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Sent: Friday, March 27, 2020 12:14 PM

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<<u>David.Mednick@fda.hhs.gov</u>>; Heller, Seth <<u>Seth.Heller@fda.hhs.gov</u>> **Subject:** RE: JRC Petition for Stay - URGENT REVIEW REQUESTED

All,

As discussed, FDA is issuing the attached partial grant of your stay request. In addition to this stay, FDA will exercise enforcement discretion as described herein.

We understand that the Judge Rotenberg Educational Center (JRC) and a number of others filed appeals on March 26, 2020, challenging the Final Rule to Ban Electrical Stimulation Devices (ESDs) for Self-Injurious or Aggressive Behavior, 85 Fed. Reg. 13312 (Mar. 6, 2020), in the D.C. Circuit. Pending judicial review of the merits of those appeals, FDA does not intend to initiate enforcement action against JRC nor initiate or support a referral for any enforcement action to the U.S. Department of Justice against JRC with respect to patients currently treated with ESDs for SIB and AB. FDA understands that JRC, doctors, and patients will continue the use of ESDs for SIB and AB for existing patients being treated with GEDs while the abovementioned petitions for review are pending in federal court.

FDA's decision to exercise enforcement discretion does not extend to JRC patients who are not being treated with ESDs for SIB and AB at this time; FDA does not intend to bring an enforcement action with respect to the Final Rule against JRC while the appeals are pending without first completing an inspection of JRC.