DETERMINATION OF A PUBLIC HEALTH EMERGENCY AND DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING AUTHORIZATIONS PURSUANT TO SECTION 564(b) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3

As of this date, I hereby determine pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Date  FEB-04-2020

Alex M. Azar II