



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 895

[Docket No. FDA-2016-N-1111]

Medical Devices; Petition for an Administrative Stay of Action: Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; notification of administrative stay.

SUMMARY: The Food and Drug Administration (FDA or Agency) is providing notice of a stay of the effectiveness of provisions for devices in use on specific individuals who have or would need to obtain a physician-directed transition plan as of the date of publication on March 6, 2020, of the final regulation banning electrical stimulation devices (ESDs) for self-injurious or aggressive behavior. FDA is publishing this notification in response to petitions for an administrative stay of action in accordance with regulatory requirements.

DATES: FDA is administratively staying temporarily the final regulation published on March 6, 2020 (85 FR 13312), for those devices in use on specific individuals as described in

SUPPLEMENTARY INFORMATION. FDA will publish a document in the *Federal Register* lifting the stay or taking further action as needed.

ADDRESSES: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville,

MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527, rebecca.nipper@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of March 6, 2020 (85 FR 13312), FDA issued a final regulation banning electrical stimulation devices (ESDs) for self-injurious behavior (SIB) or aggressive behavior (AB). This final regulation provided two operational dates. The ban is in effect for all devices as of April 6, 2020, 30 days after the date of publication. However, for devices in use on specific individuals as of the date of publication and subject to a physician-directed transition plan, compliance is required on September 2, 2020, 180 days after the date of publication of the final rule.

FDA received two requests under 21 CFR 10.35 to immediately and indefinitely stay these dates for the final regulation banning ESDs for SIB or AB. The first petition, dated March 20, 2020, is from Eckert Seamans Cherin & Mellot, LLC on behalf of their client, the Judge Rotenberg Educational Center, Inc. (JRC) (see Docket No. FDA-2020-P-1166). As described below, FDA temporarily granted this petition (JRC petition) in part on March 27, 2020. The second petition, dated March 24, 2020, is from Todd & Weld, LLP on behalf of their clients the parents and guardians of certain patients at JRC, as well as the patients themselves, and the JRC Parents and Friends Association, Inc. (see Docket No. FDA-2020-P-1181). This petition (Parent petition) was routed for review and response after FDA's March 27, 2020, letter granting JRC's request for a stay in part. Although filed by different parties, the Parent petition requested the same action as the JRC petition and did not necessitate a different response or change in the stay

FDA granted in response to the JRC petition. Both petitions request a stay based on all four criteria for a mandatory stay or, alternatively, based on being “in the public interest and in the interest of justice” for a discretionary stay (§ 10.35 (21 CFR 10.35(e))). Because the petitions request the same action for substantially similar reasons, FDA has determined that its March 27, 2020, response to the JRC petition is equally applicable to the Parent petition. FDA notes that both sets of petitioners filed legal challenges to the ban in the U.S. Court of Appeals for the D.C. Circuit, which challenges have now been consolidated before that court.

By a letter dated March 27, 2020, FDA responded to the JRC petition granting in part a discretionary temporary stay. As the letter states, it is in the public health interest and interest of justice to stay the compliance date for devices subject to the ban that are currently in use on specific individuals who would need to obtain a physician-directed transition plan to cease use of such devices. The stay is in the public interest and interest of justice because of the ongoing national emergency caused by “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2) and the disease it causes “Coronavirus Disease 2019 (COVID-19).” Specifically, the creation or implementation of a physician-directed transition plan has the potential to increase the risk of transmission or exposure to COVID-19, and it may divert healthcare delivery resources from other uses during the pandemic.

The stay is intended to remain in effect for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act (42 U.S.C. 247d(a)(2)). Once the public health emergency ends, FDA will substantively respond to the petitions, and issue another notification in the *Federal Register*, if necessary, in accordance with § 10.35. If the public health emergency ends while the consolidated legal challenge in the D.C. Circuit is still pending, the

stay will continue in effect until: (1) FDA substantively responds to the petitions and (2) if FDA does not grant the petitions, the parties have had adequate time and reasonable opportunity to obtain a ruling from the D.C. Circuit regarding a stay of FDA's response to the petitions.

FDA's partial stay is limited to those devices currently in use on specific individuals who have or would need to obtain a physician-directed transition plan to cease use of such devices in order to comply with the final regulation banning ESDs. For all other devices, the ban became effective on, and required compliance by, April 6, 2020.

Dated: July 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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