

0805, may be submitted to FDA using Forms FDA 3913 and FDA 3914, respectively.

Patent infringement notifications are also included in the scope of collection activity. Section 351(l) of the PHS Act provides for the exchange of patent information and resolution of patent disputes between a 351(k) biosimilar applicant and the holder of the 351(a) BLA reference product. If a biosimilar applicant is served with a complaint in an action for a patent infringement described in section 351(l)(6) of the PHS Act, the biosimilar applicant is required to provide the Secretary of HHS with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

Relevant information regarding applicable statutory requirements is discussed in topical guidance documents, issued consistent with our BsUFA Commitment Letter and Agency Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The following draft and final guidance documents include instructional and procedural information on communicating with FDA regarding the BsUFA program:

- “Assessing User Fees Under the Biosimilar User Fee Amendments of 2022” (July 2023), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-biosimilar-user-fee-amendments-2022>. The guidance document instructs respondents on requesting discontinuation from the BPD program, as well as requesting to move products to the discontinued section of the biosimilar list. The guidance document also provides information on the consequences of failing to pay BsUFA III fees as well as processes for submitting reconsideration and appeal requests.

- “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products” (August 2023), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry>. The guidance document explains standardized procedures for requesting, preparing, scheduling, conducting, and documenting formal meetings with FDA, and discusses good meeting management practices.

- As listed on our Center for Drug Evaluation and Research 2023 and 2024 Annual Guidance agenda (available at: <https://www.fda.gov/media/134778/>

download), we are planning to issue a draft guidance for industry entitled “Pediatric Study Plans for Biosimilar Products,” to help implement provisions of the Pediatric Research Equity Act, codified in section 505B of the FD&C Act (21 U.S.C. 355c). For more information regarding FDA guidance documents, including ways to participate, please visit <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

Description of Respondents: Sponsors and applicants who have or intend to submit an application for a biosimilar product for licensure under section 351(k) of the PHS Act or who intend to submit an initial pediatric study plan (iPSP) as described in section 505B(e) of the FD&C Act for those products intended to be licensed under section 351(k) of the PHS Act and being developed as a proposed biosimilar to a reference product.

In the **Federal Register** of September 23, 2024 (89 FR 77531), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form; survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilar User Fee Cover Sheet (Form FDA 3792)	30	2	60	0.5 (30 minutes)	30
Request for discontinuation from BPD program or to move products to discontinued section of Biosimilar List.	6	1	6	1	6
Biosimilar product & interchangeable product applications (351(k)); patent infringement notifications (351(l)).	16	1.94	31	610.90	18,938
Formal meeting requests as recommended in FDA guidance	135	2.30	311	21.42	6,661
Submission of Pediatric Assessment; iPSP template information, including deferrals of pediatric assessments for proposed biosimilar products; iPSP amendments as recommended in FDA guidance.	11	1	11	38.18	420
Total	419	26,055

Our estimated burden for the information collection reflects an overall increase of 13,069 hours and 105 responses annually. Although part of the increase may be attributed to the inclusion of burden associated with the submission of pediatric study plans, the majority of adjustments correspond with an increase in submissions we are receiving.

Dated: January 28, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2803-25]

Vacatur of 2025 Temporary Protected Status Decision for Venezuela

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice of Temporary Protected Status (TPS) vacatur.

SUMMARY: Through this notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) has decided to vacate the January 10, 2025, decision of former Secretary of Homeland Security Alejandro Mayorkas regarding TPS for Venezuela. Former Secretary Mayorkas extended the 2023 designation of Venezuela for TPS for 18 months, allowed a consolidation of filing processes such that all eligible Venezuela TPS beneficiaries (whether under the 2021 or 2023 designations) may obtain TPS through the same extension date of October 2, 2026, and extended certain Employment Authorization Documents (EADs). All of this also had the effect of extending the 2021 designation. This notice vacates Mayorkas' notice immediately.

DATES: The vacatur is effective immediately.

FOR FURTHER INFORMATION CONTACT: Samantha Deshombres, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 800-375-5283.

