THE VISION COUNCIL

April 29, 2020

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20903

Re: Request by The Vision Council to Further Delay
UDI Enforcement on Class I and Unclassified Devices

Dear Dr. Shuren:

The Vision Council respectfully requests that the U.S. Food and Drug Administration (FDA) extend by one year the existing moratorium on the enforcement of the Unique Device Identifier (UDI) formatting, labeling, and GUDID data submission requirements for class I and unclassified medical devices manufactured and labeled on or after September 24, 2018. Serving as the global voice for vision care products and services, including optical laboratories, The Vision Council is a nonprofit organization representing the manufacturers, suppliers and retailers of the optical industry through education, advocacy and consumer outreach. Our members include companies that manufacture, import and distribute eyeglasses, spectacle lenses, spectacle frames, sunglasses, reading glasses, low vision products and ophthalmic equipment as well as optical retail companies that sell these class I medical devices.

On January 16, 2018, the FDA issued an enforcement moratorium on class I and unclassified medical devices, agreeing to push off the enforcement date for formatting, labeling and GUDID data submission from September 24, 2018 to September 24, 2020. The vast majority of our members are involved with class I medical devices and have used the past two years to meet the upcoming deadline, however, the extraordinary situation caused worldwide by the COVID-19 pandemic is impacting our members' abilities to complete their preparations to be compliant by this coming September.

The Vision Council's members remain committed to implementing UDI compliance into their operations, however, the COVID-19 situation, especially the "shelter-in-place" policies our members and their vendors are experiencing, are interfering with completing that integration. By pushing this deadline off an additional 12 months to September 24, 2021, the FDA would allow our members as well as all companies involved with class I and unclassified medical devices additional time to complete the necessary preparations for UDI compliance.

Extending the enforcement deadline will likely benefit the FDA as well. It will alleviate the administrative burden on the agency and its personnel as it ramps up for the large increase in UDI

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reporting when class I and unclassified medical device reporting becomes enforceable. These FDA resources can then be focused on the pressing health and safety issues connected to the medical device supply chain for those devices used in combating COVID-19. Furthermore, work already done by public and private actors involved in UDI compliance and enforcement is not compromised by a temporary postponement of the enforcement date.

Thank you for your consideration of our request. Please feel free to contact either of us if you require any more information regarding this letter.

Sincerely,

Ashley Mills
Chief Executive Officer

Rick Van Arnam
Regulatory Affairs Counsel