Congress of the United States
Washington, DC 20515

April 28, 2025

The Honorable Robert F. Kennedy Jr.
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Kennedy:

We write to express our deep concern regarding the U.S. Department of Health and Human Services' (HHS) reduction in force (RIF) and reorganization plans at the Food and Drug Administration (FDA)[1] impacting FDA's San Juan Medical Products Laboratory (SJNLMP).[2] According to our constituents, since a RIF notice was distributed to employees on April 1st, 2025, the laboratory has ceased operations. Shutting down this laboratory is against your commitment to protect "essential services" and "frontline jobs"[3] as doing so jeopardizes the safety of millions of Americans by weakening FDA's ability to detect contaminated pharmaceuticals, respond to health emergencies, and safeguard national security. Additionally, this decision would eliminate over 20 highly skilled jobs in Puerto Rico.

The SJNLMP is one of the few FDA-owned and operated facilities specialized in pharmaceutical drug analysis. It has evaluated and removed thousands of adulterated products from the market that otherwise would have exposed American consumers to unsafe products. For instance, its work has been critical in ensuring the safety of medicines used to treat cancer, diabetes, and cardiovascular conditions. Additionally, the SJNLMP has been key in responding to public health emergencies. During the COVID-19 pandemic, the laboratory analyzed hundreds of hand sanitizer samples, removing those products with dangerous levels of methanol from the market. The San Juan laboratory also supports HHS' Strategic National Stockpile (SNS). The SNS is a federal program that maintains lifesaving supplies, medicines, and devices that can be deployed to state and local entities when they do not have enough supply during emergencies.[4]

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[1] Cierre de Laboratorio de FDA en PR Causará Retrasos en Aprobación de Fármacos, Telemundo Puerto Rico (Apr. 1, 2024), https://www.telemundopr.com/programas/rayos-x/cierre-de-laboratorio-de-fda-en-pr-causara-retrasos-en-aprobacion-de-farmacos/2704483/.

[2] According to a letter shared by our constituents, a RIF notice was given to employees on April 1st, 2025, which stated that employees were going to be separated from their federal service on June 2nd, 2025.

[3] Cheyenne Haslett**,** *RFK Jr. Announces HHS Reinstating Some Programs, Employees Cut by Mistake*, ABC News (Apr. 3, 2025), https://abcnews.go.com/Politics/rfk-jr-announces-hhs-reinstating-programs-employees-cut/story?id=120463293.

[4] U.S. Dep't of Health & Hum. Servs., *Emergency Preparedness and Response*, ASPR, https://aspr.hhs.gov/SNS/Pages/Emergency-Preparedness-and-Response.aspx

Some of the critical safety programs supported by the SJNLMP that would become impacted by the HHS RIF plans are:

- The **Health Fraud Program**[5]: This program focuses on identifying potentially unsafe medication products that are marketed with unproven, false, or misleading claims about the products' ability to diagnose, cure, mitigate, treat, or prevent diseases or conditions. As part of these efforts, SJNLMP's expert analysts routinely test dietary supplements for the presence of drugs. With more than 75% of samples analyzed over the last five years found to be adulterated, the laboratory has prevented unsafe products from reaching consumers across the U.S. mainland and Puerto Rico.
- The **Shelf-Life Extension Program (SLEP)**[6]: This program verifies the stability of drugs in the SNS. The SJNLMP examines samples from the HHS' stockpile and helps guarantee that drugs and medical products remain safe and available for the nation's armed forces and civilian populations during emergencies and conflicts.
- The **Cooperative Research and Development Agreement (CRADA)**[7]: Through this strategic partnership, the FDA collaborates with external organizations to advance analytical methods for drug safety. The SJNLMP plays a pivotal role by certifying United States Pharmacopeia (USP) reference standards and driving the modernization of over a dozen of key methods, significantly enhancing drug quality in the pharmaceutical industry.
- **Import and Surveillance Programs**[8]: SJNLMP monitors pharmaceutical imports from the Caribbean, Europe, Asia and Latin America into the U.S., maintaining regulatory compliance even during emergencies like natural disasters, pandemics, and geopolitical conflicts. Its strategic location strengthens U.S. emergency preparedness and counterterrorism efforts.

Notably, SJNLMP is the only specialized pharmaceutical laboratory in the nation that uses Ion Chromatography (IC)[9] to detect nitrates and nitrites contaminants. These can be found in toothpaste and pediatric dental anesthetics, particularly harming children. The laboratory is also fully equipped to conduct comprehensive analysis of opioids and nitrosamines, which are potentially cancer-causing substances found in pharmaceuticals. Further, SJNLMP stands out for

[5] U.S. Food & Drug Admin., *Medication Health Fraud*, FDA, https://www.fda.gov/drugs/buying-using-medicine-safely/medication-health-fraud.
[6] U.S. Food & Drug Admin., *Expiration Dating Extension*, FDA, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension.
[7] U.S. Food & Drug Admin., *Cooperative Research and Development Agreements (CRADAs)*, FDA, https://www.fda.gov/science-research/fda-technology-transfer-program/cooperative-research-and-development-agreements-cradas
[8] U.S. Food & Drug Admin., *Import Program Tools*, FDA, https://www.fda.gov/industry/import-program/import-program-tools; U.S. Food & Drug Admin., *Postmarketing Surveillance Programs*, FDA, https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs
[9] U.S. Food & Drug Admin., *San Juan Medical Products Laboratory (SJNLMP),* FDA, https://www.fda.gov/science-research/field-science-and-laboratories/san-juan-medical-products-laboratory-sjnlmp

its partnership with the Center for Drug Evaluation and Research (CDER) to develop a method for detecting benzene in hand sanitizers, sunscreens, and other products, ensuring consumers' protection from this carcinogen agent.

Given the breadth of the safety work completed by the laboratory, its shutdown clearly undermines FDA's ability to ensure that pharmaceutical products used by Americans are safe.

Therefore, we urge you to swiftly reconsider and reverse your RIF and reorganization plans negatively impacting the critical work completed at the SJNLMP to protect Americans' health. In light of these concerns, we request that you provide written responses to the following questions no later than May 5th, 2025:

1. What criteria did HHS use to select the SJNLMP for RIF and subsequent shutdown?
2. Has the FDA assessed how the laboratory closure might affect public health emergency preparedness and national security? If yes, please share your results. If not, please explain why this assessment was not conducted.
3. What contingency plans does the FDA have in place to address potential delays in pharmaceutical product testing and approvals following the closure of the SJNLMP, and how does the FDA plan to ensure the timely analysis of pharmaceutical samples previously completed at this laboratory?
4. How will the FDA ensure that the quality and regulatory oversight standards for pharmaceutical products are maintained or improved despite the closure of the SJNLMP? In particular, how will the agency address the need for inspection support, previously provided by this laboratory, focused on verifying the accuracy and integrity of the data submitted to the agency?
5. What data or financial analysis supports the claimed cost savings from closing the SJNLMP and how was that weighed against the public health impact?

Thank you for your attention to this critical matter. We urge you to prioritize the health of the American people and the integrity of our pharmaceutical supply chain by ensuring that the San Juan Medical Products Laboratory remains fully staffed and operational.

Sincerely,

Congress of the United States
Washington, DC 20515

Nydia M. Velázquez
Member of Congress

Alexandria Ocasio-Cortez
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