navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6010(b) Alaskan VOR Federal Airways.

* * * * *

V–477 [Amended]

From Galena, AK; Huslia, AK; to Selawik, AK.

* * * * *

Issued in Washington, DC, on March 20, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–06230 Filed 3–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 895

[Docket No. FDA–2023–N–3902]

RIN 0910–AI84

Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to ban electrical stimulation devices (ESDs) intended for self-injurious behavior (SIB) or aggressive behavior (AB). FDA has determined these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. This proposal follows a court decision vacating a prior ban and amendment to the Federal Food, Drug, and Cosmetic Act clarifying our authority to ban a device for one or more intended uses. This action, if finalized, will mean ESDs for SIB and AB are adulterated and not legally marketed.

DATES: Either electronic or written comments on the proposed rule must be submitted by May 28, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 28, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3902 for ''Banned Devices; Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you

must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words as required by the ''Providing Accountability Through Transparency Act,'' or the electronic and written/paper comments received, 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, 240–402–7500.

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:

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to ban ESDs intended for self-injurious behavior (SIB) or aggressive behavior (AB) pursuant to the Agency's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) after determining that the devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. FDA previously issued a final rule in 2020 banning these devices (2020 Final Rule) (85 FR 13312, March 6, 2020), which was vacated by the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) on July 6, 2021. The D.C. Circuit opined that FDA's authority to ban devices intended for human use under the FD&C Act, as it existed at the time, did not permit FDA to ban a device for some (but not all) of its intended uses. Following the D.C. Circuit's decision, Congress amended the FD&C Act to expressly state that FDA's authority to ban a device includes the authority to ban some intended uses of a device, even if the Agency does not seek to ban it for all intended uses. The amendment to the FD&C Act thereby authorizes FDA to issue a ban that applies to specific intended uses, such as the previous ban on ESDs for self-injurious and aggressive behavior. This proposed rule, if finalized, would reestablish the ban now that it is clear that FDA has the authority to do so.

ESDs are aversive conditioning devices that apply a noxious electrical stimulus (a shock) to a person's skin to condition behavior to reduce or cease SIB and AB. SIB and AB frequently manifest in the same individual, and people with intellectual or developmental disabilities exhibit these behaviors at disproportionately high rates. Notably, some people with intellectual or developmental disabilities who exhibit SIB and AB have difficulty communicating and cannot make their own treatment decisions because of such disabilities, meaning they are part of a vulnerable population.

In issuing the 2020 Final Rule, FDA determined that the medical literature shows that ESDs for SIB or AB pose a number of psychological harms including depression, post-traumatic stress disorder (PTSD), anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage. We also found that other sources, such as experts in the field, State agencies that regulate ESD use, and records from the only facility that has recently manufactured and is currently using ESDs for SIB or AB, indicate that ESDs pose additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling. We also determined that state-of-the-art treatments for this patient population have evolved away from ones that include ESD use and toward various positive behavioral treatments, sometimes combined with pharmacological treatments. Although the available data and information suggest that some individuals subject to ESDs exhibit an immediate reduction or cessation of the targeted behavior, the available evidence has not established a durable long-term conditioning effect or an overall favorable benefit-risk profile for ESDs for SIB and AB.

For this proposed rule, FDA has determined that there have been no material changes regarding these topics in the available literature that impact our findings and assessments in the 2020 Final Rule. Accordingly, FDA has determined on the basis of all available data and information that ESDs for SIB or AB present an unreasonable and substantial risk of illness or injury and that such risk cannot be corrected or eliminated by labeling or by a change in labeling. FDA is issuing this proposed rule to give notice of FDA's determination and give interested persons an opportunity to comment on the determination and FDA's proposal to ban ESDs for SIB and AB. All references to section numbers are references to section numbers in this proposed rule unless otherwise specified.

