



February 25, 2019

Scott Gottlieb, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Docket No. FDA-2013-D-1445

Dear Commissioner Gottlieb:

The National Federation of the Blind, the largest organization of blind people in the United States, submits the following comments to the Food and Drug Administration's (FDA) Draft Guidance for Industry and Food and Drug Administration Staff—Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use. The draft document has a total lack of guidance concerning the accessibility of these systems in evaluating their accuracy, reliability, and safe use. We are disappointed to see this disregard for the needs of blind or low-vision healthcare professionals.

A number of doctors, nurses, and other healthcare providers have disabilities, including blindness and low vision. It is critical that the medical equipment they use to treat their patients be designed and manufactured to be non-visually accessible to enable these healthcare professionals to provide the same standard of care to their patients as sighted healthcare providers. Not only does the inability of blind and low-vision healthcare providers to use the same diagnostic tools and equipment as their sighted colleagues adversely impact patients, but it has the potential for discriminating against the employment and job advancement of blind and low-vision healthcare providers.

The above-referenced draft guidance fails to include any standards and recommendations to the industry to design and develop blood glucose monitoring systems in a manner accessible to blind and low-vision users. Irrespective of the acuity of their vision, healthcare providers should have meaningful access to the same life-changing diabetes information, diagnostic tools, and treatments to care for their patients as are available to their sighted colleagues. The accessibility of medical technology is critical to the ability of blind and low-vision healthcare providers to safely and effectively care for their patients.

Blood glucose devices can be made non-visually accessible through tactile markers, speech output capabilities, screens that are readable for people with low vision, accessible smartphone applications, or Braille access. The design of these devices should take into consideration how a blind person would be able to perform tasks such as obtaining a blood glucose measurement, adjusting device settings, reading past measurements in memory, reading the instruction manual, accessing warnings and error messages, and reading the screen and function buttons in a manner that is equally effective, equally integrated, and with equivalent ease of use as a sighted user.

For the reasons stated, the National Federation of the Blind strongly urges the FDA to modify the final version of its guidance to recommend to stakeholders that non-visual accessibility be included as an important design consideration and as part of the recommended standard for the development of new blood glucose monitoring test systems for prescription point-of-care use when submitting premarket submissions for these systems.

The National Federation of the Blind appreciates the opportunity to comment on the Food and Drug Administration's draft guidance, and we look forward to working with the Administration in the future. Please contact John Paré at 410-659-9314, extension 2218 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Riccobono", with a long horizontal flourish extending to the right.

Mark Riccobono, President  
National Federation of the Blind

MAR/sd

National Federation of the Blind