



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

**DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING
AUTHORIZATIONS PURSUANT TO SECTION 564 OF THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3**

On February 4, 2020, I determined 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). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

MAR 24 2020

Date



Alex M. Azar II