SUPPLEMENTARY INFORMATION:

I. Temporary Protected Status (TPS) Generally

The Immigration and Nationality Act (INA) authorizes the Secretary, after consultation with appropriate U.S. Government agencies, to designate a foreign state (or part thereof) for TPS if the Secretary determines that certain country conditions exist. INA 244(b)(1), 8 U.S.C. 1254a(b)(1).¹ The determination whether to designate any foreign state (or part thereof) for TPS is discretionary, and there is no judicial review of "any determination of the

¹ Although section 244(b)(1) of the INA continues to refer to the Attorney General, this authority now resides with the Secretary of Homeland Security by operation of the Homeland Security Act of 2002, Public Law 107-296, 116 Stat. 2135, as amended. See, e.g., 6 U.S.C. 557; 8 U.S.C. 1103(a)(1). The Secretary may designate a country (or part of a country) for TPS on the basis of (1) an ongoing armed conflict such that returning would pose a serious threat to the personal safety of the country's nationals, (2) an environmental disaster (including an epidemic), or (3) extraordinary and temporary conditions in the country that prevent the safe return of the country's nationals. For environmental disaster-based designations, certain other statutory requirements must be met, including that the foreign government must officially request a TPS designation. A designation based on extraordinary and temporary conditions cannot be made if the Secretary finds that allowing the country's nationals to remain temporarily in the United States is contrary to the U.S. national interest. INA sec. 244(b)(1), 8 U.S.C. 1254a(b)(1).

[Secretary] with respect to the designation, or termination or extension of a designation, of a foreign state" for TPS. INA 244(b)(5)(A), 8 U.S.C. 1254a(b)(5)(A). The Secretary, in the Secretary's discretion, may then grant TPS to eligible nationals of that foreign state (or individual aliens having no nationality who last habitually resided in the designated foreign state). See INA 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a foreign state's TPS designation or extension, the Secretary, after consultation with appropriate U.S. Government agencies, must review the conditions in the foreign state designated for TPS to determine whether they continue to meet the conditions for the TPS designation. See INA 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that the conditions in the foreign state continue to meet the conditions for TPS designation, the designation will be extended for an additional period of 6 months or, in the Secretary's discretion, 12 or 18 months. See INA 244(b)(3)(A), (C), 8 U.S.C. 1254a(b)(3)(A), (C). If the Secretary determines that the foreign state no longer meets the conditions for TPS designation, the Secretary must terminate the designation. See INA 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

II. Background

On March 9, 2021, Secretary Mayorkas designated Venezuela for TPS on the basis of extraordinary and temporary conditions in Venezuela that prevented nationals of Venezuela from returning in safety (2021 designation). See *Designation of Venezuela for Temporary Protected Status and Implementation of Employment Authorization for Venezuelans Covered by Deferred Enforced Departure*, 86 FR 13574 (Mar. 9, 2021).

On September 8, 2022, DHS extended the Venezuela 2021 TPS designation for 18 months. See *Extension of the Designation of Venezuela for Temporary Protected Status*, 87 FR 55024 (Sept. 8, 2022). On October 3, 2023, DHS extended the Venezuela 2021 TPS designation for another 18 months with an expiration date of September 10, 2025, and separately newly designated Venezuela, which then Secretary Mayorkas called a "redesignation," for 18 months (the Venezuela 2023 designation) with an expiration of April 2, 2025, resulting in two separate and concurrent Venezuela TPS designations. See *Extension and Redesignation of Venezuela for Temporary Protected Status*, 88 FR 68130 (Oct. 3, 2023).

The Venezuela 2023 TPS designation expires on April 2, 2025, and the Secretary must make a decision by February 1, 2025. The Venezuela 2021 TPS designation expires on September 10, 2025, and the Secretary must make a decision by July 12, 2025. Notwithstanding the fact that these are both decisions that would lie with new Secretary of Homeland Security Kristi Noem, Secretary Mayorkas took action with respect to both designations.

