

Erratum to FDA Briefing Document

Endocrinologic and Metabolic Drugs Advisory Committee Meeting

October 24-25, 2018

This erratum contains corrections to FDA’s briefing information for the October 24-25, 2018 Endocrinologic and Metabolic Drugs Advisory Committee Meeting. At this meeting the committee will discuss the “Guidance for Industry: Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes” (<https://www.fda.gov/downloads/Drugs/Guidances/ucm071627.pdf>), and the cardiovascular risk assessment of drugs and biologics for the treatment of type 2 diabetes mellitus.

1) On page 19, first paragraph, first sentence:

“SUSTAIN-6 was a multi-center, double-blinded trial comparing the risk for major adverse cardiovascular events in patients treated with liraglutide or placebo on top of standard of care treatments for type 2 diabetes.”

Should be revised to read (change bolded and underlined)

“SUSTAIN-6 was a multi-center, double-blinded trial comparing the risk for major adverse cardiovascular events in patients treated with **semaglutide** or placebo on top of standard of care treatments for type 2 diabetes.”