U.S. FOOD & DRUG ADMINISTRATION

September 10, 2020

Max D. Stern
Todd & Weld, LLP
One Federal Street
Boston, MA 02110

Re: Petition for Stay of Action
Docket No. FDA-2020-P-1181

Dear Mr. Stern:

This letter responds to the above-referenced petition for a stay of action dated March 23, 2020, which you submitted on behalf of your clients, the parents and guardians of certain patients at the Judge Rotenberg Educational Center, Inc. (JRC), as well as the patients themselves, and the JRC Parents and Friends Association, Inc., collectively referred to as "Petitioners." In this petition, you request that the U.S. Food and Drug Administration (FDA) stay the "two effective dates" for the final rule banning electrical stimulation devices (ESDs) for self-injurious (SIB) or aggressive behavior (AB). For the reasons explained below, we conclude that your petition does not necessitate a different response or a change in the stay FDA granted to a substantially similar petition.

I. Background

On March 6, 2020, FDA issued a final rule banning ESDs for SIB or AB, finding that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling in accordance with section 516 of the Federal Food, Drug, and Cosmetic Act (85 FR 13312). The ban affects both new devices and devices already in distribution and use upon the effective date of the final rule, which was 30 days after publication of the final rule (April 6, 2020). However, for those individuals currently subject to ESDs for the identified intended use, the ban provides time to transition away from the use of ESDs under the supervision of a physician because FDA recognized that affected parties may need some time to establish or adjust treatment plans. Therefore, for devices currently in use on specific individuals subject to a physician-directed transition plan, compliance is required 180 days after the date of publication of the final rule (September 2, 2020). These two dates comprise the effective dates referenced in your petition.

On March 23, 2020, FDA received a petition filed by Eckert Seamans Cherin & Mellot, LLC, on behalf of their client, JRC (JRC petition), which references your petition, seeking the same request for an administrative stay of action under 21 CFR 10.35 as your petition.

On March 27, 2020, FDA provided a written response partially granting the JRC petition. Specifically, FDA granted a stay of the compliance date for devices subject to the ban which are currently in use on specific individuals who have or would need to obtain a physician-directed

transition plan to cease use of such devices. The stay is intended to remain in effect for the duration of the public health emergency declared by HHS relating to "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2), and the disease it causes "Coronavirus Disease 2019" (COVID-19)," which impacts the ability for individuals to create or implement a physician-directed transition plan and may divert healthcare delivery resources from other uses during the pandemic. The stay will continue thereafter for a period of time described in FDA's March 27, 2020 response if the public health emergency ends while the legal challenge to the ban is pending in the United States Court of Appeals for the D.C. Circuit. All documents are publicly available with the JRC petition docket number, FDA-2020-P-1166, at https://www.regulations.gov. Likewise, in accordance with 21 CFR 10.35(f), FDA published notice of the partial stay in the *Federal Register* of August 19, 2020 (85 FR 50950).

II. Conclusion

FDA has reviewed your petition and finds that it is substantially similar to the JRC petition and does not necessitate a different response or change in the stay FDA granted in response to the JRC Petition. As such, the stay described in FDA's March 27, 2020, letter and the *Federal Register* notice remains unchanged.

Sincerely,

Jeffrey E. Shuren -S

Digitally signed by Jeffrey E. Shuren -S
Date: 2020.09.14 12:45:18 -04'00'

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and
Radiological Health