On January 17, 2025, Secretary Mayorkas issued a notice extending the 2023 designation of Venezuela for TPS for 18 months (Mayorkas Notice). The notice was based on Secretary Mayorkas' January 10, 2025, determination that the conditions for the designation continued to be met. See INA 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). In the Mayorkas Notice, Secretary Mayorkas did not expressly extend or terminate the 2021 designation. Instead, the notice allowed for a consolidation of filing processes such that all eligible Venezuela TPS beneficiaries (whether under the 2021 or 2023 designations) could obtain TPS through the same extension date of October 2, 2026. See *Extension of the 2023 Designation of Venezuela for Temporary Protected Status*, 90 FR 5961 (Jan. 17, 2025). The notice also extended certain EADs. The effect of Secretary Mayorkas' actions, however, resulted in an extension of the 2021 Venezuela TPS designation.

III. Vacatur of the 2025 Decision

The Secretary of Homeland Security is vacating the January 10, 2025 decision of Secretary Mayorkas which (1) extended the 2023 Venezuela TPS designation and (2) allowed the consolidation of filing processes for both designations, which had the effect of extending the 2021 Venezuela TPS designation, and (3) extended certain EADs. An agency has inherent (that is, statutorily implicit) authority to revisit its prior decisions unless Congress has expressly limited that authority. The TPS statute does not limit the Secretary's inherent authority under the INA to reconsider any TPS-related determination, and upon reconsideration, to vacate or amend the determination.²

² See INA 103(a), 244(b)(3), (b)(5)(A); 8 U.S.C. 1103(a), 1254a(b)(3), (b)(5)(A); *Reconsideration and Rescission of Termination of the Designation of El Salvador for Temporary Protected Status; Extension of the Temporary Protected Status Designation for El Salvador*, 88 FR 40282, 40285 (June 21, 2023) ("An agency has inherent (that is, statutorily implicit) authority to revisit its prior decisions unless Congress has expressly limited that authority. The TPS statute does not limit the Secretary's inherent authority to reconsider any

A. Reason for the Vacatur

The Mayorkas Notice adopted a novel approach of implicitly negating the 2021 Venezuela TPS designation by effectively subsuming it within the 2023 Venezuela TPS designation. As described above, Secretary Mayorkas explicitly made a determination to extend the 2023 designation. While he did not make an explicit determination to extend the 2021 designation, he did allow consolidated filing processes for both the 2021 and 2023 designations, which in effect extended the 2021 designation by up to 13 months. Furthermore, he allowed extensions for certain EADs.

The Mayorkas Notice states that *Existing TPS beneficiaries, including those registered under the October 3, 2023 TPS designation or the prior March 9, 2021 TPS designation, who wish to extend their status through October 2, 2026, must re-register during the re-registration period described in the January 2025 decision.* This, and other language in the Mayorkas Notice, indicate that the practical effect of Secretary Mayorkas' decision was to combine both designations and to provide an extension until October 2, 2026, for the population of *both* designations.

The Mayorkas Notice did not acknowledge the novelty of its approach or explain how it is consistent with the TPS statute. *See* INA 244(b)(2)(B), 8 U.S.C. 1254a(b)(2)(B) (providing that a TPS country designation “shall remain in effect until the effective date of the termination of the designation under [INA 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B)]”). This novel approach has included multiple notices, overlapping populations, overlapping dates, and sometimes multiple actions happening in a single document. While the Mayorkas Notice may have made

TPS-related determination, and upon reconsideration, to change the determination.”); *see also, e.g., Ivy Sports Medicine, LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) (Kavanaugh, J.) (“[A]dministrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion. . . . “[I]nherent authority for timely administrative reconsideration is premised on the notion that the power to reconsider is inherent in the power to decide.” (quotation marks and citations omitted)); *Macktal v. Chao*, 286 F.3d 822, 825–26 (5th Cir. 2002) (“It is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.”) (collecting cases); *Mazaleski v. Treusdell*, 562 F.2d 701, 720 (D.C. Cir. 1977) (“We have many times held that an agency has the inherent power to reconsider and change a decision if it does so within a reasonable period of time.”); *cf. Last Best Beef, LLC v. Dudas*, 506 F.3d 333, 340 (4th Cir. 2007) (agencies possess especially “broad authority to correct their prior errors”).

