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# US FDA Looks To Re-Establish African Foreign Office, Add Brazil Post

by **Derrick Gingery**

As Congress pressures FDA to increase foreign inspections, the agency unveils plans to strengthen its overseas presence, including new offices and more staff in the New Delhi, India, post. Deputy Commissioner Kimberlee Trzeciak notes the moves are resource dependent.

As Congress pressures the US Food and Drug Administration to increase foreign inspections, the agency is offering plans to reestablish its presence in Africa, as well as add another South American post.

A new foreign office is planned for Kigali, Rwanda, Kimberlee Trzeciak, FDA deputy commissioner for policy, legislation and international affairs, said. The city is the home for the new African Medicines Agency.

Another new office is slated for Brasília, the capital of Brazil. And the FDA is hoping to add more personnel to its existing office in New Delhi, India.

Trzeciak said both new offices are resource-dependent, but the moves are part of the agency's effort to "bolster our foreign presence."

"These are steps forward and there's more that we can do in the future, but I think they are important because these global collaborations post-COVID are going to continue to be a big priority for the agency," she said during a webinar last month sponsored by the Alliance for a Stronger FDA.

The FDA would not provide information on the number of employees needed for the new offices and to be added at the New Delhi office or their occupations. The agency also would not offer an expected schedule for the new offices opening or comment on whether other foreign posts would be impacted.

President Biden allocated \$1m in the fiscal year 2025 budget request to expand the FDA's "foreign office footprint and number of deployed personnel," according to the Health and Human Services Department's budget in brief [document](#). Officials wrote that the additional offices would grow the FDA's knowledge of imported products and its "ability to quickly complete in-person inspections of foreign facilities in specific countries."

FDA officials closed a foreign office in Pretoria, South Africa in early 2015. African countries now are covered through the FDA's White Oak, MD headquarters. Several other foreign offices were closed from 2012 through 2014. (Also see "[FDA Posts OCI Agent In Singapore, But Other Foreign Offices Close](#)" - Pink Sheet, 18 Jan, 2016.)

### **Rwanda Office Would Be Near New African Medicines Agency**

The agency uses its foreign offices to conduct facility inspections, as well as work with other regulators. The seven existing offices are located in Mexico, Costa Rica, Chile, Belgium, The Netherlands, India and China. (See map below.)

Rwanda in 2023 agreed to host the newly launched African Medicines Agency, which will promote regulatory harmonization and improve access to medical products throughout the continent.

While the city and country have strategic value for the FDA, attorney Howard Sklamberg, a partner at Arnold and Porter and former FDA deputy commissioner for global regulatory operations and policy, said the agency likely would not be advising the regulatory body.

Sklamberg said Africa mostly exports food to the US, such as coffee, but Rwanda aspires to become a tech and clinical trial center. The country's safe living environment and political stability also make it an attractive location for the agency to place employees, he said.

"When you're staffing foreign offices it has to be a place people are willing to go," he said. "They want a place that is stable – no health risks or a political environment that is difficult."

The European Medicines Agency has announced a \$10.75m grant for the African Medicines Agency to hire experts to help its staff and technical committees, as well as assist in creating its new governance processes. The European medicines regulatory network also will offer training for African regulators. (Also see "[EMA Steps Up Support For Creation Of African Medicines Agency](#)" - Pink Sheet, 6 Feb, 2024.)

### **Plans Announced Shortly After Israel Speculation**

Interestingly, the news of the agency's plans to open an office in Africa comes after it denied speculation that an office in Israel was in the works.

Officials from the Israeli embassy met with FDA Associate Commissioner for Global Policy and Strategy Mark Abdoo in December 2023, prompting questions after the session was publicly disclosed. FDA officials quickly said there were no plans for opening an office in the country. (Also see "[US FDA Resists Proposals For Mideast Presence To Boost Pharmaceutical Imports From Allies](#)" - Pink Sheet, 12 Jan, 2024.)

Even if the new offices are approved and funded, finding staff willing to relocate to foreign lands always is difficult. The agency has been developing a strategy to temporarily detail investigators to foreign countries to help deal with the problem.

Diplomatic problems also can derail foreign staffing plans. In 2013, the FDA could not send additional employees to its China office because of problems obtaining the necessary visas. (Also see "[FDA Talks Drug Safety With China, But Visas Still Elusive For Staff](#)" - Pink Sheet, 22 Sep, 2014.)

## Brazil Growing Its Drug Manufacturing

Brazil is among the largest manufacturers of medical devices, which would explain the FDA's interest in the country, Sklamberg said.

Brazil also is part of the Medical Device Single Audit Program, which is similar to the mutual recognition agreement system the FDA has with other regulators for drug manufacturing inspections, he said. (Also see "[MDSAP And USMCA: 3 Ways Mexico Can Come Up-To-Speed With The Single-Audit Program Targeted By New Free-Trade Accord](#)" - Medtech Insight, 28 Jan, 2020.)

Sklamberg also said the country is increasing its drug production, but not at the level of India and China.

## Surprise Inspections Could Increase In India

Additional staff in India could enhance efforts to increase surprise foreign inspections, which declined because of travel restrictions during the COVID-19 pandemic. Republicans have argued for the program to be restored to pre-pandemic levels. (Also see "[Congress Explores Plans For Catching Up On US FDA Foreign Inspections](#)" - Pink Sheet, 6 Feb, 2024.)

India's large generic drugs manufacturing base, as well as several high-profile production problems found there in recent years, make the country a primary focus for the FDA. (Also see "[Will US FDA Offer Regulatory Flexibility For ANDAs Downgraded Because Of CRO Investigation?](#)" - Pink Sheet, 21 Feb, 2022.)

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