(vii) and other serious events—e.g. refractory seizures,

strictly output-limited consistent with conventional tDCS protocols.

The FDA has developed various guidance documents for expedited regulation of non-invasive electrical stimulation devices (with indications ranging from esthetic to clinical) with either prescription of over-the-counter access; although pending these provide a basis for considering ‘‘Limited Output’’ tDCS. tDCS should not be confused with FDA designated Cranial Electrotherapy Stimulation (CES) that is not a comparable dose (not Direct Current) (104).