

WEARING OF DOUBLE FACE MASKS FOR COVID-19 PREVENTION IN THE WAKE OF EMERGING NEW SARS-COV-2 VARIANTS – THE FDA’S PERSPECTIVE

Generally, all viruses, including the SARS-CoV-2, change over time through mutation (i.e., the alteration in the nucleotide sequence of the genome of a virus). New variants of viruses are thus expected to emerge and, in some cases, disappear over time or persist in other cases.

Globally, multiple variants of the SARS-CoV-2 virus have been identified. These variants include but are not limited to: Cluster 5 (L452R), VOC 202012/01 (B.1.1.7), 20H/501Y.V2 (B.1.351) and 20J/501Y.V3 (P.1) which originated from Denmark, United Kingdom, South Africa and Brazil respectively. Most of these variants resulting from mutations, have been confirmed to be circulating in numerous countries around the world.

The variants have several mutations or genomic changes such as:

- Mutations in the receptor binding domain (RBD) of the spike protein
- Nucleotide substitutions
- Nucleotide deletions

While preliminary data suggest that the effective reproductive number of some of these new variants are elevated, thus potentially enhancing their transmissibility (ability to spread from person to person), there is no conclusive scientific evidence of a drastic change in the morphology and sizes of the new viral variants for which one will need to double up face masks for enhanced protection from COVID-19. Also, the sizes of respiratory droplets and/or droplet nuclei which are media for droplet transmissions of COVID-19 are not impacted by mutation of the virus.

It must be noted that, the doubling of face masks debate is predicated on the lack of ample evidence on the quality and filtration efficiency of some thin or flimsy fabric masks used in certain jurisdictions.

In Ghana, however, the Food and Drugs Authority (FDA) conducted studies/evaluation on fabrics/materials and approved viable three-layered fabric combination for the production of effective homemade/fabric face masks. This was published by the Ghana Standards Authority as a Ghana Standard for Publicly Available Specification

for Re-useable Face Masks (GS PAS 4:2020). Consequently, homemade face masks which comply with the Ghana Standard are guaranteed to have adequate filtration efficiency and thus do not require double masking.

The breathability of these masks is ascertained by the porosity test. Doubling up such face masks that already have adequate filtration efficiency, may result in breathing difficulty which could lead to health problems.

In the light of the above, the current FDA approved face masks, when properly used and handled, and in combination with the other public health preventative protocols such as cough/sneeze etiquette, good hand hygiene and observing physical distancing, can adequately protect and prevent the spread of the SARS-CoV-2 virus.

Cloth face masks must be washed daily after use, dried in open sun and ironed prior to reuse. Cloth facemasks must be discarded after a maximum of ten (10) washes or as specified by the manufacturer.

Currently, the extent and public health significance of these new variants of the SARS-CoV-2 virus require further epidemiological and laboratory investigations. Scientific investigations are ongoing to better understand the impact of these emerging SARS-CoV-2 variants on disease transmission, clinical severity of infection, laboratory diagnostics, therapeutics, vaccines, or public health preventive measures.

The FDA will continue to update the general public on developments as and when new evidence becomes available to the Scientific Community.

Meanwhile, the FDA wishes to take the opportunity to encourage the general public to ensure that they patronize only FDA-approved regulated products including face masks since their quality and performance can be guaranteed by the Authority.