June 11, 2022

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." As discussed in detail below, FDA dismisses this petition under 21 CFR 10.35(e) because changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot.

I. Background

On March 6, 2020, FDA issued a final rule banning electrical stimulation devices (ESDs) for self-injurious behavior (SIB) or aggressive behavior (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 Fed. Reg. 13312 (March 6, 2020). The ban affected 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 who at the time were currently subject to ESDs for the identified intended use, the ban provided time to transition away from the use of ESDs under the supervision of a physician because FDA recognized that affected parties might have needed some time to establish or adjust treatment plans. Therefore, for devices which at the time were currently in use on specific individuals subject to a physician-directed transition plan, compliance was 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 to stay the "two effective dates" for the final rule banning ESDs for SIB or AB under 21 CFR 10.35 (the JRC Petition). Shortly thereafter, you filed a similar petition containing substantially the same request.

On March 27, 2020, FDA partially granted the JRC Petition. Specifically, FDA granted a stay of the compliance date for devices subject to the ban which at the time were currently in use on specific individuals who had or would have needed to obtain a physician-directed transition plan

to cease use of such devices. FDA indicated in its letter to JRC and the subsequent Federal Register notice (85 FR 50950) that the stay was 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. Additionally, FDA stated that the stay would continue thereafter if the public health emergency ended while the legal challenge to the ban was pending in the United States Court of Appeals for the D.C. Circuit.

In accordance with 21 CFR 10.35(f), FDA published notice of the partial stay in the *Federal Register.* 85 Fed. Reg. 50950 (August 19, 2020). On that same day, FDA responded to your petition. FDA explained that it determined that your petition contains a substantially similar request to the JRC Petition and that a different response or change in the stay FDA granted in response to the JRC Petition was not warranted. FDA further indicated that we would substantively respond to your petition when we respond to the JRC petition.

II. 21 CFR 10.35 Petitions

Under 21 CFR 10.35, an interested person may request FDA stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period (21 CFR 10.35(b)). Request for a stay must be submitted no later than 30 days after the date of the decision involved. FDA may grant or deny a petition for stay of action, in whole or in part, if it is in the public interest and in the interest of justice (21 CFR 10.35(e)). FDA must grant a stay if all of the following apply: (1) The petitioner will otherwise suffer irreparable injury; (2) The petitioner's case is not frivolous and is being pursued in good faith; (3) The petitioner has demonstrated sound public policy grounds supporting the stay; and (4) The delay resulting from the stay is not outweighed by public health or other public interests. (21 CFR 10.35(e)). If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition. (21 CFR 10.35(e)).

III. Decision

On July 6, 2021, the D.C. Circuit vacated FDA's final rule. *Judge Rotenberg Educ. Ctr., Inc. v. United States*, 2021 U.S. App. LEXIS 19958 (D.C. Cir. July 6, 2021). This decision constitutes a change in law, facts, or circumstances that renders your petition moot. Because the Final Rule has no legal effect, the partial stay granted on March 27, 2020, is no longer necessary. Your petition is hereby dismissed as moot.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2022.06.11 19:15:03 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Center for Devices and
Radiological Health