

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. A transcript of the public meeting will be made available in the docket, as well as on the FDA website at: <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

FOR FURTHER INFORMATION CONTACT: Madeline Faunce, on detail to Office of Operations, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 301–796–3464, ADUFAReauth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for ADUFA expires September 30, 2028. Without new legislation, FDA will no longer have the authority to collect user fees to help fund the new animal drug review process for future fiscal years. Prior to beginning negotiations with the regulated industry on ADUFA reauthorization, section 740A(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-13(d)(2)) requires FDA to: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in

section 740A(a) of the FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA’s website. This notice, the public meeting, the comment period after the meeting, and the posting of the comments on the FDA website will satisfy these requirements. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of ADUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?
2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

II. Background

FDA considers the timely review of new animal drug submissions to be central to the Agency’s mission to protect and promote human and animal health. The ADUFA program began in FY 2004 and is currently in the fifth authorization (ADUFA V). FDA has published a number of reports that provide useful background on ADUFA I, ADUFA II, ADUFA III, ADUFA IV and ADUFA V. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: <https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa>.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register no later than midnight Eastern time on May 22, 2026, by emailing complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and if you need reasonable accommodations due to a disability (e.g., Closed Captioning) to ADUFAReauth@fda.hhs.gov. Registration is free and early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

Requests for Oral Presentations: During online registration you may indicate if you wish to make an oral presentation during the public meeting. To facilitate agenda development, registrants requesting to present will be

asked to provide information regarding which topics they intend to address and the title of their presentation. We will do our best to accommodate requests to make an oral presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate. All requests to make oral presentations must be received by May 1, 2026.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by May 8, 2026. Presenters planning to use an electronic slide deck must email an electronic copy of their presentation to Madeline Faunce at ADUFAReauth@fda.hhs.gov (see **FOR FURTHER INFORMATION CONTACT**) with the subject line “ADUFA Public Meeting Presentation” on or before May 15, 2026. If presenters choose not to use a slide deck, they are requested to email a single slide with their name, affiliation, title of their presentation, and contact information. No commercial or promotional material will be permitted to be presented at the public meeting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Notice.

Proposed Project: Evaluation of the Projects for Assistance in Transition From Homelessness (PATH) Program—Reinstatement

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, (SAMHSA will publish periodic summaries of proposed projects. To request more information on the

proposed projects or to obtain a copy of the information collection plans, email the SAMHSA Reports Clearance Officer at: samhsapra@samhsa.hhs.gov.

Comments are invited on: (a) whether the proposed collections of information are 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) ways to enhance 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.

SAMHSA is conducting the federally mandated Evaluation of the PATH program. The PATH grant program, created as part of the Stewart B. McKinney Homeless Assistance Amendments Act of 1990, is administered by SAMHSA's Center for Mental Health Services' Division of State and Community Systems Development. The PATH program is authorized under Section 521 *et seq.* of the Public Health Service (PHS) Act, as amended. The PATH program funds each fiscal year the 50 states, the District of Columbia, Puerto Rico, and four U.S. Territories (the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands). The PATH grantees make grants to local, public and non-profit organizations to provide PATH-allowable services.

The SAMHSA Assistant Secretary is required under Section 528 of the PHS Act to evaluate the expenditures of PATH grantees at least once every 3 years to ensure they are consistent with

legislative requirements and to recommend changes to the program design or operations.

The primary task of the PATH evaluation is to meet the mandates of Section 528 of the PHS Act. The second task of the PATH evaluation is to conduct additional data collection and analysis to further investigate the sources of variation in key program output and outcome measures that are important for program management and policy development. The PATH evaluation builds on the previous evaluation which was finalized in 2016 and was conducted as part of the National Evaluation of SAMHSA Homeless Programs. Previously, the data collections activities also included PATH Intermediary Web Survey, a PATH Provider Web Survey, and a PATH Telephone Interview Guide. The current PATH evaluation will be limited to the State PATH Contact (SPC) Web Survey and PATH Site Visit Discussion Guides to facilitate the collection of information regarding the structures and processes in place at the grantee and provider level. The SPC Web Survey was shortened from 82 to 49 questions. Data regarding the outputs and outcomes of the PATH program will be obtained from grantee applications, providers' intended use plans and PATH annual report data, which is also required by Section 528 of the PHS Act and is approved under OMB No. 0930-0205.

Web Surveys will be conducted with all SPCs. The Web Surveys will capture detailed and structured information in the following topics: selection, monitoring, and oversight of PATH providers; populations served; the PATH allowable or eligible services provided; sources for match funds; provision of training and technical

assistance; implementation of Evidence Based Practices and innovative practices including the Supplemental Security Income/Social Security Disability Insurance Outreach, Access, and Recovery program; data reporting, use of data and the Homeless Management Information System; and collaboration, coordination and involvement with Continuums of Care and other organizations. The SPCs for all grantees (56) will be contacted to complete the web surveys. The Web Surveys will be administered once per triennial evaluation cycle.

Site Visits will be conducted with a purposive sample of PATH grantees and providers to collect more nuanced information than will be possible with the web survey. Semi-structured discussions will take place with the SPCs, grantee staff, PATH provider staff, outreach workers, case managers and other clinical treatment staff, and consumers. Five grantees will be selected for Site Visits and visited within each grantee will be one to two PATH providers. The Site Visits will be utilized to collect information on provider and state characteristics; practices and priorities; context within which the grantees and providers operate; and services available within the areas the providers operate. The successes, barriers, and strategies faced by PATH grantees and providers will also be discussed. Focus groups will be held with current or former consumers of the PATH program to obtain consumer perspectives regarding the impact of the programs. The Site Visits will be conducted once per triennial evaluation cycle.