B. Summary of the Major Provisions of the Proposed Rule

We are proposing to amend part 895 (21 CFR part 895) to designate ESDs for SIB or AB as banned devices. If this proposed rule is finalized as proposed, the ban would include only aversive conditioning devices intended to apply a noxious electrical stimulus to a person's skin to reduce or cease aggressive or self-injurious behavior. The proposed ban would apply to devices already in commercial

distribution and devices already in use by the ultimate (end) user, as well as devices to be sold or commercially distributed in the future. A banned device is an adulterated device, subject to enforcement action. Additionally, a device that is banned for one or more intended uses is not legally marketed within the meaning of section 1006 of the FD&C Act (21 U.S.C. 396) when intended for such use or uses. The ban would not, however, prevent further study of such devices pursuant to an investigational device exemption if the requirements for such an exemption are met. We also are proposing conforming edits to 21 CFR part 882 to clarify that ESDs are banned when used to reduce or cease SIB or AB.

C. Legal Authority

We are proposing to issue this rule pursuant to FDA's authority to ban devices intended for human use, as recently amended by Congress. We also are proposing to issue this rule under the authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

This proposed rule, if finalized, would reestablish the ban of ESDs for SIB or AB. FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. The proposed rule, if finalized, would apply to both new devices and devices already in distribution and use. Unquantified benefits would include reduction in physical and psychological adverse effects from using ESDs on individuals, as well as benefits to society in terms of protecting vulnerable populations. We quantify costs for the case in which the affected individuals might move to another facility and costs to the affected entities, who use the device on such individuals, to read and understand the rule. We estimate that the annualized costs over 10 years would range from $0.00 million to $9.17 million with a primary estimate of $4.59 million at both a 7 percent and a 3 percent discount rate.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/ acronym	What it means
AB	Aggressive Behavior.
ABA	Applied Behavior Analysis.
ABAI	Association for Behavior Analysis International.
AE	Adverse Event.
DBT	Dialectical Behavioral Therapy.
EA	Environmental Assessment.
ESD	Electrical Stimulation Device.
FA	Analogue Functional Analysis.
FDORA	Food and Drug Omnibus Reform Act of 2022.
FONSI	Finding of No Significant Impact.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
GED	Graduated Electronic Decelerator.
mA	Milliampere.
MSW	Municipal Solid Waste.
PBS	Positive Behavioral Support.
PTSD	Post-traumatic Stress Disorder.
SIB	Self-Injurious Behavior.

III. Background

FDA is proposing to ban certain devices that apply a noxious electrical stimulus to attempt to reduce or stop undesirable, injurious behaviors frequently manifested by vulnerable people. Specifically, this rulemaking would ban ESDs for SIB or AB because the devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. This is the second ban on these devices we are undertaking to protect and promote the public health. As we will explain in more detail, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) vacated the first ban.

A. Introduction

ESDs for SIB or AB give people an often-painful electric shock to try to make them stop behaving in ways that are harmful and/or dangerous and that are often related to other underlying intellectual or developmental disabilities. More specifically, ESDs are a type of aversive conditioning device that apply a noxious electrical stimulus (the shock) to a person's skin in an attempt to reduce or cease self-injurious or aggressive behaviors. SIB commonly includes head-banging, hand-biting, excessive scratching, and picking of the skin. However, SIB can be more extreme and result in bleeding; broken, even protruding bones; blindness from eye-gouging or poking; other permanent tissue damage; or injuries from swallowing dangerous objects or substances. AB can involve repeated physical assaults and can be a danger to the individual, others, or property. In this proposed rule, like much of the scientific literature, we discuss SIB and AB in tandem and use the phrase ''SIB or AB'' to refer to SIB, AB, or both. A more detailed discussion of SIB and AB and intellectual or developmental disabilities as they relate to individuals with SIB or AB can be found in section I.B of the previous proposed rule to ban these devices (2016 Proposed Rule) (81 FR 24386 at 24389).