attempts to address these overlapping populations, the explanations in the Mayorkas Notice, particularly the explanation for operational impacts, are thin and inadequately developed. Given these deficiencies and lack of clarity, vacatur is warranted to untangle the confusion, and provide an opportunity for informed determinations regarding the TPS designations and clear guidance.³

Given the exceedingly brief period in which the January 17, 2025 extension notice has been in effect and the fact that the effect of this vacatur will restore the status quo preceding that notice, any putative reliance interests on the extension notice are negligible. Venezuela 2023 registrants will retain their temporary protected status under the pre-existing designation at least until April 2, 2025. With respect to any Venezuela 2021 registrants who elected, pursuant to the Mayorkas Notice, to register under the Venezuela 2023 designation, USCIS will restore their Venezuela 2021 registration. And, in any event, any putative reliance interests arguably engendered by the Mayorkas Notice are outweighed by the overriding interests and concerns articulated in this notice.

B. Effect of the Vacatur

As a result of the vacatur, the 2021 Venezuela TPS designation and the 2023 Venezuela designation remain in effect and their associated statutory deadlines remain in effect. The statutory deadline⁴ for each of those designations is as follows: The Secretary (1) must determine, by February 1, 2025, whether to extend or terminate the 2023 Venezuela TPS designation and (2) must determine, by July 12, 2025, whether to extend or terminate the 2021 Venezuela TPS designation.

If the Secretary does not make a timely determination (for example, if the Secretary were *not* to make determination by February 1, 2025 whether to extend or terminate the 2023 Venezuela TPS designation), then the statute provides for an automatic extension of the designation for an

³ *See* Exec. Order, *Protecting the American People Against Invasion*, sec. 16(b) (Jan. 20, 2025), available at <https://www.whitehouse.gov/presidential-actions/2025/01/protecting-the-american-people-against-invasion/>.

⁴ If there is an existing TPS designation for a foreign state, the Secretary must review country conditions in consultation with appropriate U.S. Government agencies and make a determination—at least 60 days before the designation is set to expire—whether to extend or terminate that country's TPS designation (*i.e.*, whether the conditions for the designation continue to be met). INA 244(b)(3), 8 U.S.C. 1254a(b)(3).

additional period of 6 months. INA 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C).

Pursuant to this vacatur, USCIS will no longer accept Venezuela TPS re-registration applications (Form I–821) and associated Applications for Employment Authorization (Form I–765) filed under the Mayorkas Notice. For TPS beneficiaries who have already filed applications to re-register for TPS pursuant to the Mayorkas Notice and paid any fees associated with their applications, USCIS will cease processing their applications, and issue refunds of any fees paid by those aliens.⁵ Additionally, USCIS will invalidate EADs; Forms I–797, Notice of Action (Approval Notice); and Forms I–94, Arrival/Departure Record (collectively known as TPS-related documentation) that have been issued with October 2, 2026 expiration dates under the Mayorkas Notice. USCIS will provide refunds to any fees paid by these aliens as well.

Additionally, pursuant to this vacatur the automatic EAD extensions provided in the Mayorkas Notice are hereby rescinded. USCIS will provide additional guidance regarding the two Venezuela TPS designations on a future date in accordance with applicable laws.

IV. Notice of Vacatur of Secretary Mayorkas' 2025 Decision

By the authority vested in me as Secretary under section 244 of the Immigration and Nationality Act, 8 U.S.C. 1254a, I am vacating the decisions announced in the January 17, 2025 notice titled *Extension of the 2023 Designation of Venezuela for TPS*. In doing so, I am vacating the (1) extension of the Venezuela 2023 TPS designation, (2) the consolidation of filing processes for both designations, which, in effect, resulted in the extension of the 2021 TPS designation, and (3) the EADs that were extended. As a result, the Venezuela 2023 TPS designation and the Venezuela 2021 TPS designation remain in effect and their associated statutory deadlines remain in effect.

Kristi Noem,

Secretary, U.S. Department of Homeland Security.

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⁵ As noted above, any Venezuela 2021 registrants who elected, pursuant to the Mayorkas Notice, to register under the Venezuela 2023 designation will have their Venezuela 2021 registration restored.