



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-1446

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of blind people in the United States, submits the following comments to the Food and Drug Administration's (FDA) Draft Guidance for Industry and Food and Drug Administration Staff—Monitoring Blood Glucose Test Systems for Over-the-Counter Use, which proposes standards for the improved safety and performance of blood glucose monitors used for patient management of diabetes. 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 Americans with diabetes who, like all other Americans, have the right to safely and independently care for themselves.

A close relationship exists between diabetes and vision loss. People with diabetes are 40 percent more likely to develop glaucoma and 60 percent more likely to develop cataracts.¹ As a result, it is critical that the technology that enables individuals with diabetes to monitor and cope with this disease be usable by the blind.

Nevertheless, blind Americans with diabetes face a crisis stemming from a near total lack of accessible diabetes-management technologies and devices. With rare exceptions, the hundreds of different devices and varying makes and models of those devices that are available to sighted people with diabetes are inaccessible and, as a result, not usable by blind people with diabetes. This landscape forces blind Americans with diabetes to undertake dangerous and ineffective approaches to managing their diabetes or sacrifice their independence, dignity, and privacy by relying exclusively on others.

¹ "Eye Complications," American Diabetes Association, last edited November 19, 2018, <http://www.diabetes.org/living-with-diabetes/complications/eye-complications/>.

The above-referenced draft guidance fails to include any standards and recommendations for manufacturers to design and develop blood glucose test systems in a manner accessible to blind and low-vision users. Accessibility is critical to the ability of blind and low-vision patients to safely and effectively use these devices and accurately interpret their test results.

The FDA should recommend and encourage manufacturers to incorporate non-visually accessible technology into the design of blood glucose monitoring systems so that blind individuals are provided with meaningful access to the same life-changing diabetes information, diagnostic tools, and treatments available to others. 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 apps, 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 self-monitoring blood glucose systems for over-the-counter 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, sweeping horizontal line extending to the right.

Mark Riccobono, President
National Federation of the Blind

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National Federation of the Blind