coverage through the Exchange. The BHP gives States the ability to provide more affordable coverage for these low-income residents and improve continuity of care for people whose income fluctuates above and below Medicaid and Children's Health Insurance Program (CHIP) levels. This iteration proposes to revise the active collection of information instruments and (in line with sections 71301 and 71302 of the Working Families Tax Cut legislation) remove State eligibility for BHP funding attributable to certain non-citizens while maintaining BHP program eligibility for the same non-citizens. *Form Number:* CMS–10510 (OMB control number: 0938–1218); *Frequency:* Monthly and annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 4*; Number of Responses:* 55; *Total Annual Hours:* 7,744. For policy questions regarding this collection contact Carrie Grubert 410–786–8319.

3. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2028 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All-Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private Sector—Not-for-profit institutions and Business or other for-profits; *Number of Respondents:* 750; *Total Annual Responses:* 380; *Total Annual Hours:* 1,643.47. (For policy questions regarding this collection contact April Forsythe at 410–786–8493 or *April.Forsythe@cms.hhs.gov.*)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0NEW]

Emergency Office of Management and Budget Review and Public Comment: Questionnaire for the Refugee Outreach and Well-Being Initiative

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services, is requesting emergency review of an information collection request from the Office of Management and Budget (OMB) and inviting public comments on and extension to the proposed collection. This questionnaire is used during brief telephone interviews with Afghan arrivals who might have received ORR benefits and services, to identify any additional service needs that may support assimilation, self-sufficiency, and citizenship for eligible populations.

DATES: Comments due November 2, 2026. As an emergency approval, this questionnaire will be approved for use immediately. Comments will be considered for the following extension request.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is requesting that OMB grant 180-day approval for this request under procedures for emergency processing (see 5 CFR 1320.13). If ORR cannot collect this information quickly, vulnerable Afghan families who need additional support may face significant harm, including loss of income, unstable housing, food insecurity, or loss of immigration status. Emergency clearance ensures ORR can rapidly identify needs and intervene, as appropriate, before these situations worsen.

In compliance with the PRA, ACF will request review under normal procedures within 180 days of the approval for this request. Any edits resulting from public comment will be incorporated into the submission under normal procedures.

The questionnaire requests information to inform ORR's understanding of the current needs and service access of resettled Afghan individuals and families. ORR intends to use the information to:

- Identify common challenges (*e.g.,* housing, employment, access to critical support);
- Assess whether additional resources are necessary to support assimilation, pathways to citizenship, and self-sufficiency, and help with identified vulnerabilities;
- Inform technical assistance to resettlement agencies and interagency coordination; and
- Inform Department and White House leadership on trends and the current challenges that this population faces as they work toward successful assimilation.

Personally identifiable information will be collected solely for the purpose of confirming cases that were interviewed. This information will be used to verify client identities and confirm their current locations to ensure they can access appropriate services, and, when appropriate and permitted by law, information provided by respondents may also be shared with other government entities or service providers, including ORR grantees, to facilitate referrals to available services or inform the development of additional services or resources.

ORR may have situations in the future for which this survey may be useful for

additional populations. If necessary, ORR will work with OMB to reflect updates to the survey or respondents through revision or nonsubstantive change requests.

As an emergency approval, this questionnaire will be approved immediately. Comments will be considered for the following extension request, if pursued.

Respondents: Afghans who might have received ORR benefits and services.

Annual Burden Estimates: Semi-structured telephone interviews will be conducted with Afghans who received ORR benefits and services and are likely to have additional assistance needs and vulnerabilities. Interviews will be based on available contact information. Phone interviews are voluntary and are expected to take about 30 minutes.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
ROWI Questionnaire	1,800	1	.50	900

Comments: The Department 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 60 days of this publication.

Authority: ORR is authorized to conduct this survey under the Refugee Act of 1980 (8 U.S.C. 1522(a)(3)).

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–6538]

Determination That NAMENDA (Memantine Hydrochloride) Tablets, 5 Milligrams and 10 Milligrams, 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, Agency, or we) has determined that NAMENDA (memantine hydrochloride) tablets, 5 milligrams (mg) and 10 mg, 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 the ANDAs meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, are the subject of NDA 021487, held by AbbVie Inc., and initially approved on October 16, 2003. NAMENDA is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Newcastle Bioscience LLC submitted a citizen petition dated June 5, 2026 (Docket No. FDA–2026–P–6538), under 21 CFR 10.30, requesting that the Agency determine whether NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, from sale. We have also independently evaluated