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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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

mysoline (primidone) suspension, 250 mg/5 mL, is the subject of NDA 010401, held by FHTA LLC, and initially approved on July 5, 1956. mysoline, used alone or concomitantly with other anticonvulsants, is indicated in the control of grand mal, psychomotor, and focal epileptic seizures. It may control grand mal seizures refractory to other anticonvulsant therapy.

mysoline (primidone) suspension, 250 mg/5 mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated

December 8, 2022 (Docket No. FDA-2022-P-3118), under 21 CFR 10.30, requesting that the Agency determine whether mysoline (primidone) suspension, 250 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.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 mysoline (primidone) suspension, 250 mg/5 mL, was withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that mysoline (primidone) suspension, 250 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of mysoline (primidone) suspension, 250 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

mysoline (primidone) suspension, 250 mg/5 mL, was discontinued in 2001 after antimicrobial effectiveness testing raised concerns about potential microbial contamination, in particular with *Pseudomonas aeruginosa*. As a scientific matter, before mysoline (primidone) suspension, 250 mg/5 mL, could be considered for reintroduction to the market, a reformulation would be required including establishment of preservative content acceptance criteria and correlation with passing antimicrobial effectiveness testing results. The NDA holder for mysoline (primidone) suspension, 250 mg/5 mL, would have to demonstrate the safety and effectiveness of the reformulated product. At this time, no new formulation has been approved for mysoline (primidone) suspension, 250 mg/5 mL.

Accordingly, under § 314.162 the Agency will remove mysoline (primidone) suspension, 250 mg/5 mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-24196 Filed 12-31-25; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information

Collection Activity Under OMB Review: Pipeline Corporate Security Reviews and TSA Security Directive Pipeline-2021-02 Series

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0056, abstracted below, to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection allows TSA to assess the current security practices in the pipeline industry through TSA’s Pipeline Corporate Security Review (CSR) program and allows for the continuation of mandatory cybersecurity requirements under the TSA Security Directive (SD) Pipeline-2021-02 series.

DATES: Send your comments by February 2, 2026. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” and by using the find function.

FOR FURTHER INFORMATION CONTACT:

Christina A. Walsh, TSA PRA Officer, Information Technology, TSA-11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598-6011; telephone (571) 227-2062; email TSAPRA@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 1, 2025, 90 FR 36169. TSA did not receive any comments on the notice.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501

et seq.), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at <https://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Pipeline Corporate Security Reviews and TSA Security Directive Pipeline–2021–02 series.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0056.

Forms(s): Pipeline CSR Protocol Form and documents submitted to TSA pursuant to the requirements in the Security Directive.

Affected Public: Hazardous Liquids and Natural Gas Pipeline Industry.

Abstract: Under the Aviation and Transportation Security Act¹ and delegated authority from the Secretary of Homeland Security, TSA has broad responsibility and authority for “security in all modes of transportation . . . including security responsibilities . . . over modes of transportation that are exercised by the Department of Transportation.”² TSA is specifically empowered to assess threats to

¹ Public Law 107–71 (115 Stat. 597; Nov. 19, 2001), codified at 49 U.S.C. 114.

² See 49 U.S.C. 114(d). The TSA Administrator's current authorities under the Aviation and Transportation Security Act have been delegated to him by the Secretary of Homeland Security. Section 403(2) of the Homeland Security Act of 2002, Public Law 107–296 (116 Stat. 2135, Nov. 25, 2002), transferred all functions of TSA, including those of the Secretary of Transportation and the Under Secretary of Transportation of Security related to TSA, to the Secretary of Homeland Security. Pursuant to DHS Delegation Number 7060.2, the Secretary delegated to the Administrator of TSA, subject to the Secretary's guidance and control, the authority vested in the Secretary with respect to TSA, including that in section 403(2) of the Homeland Security Act.

transportation;³ develop policies, strategies, and plans for dealing with threats to transportation;⁴ oversee the implementation and adequacy of security measures at transportation facilities;⁵ and carry out other appropriate duties relating to transportation security.⁶ The Implementing Recommendations of the 9/11 Commission Act of 2007 included a specific requirement for TSA to conduct assessments of critical pipeline facilities.⁷

Establishing Compliance With Voluntary Pipeline CSR Program Information Collection Requirements

TSA has historically assessed industry security practices through its Pipeline CSR program.⁸ Pipeline CSRs are voluntary, face-to-face visits, usually at the headquarters facility of the pipeline Owner/Operator. TSA has developed a Question Set to aid in the conducting of CSRs. The CSR Question Set structures the TSA and pipeline Owner/Operator discussion and is the central data source for the physical security information TSA collects.

Establishing Compliance With Mandatory Requirements in the TSA SD Pipeline–2021–02 Series; Information Collection Requirements

While the CSR collection supports physical security plans and processes, TSA issued the SD Pipeline–2021–02 series with mandatory requirements in order to mitigate specific cybersecurity concerns posed by current threats to national security. Pipeline Owner/Operators designated by TSA as critical must:

- Submit a Cybersecurity Implementation Plan to TSA for approval (there is no designated form or format). Once approved by TSA, pipeline Owner/Operators must implement and maintain all measures. Owner/Operators must submit changes to their Cybersecurity Implementation Plan for approval in accordance with the instructions in the SD.

- Develop and maintain an up-to-date Cybersecurity Incident Response Plan for their designated critical cyber systems to reduce the risk of operational disruption, or the risk of other significant impacts on business critical functions. Owner/operators must test the effectiveness of the Cybersecurity

³ 49 U.S.C. 114(f)(2).

⁴ 49 U.S.C. 114(f)(3).

⁵ 49 U.S.C. 114(f)(11).

⁶ 49 U.S.C. 114(f)(15).

⁷ See section 1557 of Public Law 110–53 (121 Stat. 266, Aug. 3, 2007) as codified at 6 U.S.C. 1207.

⁸ See section 1557 of Public Law 110–53 (121 Stat. 266; Aug. 3, 2007) as codified at 6 U.S.C. 1207.

Incident Response Plan no less than annually.

- Submit a Cybersecurity Assessment Plan on an annual basis to TSA for approval (there is no designated form or format).

- Maintain records that establish compliance with the SD Pipeline–2021–02 series and make them available to TSA upon request for inspection and/or copying.

Submissions by pipeline owner/operators in compliance with the voluntary PCSR or the mandatory SD Pipeline–2021–02 series requirements are deemed Sensitive Security Information (SSI) and are protected in accordance with procedures meeting the transmission, handling, and storage requirements of SSI in 49 CFR part 1520.

Revision of the Collection

TSA is revising the title of the collection from “Pipeline Corporate Security Reviews and Security Directives” to “Pipeline Corporate Security Reviews and TSA Security Directive Pipeline–2021–02 series.” This title more accurately reflects the specific TSA SD associated with this collection. TSA is seeking renewal of this information collection for the maximum 3-year approval period.

Estimated Annual Number of Respondents: 100.

Estimated Annual Burden Hours: 80,231.

Dated: December 30, 2025.

Christina A. Walsh,

*Paperwork Reduction Act Officer,
Information Technology, Transportation
Security Administration.*

[FR Doc. 2025–24198 Filed 12–31–25; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Geological Survey

[Docket No. USGS–2025–0105; OMB Control Number 1028–0132; GX19ZQ00G402A00]

Agency Information Collection Activities; ShakeAlert

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the U.S. Geological Survey (USGS) is proposing an extension to an existing information collection for approval by the Office of Management and Budget (OMB).