-796-8363, *Stacy.Kane@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved.

ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under