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April 2, 2020

Dr. Stephen M. Hahn
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
White Oak, MD 20903

Dear Commissioner Hahn:

I write to request your assistance with testing kits for COVID-19 that have been purchased by the Government of Puerto Rico and are now waiting for clearance from the U.S. Food and Drug Administration (FDA).

It has come to my attention that the Puerto Rico Department of Health purchased 6,000 rapid test kits that are currently available and could be used to increase the rate of testing on the Island. However, without FDA clearance, these cannot be used and the PRDH would have to wait until the next batch of FDA-approved tests arrive on site, which I understand could take up to 5 days.

By not using the test kits that are now available, we risk hindering contact tracing efforts that help keep the spread of the virus at minimum. Additionally, it is to my understanding that the Centers for Disease Control has approved the use of these kits. Still, FDA officials have expressed that they cannot be used and need to be repackaged. The test kit provider is Pharmatech, Inc. located in San Diego, California and the test itself is the COVID19 IgG/IgM Rapid Test.

I respectfully ask that you expedite clearance of these testing kits. This will allow Puerto Rico officials to continue testing potential COVID-19 cases on the Island. As you know, the rate of testing is crucial if we are to observe a halt in positive cases and potential spread of the coronavirus.

I appreciate your attention to this urgent matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jenniffer González-Colón".

Jenniffer González-Colón
Member of Congress