



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

**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

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Alex M. Azar II