Erratum to FDA Briefing Document

Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC)

November 4, 2021

This erratum contains corrections to FDA's briefing information for the November 4, 2021 PDAC Meeting. The committee will discuss new drug application (NDA) 214812, for carbetocin nasal spray, submitted by Levo Therapeutics, Inc., for the proposed treatment of hyperphagia, anxiety, and distress behaviors associated with Prader-Willi syndrome.

1) Page 17, second paragraph, first sentence

"Of the 37 subjects dosed, one subject in the IN carbetocin arm discontinued because of adverse events (AEs) including agitation, increased aggression, increased hyperphagia, and broken distal ulna (see Section 3.2)."

Revised text (deletions in strikethrough font and additions in bolded and underlined font):

"Of the 37 subjects dosed, one subject in the **placebo** ~~IN carbetocin~~ arm discontinued because of adverse events (AEs) including agitation, increased aggression, increased hyperphagia, and broken distal ulna (see Section 3.2)."

2) Page 32, fourth paragraph, fifth sentence

"AEs leading to discontinuation were primarily psychiatric (i.e., in addition to the two subjects who discontinued because of emotional disorder, one subject each discontinued because of aggression, agitation, behavior disorder, obsessive thoughts, and separation anxiety disorder)."

Revised text (deletions in strikethrough font and additions in bolded and underlined font):

"AEs leading to discontinuation were primarily psychiatric (i.e., in addition to the two subjects who discontinued because of emotional disorder, one subject each discontinued because of aggression, agitation, behavior disorder, **and** obsessive thoughts~~,~~ and separation anxiety disorder)."