



March 11, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

This letter clarifies the Emergency Use Authorization (“EUA”) issued by the Food and Drug Administration (“FDA”) on March 2, 2020, a copy of which is attached. The EUA, issued pursuant to section 564 of the Food, Drug, and Cosmetic (“FDCA” or “Act”), permits the emergency use and distribution of filtering facepiece respirators (“FFR”), certified by the National Institute of Occupational Safety and Health (“NIOSH”),¹ that had previously been intended for general use. Those FFRs subject to the EUA are defined in footnote 1 to the March 2 letter and are listed in Appendix A to that letter and are added to Appendix B once authorized by FDA.

As a result of the Public Health Emergency associated with Coronavirus Disease 2019 (“COVID-19”), there is shortage of FFRs intended for use by healthcare workers and others to mitigate further transmission of COVID-19. To address that shortage, the March 2, 2020 EUA letter permits NIOSH-approved FFRs to be distributed to healthcare workers and to others to mitigate further transmission of COVID-19. Given the new intended medical uses of those FFRs, those FFRs are deemed to be medical devices within the meaning of section 201(h) of the FDCA and therefore, subject to section 564 of the Act. While the EUA remains in effect, FFRs included within its scope are eligible for the liability protections of the Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148 (2005), 42 U.S.C. § 247d-6d.

Once the Public Health Emergency abates and the EUA terminates, those general use FFRs will cease being medical devices and will not be subject to the jurisdiction of the FDA, provided that they are not distributed, marketed, or labeled with an intended medical use.

We also wish to clarify that any statements in the March 2 letter about the effectiveness of FFRs are those of the Department of Health and Human Services and are not attributable to any manufacturer.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

cc: Robert P. Charrow, Esq.

¹ NIOSH is a sub-agency within the Centers for Disease Control and Prevention.