The estimated burden for the reporting requirements for the PATH evaluation is summarized in the table below.

ANNUAL BURDEN TABLE

Instrument/activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage rate	Total hour cost (\$)
Web Surveys							
SPC Web Survey	56	1	56	1	56	\$37.61	\$2,106.16
Site Visit Interviews							
Opening Session with SPC Staff	25	1	25	2	50	37.61	1,880.50
SPC Session	5	1	5	2	10	37.61	376.10
State Stakeholder Session	25	1	25	1.5	37.5	37.61	1,410.38
Provider Stakeholder Session	50	1	50	1.5	75	37.61	2,820.75
Provider Leadership Staff	50	1	50	2	100	37.61	3,761.00
PATH Provider Direct Care Staff Session ...	50	1	50	2	100	24.54	2,454.00

ANNUAL BURDEN TABLE—Continued

Instrument/activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage rate	Total hour cost (\$)
Consumer Focus Groups	100	1	100	1.5	150	7.25	1,087.50
Total	361	361	578.5	15,896.39

¹ 1 respondent * 56 SPCs = 56 respondents.
² 5 respondents * 5 site visits = 25 respondents.
³ 1 respondent * 5 site visits = 5 respondents.
⁴ 5 respondents * 5 site visits = 25 respondents.
⁵ 5 respondents * 10 site visits (2 providers per state) = 50 respondents.
⁶ 5 respondents * 10 site visits (2 providers per state) = 50 respondents.
⁷ 1 respondent * 10 site visits (2 providers per state) = 10 respondents.
⁸ 5 respondents * 10 site visits (2 providers per state) = 50 respondents.
⁹ 10 respondents * 10 site visits (10 Consumers per provider (2 providers per state) = 100 respondents.

Please send comments to the SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E45, Rockville, Maryland 20857, OR email a copy to: samhsapra@samhsa.hhs.gov. Written comments should be received by June 15, 2026.

Tanya Geiger,
 Social Science Analyst.

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DEPARTMENT OF HOMELAND SECURITY

Rescission of the Suspension of All Direct Commercial Passenger and Cargo Flights Between the United States and Venezuela

AGENCY: Office of the Secretary, Department of Homeland Security.
ACTION: Notice.

SUMMARY: This notice informs the public that the Department of Homeland Security (DHS) has determined that conditions in Venezuela no longer threaten the safety and security of passengers, aircraft, and crew and that it is not in the public interest to continue the suspension of all commercial passenger and cargo flights between the United States and Venezuela. The U.S. Department of Transportation (DOT) has rescinded the May 15, 2019, Order suspending all direct commercial passenger and cargo flights between the United States and Venezuela. DHS is in the process of re-establishing commercial air transportation for passenger and cargo operations between the United States and Venezuela and, as discussed further below, conducting individual airport assessments to ensure the safety and security of passengers, aircraft, and crew traveling between the United States and Venezuela for which the Transportation

Security Administration (TSA) has received notification from air carriers desiring to commence service.

DATES: Applicable April 15, 2026.
FOR FURTHER INFORMATION CONTACT: Eric Yatar, Executive Director, Policy, Plans, and Engagement—International Policy & Programs TSA-4, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598-6004; telephone: (571) 227-2699; email: Eric.yatar@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 44907(e) of title 49, United States Code, if “(1) a condition exists that threatens the safety or security of passengers, aircraft, or crew traveling to or from [a foreign] airport; and (2) the public interest requires an immediate suspension of transportation between the United States and that airport,” the Secretary of Homeland Security, in coordination with the Secretary of Transportation and with the approval of the Secretary of State, shall suspend flights to and from that foreign airport.

On June 4, 2019, DHS published a notice in the **Federal Register** stating that the Acting Secretary of Homeland Security had determined that conditions in Venezuela threatened the safety and security of passengers, aircraft, and crew, and that the public interest required an immediate suspension of air transportation. The June 4, 2019 determination was based on several factors, including: (1) reports of civil unrest and violence in and around the airports; (2) the inability of TSA to gain access to Venezuelan airports to conduct required security assessments to determine whether adequate security measures are in place; (3) the economic and political crisis in Venezuela; (4) cancellation of flights to Venezuela by American Airlines, the largest air carrier

providing service, and two other carriers; (5) the U.S. Department of State’s publication of Do Not Travel advisories, suspension of Embassy operations, and recommendation that TSA inspectors not enter the country owing to safety concerns; (6) the Federal Aviation Administration’s issuance of a Notice to Airmen (NOTAM) on May 1, 2019, which prohibited all flight operations by U.S. air carriers and commercial operators in Venezuela airspace below FL 260; and (7) the risk of Maduro regime actions against U.S. citizens and U.S. interests located in Venezuela. Following Secretary of State approval, the Department of Transportation concurred with this determination and suspended foreign air transportation of passengers or cargo to or from any airport in Venezuela, effective May 15, 2019. See DOT-OST-2019-0072.

Consistent with statutory requirements, DHS required that the Secretary of Homeland Security’s determination regarding conditions in Venezuela be displayed prominently in all U.S. airports with regularly scheduled air carrier operations. The Secretary of Homeland Security also instructed TSA to require that each foreign and domestic air carrier providing air transportation originating in the United States to any person with a flight itinerary that originates in, transfers or transits through, or has a final destination to any airport in Venezuela, provide written notice to such person advising that conditions in Venezuela currently present a threat to the traveling public.

Rescission

On January 3, 2026, President Donald J. Trump announced that the U.S. military had launched strikes across Venezuela that culminated in the capture and arrest of President Nicolás Maduro and his wife Cilia Flores.