ESDs that are subject to this proposed ban are intended to reduce SIB or AB according to the principle of aversive conditioning. Aversive conditioning pairs a noxious stimulus (such as, here, a noxious electric shock delivered to an individual's skin) with a target behavior; the goal is that the individual eventually associates the noxious stimulus with the behavior. Pairing a target behavior with shocks from an ESD is intended to affect behavior in two ways: by interrupting the target behavior as an immediate response to the stimulus—for example, in response to pain—and, over time, through a conditioned reduction in the target behavior if the person learns to associate the shock with the target behavior (and can learn to control the behavior). Associating the unwanted behavior with the shock is intended to decrease the frequency of the behavior or stop it altogether.

However, as explained here, ESDs pose a number of serious risks and have not been shown to be effective, and modern treatments for SIB or AB have been generally successful without involving the use of ESDs. State-of-the-art treatments instead include conducting a functional behavioral assessment to determine the causes and triggers of self-injury or aggression, then using that information to design a plan with supportive approaches, consisting of multiple elements, to modify the behavior. In some cases, pharmacotherapy is an appropriate element of a treatment plan, depending on the specific patient. These approaches have generally been successful, even for some of the most difficult cases. The use of ESDs was mostly abandoned decades ago, in part because the shocks can be painful or very painful for the recipients. Only one facility in the United States still applies these devices to individuals.

Although in 2018 a Massachusetts court found, for the purpose of considering whether to lift a consent decree, that there was no professional consensus as to whether ESDs are part of standard of care for treating individuals with intellectual and developmental disabilities,[1] the professional consensus regarding the accepted standard of care and such use of ESDs is not an issue in this rulemaking (see discussion in the 2020 Final Rule, 85 FR 13312 at 13314 through 13315). Rather, to ban a device

[1] On September 7, 2023, the Supreme Judicial Court of Massachusetts considered the narrow question of whether the probate judge abused her discretion in making that finding based upon the evidence before her at the time of that decision (all of which was from 2016 and earlier), and concluded that she had not. See *Judge Rotenberg Educational Center, Inc.* v. *Commissioner of the Department of Developmental Services,* 492 Mass. 772 (September 7, 2023).

under section 516 of the FD&C Act (21 U.S.C. 360f), FDA must determine the device presents an ''unreasonable and substantial risk of illness or injury.'' In making this determination, FDA analyzes whether the risks the device poses to individuals are important, material, or significant in relation to its benefits to the public health, and FDA compares those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice (which relates to what FDA refers to as ''the state of the art'') (85 FR 13312 at 13315; 81 FR 24386 at 24388). The purpose of considering the alternatives used in current medical practice to treat a particular patient population is to assess and compare the risks and benefits of those alternatives to the risks and benefits of the device that is the subject of the ban, not to determine whether the device that is the subject of the ban is part of the standard of care or state of the art. For these reasons, as stated in the 2020 Final Rule, whether punishment, contingent shock, or ESDs are within the standard of care or state of the art is not an issue in this rulemaking (85 FR 13312 at 13341). In sum, the court's decision has no legal or scientific bearing on this proposed ban.

B. Need for the Regulation

This rulemaking would protect and promote the public health by banning ESDs for SIB or AB, which would prevent this patient population from being subjected to a device that poses a substantial and unreasonable risk of illness or injury. As we explained in the previous rulemaking to ban ESDs for SIB and AB, people who manifest SIB or AB often have intellectual and developmental disabilities including, but not limited to, autism spectrum disorder, Down syndrome, or Tourette syndrome, as well as other cognitive or psychiatric disorders and severe intellectual impairment (including a broad range of intellectual measures) (see, *e.g.,* 81 FR 24386 at 24389). Notably, some people with such intellectual and developmental disabilities may have difficulty communicating and may not be able to make their own treatment decisions because of such disabilities (see, *e.g.,* 85 FR 13312 at 13329). This, among other reasons, means that many people who exhibit SIB or AB constitute a vulnerable population. For people who manifest SIB or AB, ESDs intended for those conditions present a substantial and unreasonable risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. As such, a ban on these devices for these intended uses is warranted.

