Respondent/data collection activity	Number of respondents (minimum)	Responses per respondent	Hours per response	Annual burden hours
Survey, Stratified Random Sample	600	1	5/60	50
Total	600	1	5/60	50

Respondent/data collection activity	Number of respondents (maximum)	Responses per respondent	Hours per response	Annual burden hours
Survey, Stratified Random Sample	5,400	1	5/60	450
Total	5,400	1	5/60	450

Dated: June 17, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–13576 Filed 6–23–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Participants of an Annual SMP/SHIP National Training Conference Hosted by the Office of Healthcare Information and Counseling [OMB #0985–New]

AGENCY: Administration for Community Living, HHS.

ACTION: Notice

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to Proposed new information collection requirements related to Evaluation of participants of an Annual SMP/SHIP National Training Conference hosted by the Office of Healthcare Information and Counseling.

DATES: Submit written comments on the collection of information by July 24, 2020.

ADDRESSES: Submit electronic comments on the collection of information by:

(a) Email to: *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Marissa Whitehouse, Administration for Community Living, Washington, DC 20201, *Marissa.Whitehouse@acl.hhs.gov* or 202–795–7425.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Office of Healthcare Information and Counseling (OHIC) hosts an annual national training conference for the federally funded programs that it administers. The audience for this training conference includes attendees from State Health Insurance Assistance Program (SHIP) and Senior Medicare Patrol (SMP) programs, which are two nationally recognized programs that provide Medicare information and counseling to Medicare beneficiaries and help, fight Medicare fraud through prevention and education. Grantee leadership is required to attend this training annually to ensure they receive critical information and technical assistance needed to help them successfully meet the requirements of their grant awards.

Grantees are encouraged to bring up to three (3) people from each program. Programs operate in each of the 50 states, the District of Columbia, Guam, Puerto Rico, and the US Virgin Islands. The information collected in this survey is necessary to ensure that ACL is meeting the technical assistance needs of the attendees and to capture valuable feedback to be used for future training meetings. By gathering feedback on the quality of the training and content provided, we can ensure attendee satisfaction and gather information for future planning. ACL administers a contract to develop and provide the training conference evaluation tool for ACL's approval. They also disseminate a tool to all participants following each training conference to evaluate attendee satisfaction. This training conference survey is introduced and explained during the program specific meetings and during the general session on the first day of the training conference. The survey is not mandatory, but is reinforced as a way for ACL to provide useful, engaging sessions that assist the attendees in successfully meeting the requirements of their grant awards. This evaluation tool will gather feedback on the quality of the training and content provided and the experience of the attendees to be used for future planning.

Comments in Response to the 60-Day Federal Register Notice

A 60-Day Notice s published in the **Federal Register** on February 7, 2020 Vol. 85 pages 7309–7310. ACL received one public comment during the 60-day public comment period; the public comment related to the current COVID–19 pandemic requesting the 2020 event be held virtually. Though it is essential for this event to be held in-person and to bring together national partners from across the country each year, this year's COVID–19 pandemic has halted all in-person event capability. ACL intends to hold the 2020 conference virtually.

For review and comment on this proposed information collection request, please visit the ACL website *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

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

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Conference Evaluation	364	1	15 minutes	91

Dated: June 17, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–13575 Filed 6–23–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–0813]

Determination That TENEX (Guanfacine Hydrochloride) Tablets, 1 Milligram, 2 Milligrams, and 3 Milligrams, Was 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 TENEX (guanfacine hydrochloride) tablets, 1 milligram (mg), 2 mg, and 3 mg, was 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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Jessica Tierney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–9120, *Jessica.Tierney@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 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 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.

TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, is the subject of NDA 019032, held by Promius Pharma LLC, and initially approved on October 27, 1996. TENEX is indicated in the management of hypertension.

TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Unichem Pharmaceuticals (USA), Inc. submitted a citizen petition dated February 13, 2020 (Docket No. FDA–2020–P–0813), under 21 CFR 10.30, requesting that the Agency determine whether TENEX (guanfacine hydrochloride) tablets, 1 mg and 2 mg, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 3 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

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 TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13594 Filed 6–23–20; 8:45 am]

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