July 21, 2021

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: The FDA's expedition and approval of Philips Respironics's silicone-based abatement foam

Dear U.S. Food and Drug Administration,

On June 14, 2021 Philips Respironics issued a voluntary recall notification on the sound abatement foam component in specific Philips Respironics Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical non-invasive ventilator devices (NIV). This recall is one of the largest in the history of the home medical equipment industry and is having a direct impact on the millions of users of these devices. These users include patients who suffer from obstructive sleep apnea (OSA) including people who struggle to breathe on their own. Users of the recalled equipment categories are typically those diagnosed with obstructive sleep apnea, COPD, ALS, chronic respiratory failure, COVID-19. These devices, specifically ventilators, have been essential in the COVID-19 healing process. The delta variant of COVID-19 is currently spreading throughout our country. The U.S. cannot once again sustain a shortage in equipment that can assist in positive clinical outcomes for respiratory illnesses and diseases. We believe the FDA should consider speeding up the approval of Philips Respironics's silicone-based abatement foam.

People diagnosed with the conditions mentioned above and therefore require one of the recalled devices, face a myriad of additional complications. These issues may be avoided but can become further exacerbated if they do not have access to these important, sometimes life-sustaining devices. Currently there is a shortage of manufacturers of these devices with inventory constraints to adequately increase production to absorb the demand for these devices typically provided by Philips

Respironics. Swift action is needed to protect access to these products and avoid a device shortage that would further burden an already stressed healthcare system.

At this time, Philips Respironics is working on a solution to meet the needs of the millions of patients who are either 1) Current users of any recalled Philips device, and 2) Patients who are being diagnosed or will be diagnosed with a condition that will require one of the device types included in the recall. We are requesting accelerated approval from the FDA for this critical replacement component for approved technicians to rapidly start the process of replacing/repairing all recalled units.

We ask that the FDA expedite this approval process to make these devices available to consumers who rely on them as quickly as possible. We understand the critical role that the FDA plays in reviewing and approving new devices and device componentry to ensure a high level of consumer safety and protection. We are not in any way asking for anything to be done that would jeopardize consumer safety. We are simply asking that you consider this situation to be a critical one and prioritize it accordingly.

Sincerely,

Clint Geffert
President, VGM & Associates

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