As discussed in section IV below, section 516(a) of the FD&C Act authorizes FDA to ban a device for one or more intended uses, by regulation, if we find, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury. Accordingly, based on the serious risks posed by ESDs for SIB or AB, the inadequacy of data to support their effectiveness, and the positive benefit-risk profiles of the state-of-the-art alternatives for the treatment of SIB or AB, FDA has determined that ESDs present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. The proposed rule would apply to devices already in distribution and use, as well as to future sale and distribution of these devices. The purpose of this notice is to seek comments on FDA's proposal to ban ESDs used for SIB or AB and comments on any other associated issues. Section V of this document discusses the information and data that support these proposed findings.

C. FDA's Current Regulatory Framework

The FD&C Act, as amended by the Medical Device Amendments of 1976 (1976 Amendments) (Pub. L. 94–295), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act establishes three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls), and class III (premarket approval) (see 21 U.S.C. 360c).

In 1979, FDA classified aversive conditioning devices as class II (see § 882.5235 (21 CFR 882.5235)), which was consistent with the recommendation of the Neurological Device Classification Panel in 1978. Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Aversive conditioning devices, as a device type, administer an electric shock or another noxious stimulus to a patient to modify undesirable behavioral characteristics (see § 882.5235). Thus, ESDs intended for SIB and AB, which administer shocks to modify target behaviors, are within the aversive conditioning device classification regulation. As discussed in more detail in section I.D. of the previous proposed rule (81 FR 24386 at 24391), in the late 1970s, FDA and the panelists of the Neurological Device Classification Panel believed that performance standards could adequately assure the safety and effectiveness of aversives and proposed a classification accordingly. We received no comments from the public on the proposed rule, and we issued the final rule classifying aversives as proposed at § 882.5235 (44 FR 51726 at 51765, September 4, 1979).

As we explained during the previous rulemaking to ban ESDs for SIB and AB, and as remains true, FDA now has a better understanding of the risks and benefits presented by these devices than we did 44 years ago when these devices were classified. As summarized in section III.B and explained more fully in section V.E. of the 2020 Final Rule, the state of the art for the treatment of SIB and AB has progressed significantly over that time period (85 FR 13312 at 13337 through 13344). The development of the scientific literature and treatments for these conditions only underscores that the risk of illness or injury from the use of ESDs for SIB and AB is unreasonable and substantial.

D. History of the Rulemaking

FDA previously banned ESDs for SIB and AB in a final rule issued on March 6, 2020, pursuant to the Agency's authority under section 516 of the FD&C Act (85 FR 13312 at 13354). Specifically, section 516 of the FD&C Act provides that FDA may ban a device intended for human use if the Agency determines that the device presents substantial deception or an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or change in labeling. Leading up to the final ban, FDA held a public meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee on April 24, 2014 (see 79 FR 17155, March 27, 2014) (Ref. 1), issued a proposed ban in the **Federal Register** of April 25, 2016, and considered comments on the proposal from interested stakeholders (81 FR 24386). These activities garnered significant interest, and FDA received and reviewed voluminous information to develop the final rule banning ESDs for SIB and AB.

FDA issued the 2020 ban because we determined, based on all available information and data at that time, that ESDs for SIB or AB present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. FDA found the weight of the evidence indicates that ESDs for SIB or AB present a number of psychological and physical risks. We determined the evidence does not establish that ESDs improve the underlying causative disorder or effectively condition individuals to achieve durable reduction of SIB or AB for a clinically meaningful period of time. FDA also found the weight of the evidence indicates that the state-of-the-art treatment for individuals with SIB or AB relies on multielement positive interventions, for example, paradigms such as positive behavior support (PBS) or dialectical behavioral therapy (DBT), sometimes in conjunction with pharmacological treatments (85 FR 13312 at 13315 and 13337). Even in cases in which behavioral modification plans include punishment techniques, the techniques are significantly less intrusive than ESDs and do not inflict pain; for example, they include timeouts.

Following the publication of the 2020 ban, the sole manufacturer and only facility to use ESDs for SIB and AB, The Judge Rotenberg Educational Center, Inc. (JRC), challenged in court FDA's authority to issue the 2020 ban. On July 6, 2021, the D.C. Circuit vacated the 2020 ban. See *Judge Rotenberg Educational Center, Inc.* v. *FDA,* 3 F.4th 390 (D.C. Cir. 2021). The court interpreted section 516 of the FD&C Act, as it existed at the time, and section 1006 of the FD&C Act, as not permitting FDA to ban devices for specific intended uses, in that instance ESDs for SIB or AB, without banning the device for all intended uses.

Following the court's decision, Congress enacted the Food and Drug Omnibus Reform Act of 2022 (FDORA) (Pub. L. 117–328). FDORA amended section 516(a) of the FD&C Act to expressly state that FDA's authority to ban a device intended for human use includes the authority to ban a device for one or more intended uses, and that a device banned for one or more intended uses is not a legally marketed device under section 1006 of the FD&C Act. As amended, the statute is clear that FDA may issue a ban such as the previous ban on ESDs for SIB or AB, which applies to one or more specific intended uses. After reviewing publications and other information that have become known to the Agency in the brief interim between the issuance of the previous ban in 2020 and now, and determining that it does not change our conclusion that ESDs for SIB or AB present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling, FDA is proposing to ban ESDs intended for SIB or AB under section 516 of the FD&C Act, as amended.

IV. Legal Authority

Under section 516 of the FD&C Act, FDA may ban a device by regulation if we find, on the basis of all available data and information, that such a device with the relevant intended use(s) presents substantial deception or an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or change in labeling (see 21 U.S.C. 360f(a)(1) and (2), as amended by section 3306 of FDORA).

Section 3306 of FDORA expressly provides that FDA has the authority to ban a device for one or more intended uses and that FDA's authority under section 516 of the FD&C Act is not limited only to bans of a device for all of its intended uses. The legislative history reinforces that section 516 of the FD&C Act, as amended, authorizes FDA to ban a device regardless of whether or not the ban includes other devices that are technologically similar but have different intended uses (see H. Rept. 117–348 at 65). The regulatory status of a device has long depended on its intended use(s), even before the enactment of the 1976 Amendments (see id.). A product's status as a device regulated by FDA, along with its classification, premarket pathway, labeling, and other requirements all ''very much depend on its intended use'' (id. at 65–66). The amendment to section 516 of the FD&C Act makes clear that the same principle applies to FDA's banning authority, permitting FDA to ban certain intended use(s) of a type of technology that meet the standard to ban devices, while not banning others that do not (see id. at 66).

A banned device, as defined in part by its intended use(s), is adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), except to the extent it is being studied pursuant to an investigational device exemption under section 520(g) of the FD&C Act (21 U.S.C. 360j(g)). The FD&C Act defines various prohibited acts respecting adulterated devices (see 21 U.S.C. 331).

This proposed rule is also issued under section 701(a) of the FD&C Act, which provides FDA authority to issue regulations for the efficient enforcement of the FD&C Act (see 21 U.S.C. 371(a)). This rule, if finalized, would enable FDA to efficiently enforce the FD&C Act.

Part 895 sets forth the regulations that apply to banning devices under section 516 of the FD&C Act. Consistent with those regulations (and other applicable legal provisions), we are proposing findings, based on all available information and data, that ESDs for SIB or AB present a substantial and unreasonable risk of illness or injury.

In determining whether a risk of illness or injury is ''substantial,'' FDA considers whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing (see § 895.21(a)(1) (21 CFR 895.21(a)(1))).

Although FDA's device banning regulations do not define ''unreasonable risk,'' we explained in the preamble to the final rule establishing part 895 that, with respect to ''unreasonable risk,'' we will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users (44 FR 29214 at 29215, May 18, 1979). The state of the art with respect to this rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior.

Thus, in determining whether a device presents an ''unreasonable and substantial risk of illness or injury'' for one or more intended uses, FDA analyzes the risks and the benefits the device poses to individuals when used for such intended use or uses, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information (H. Rept. 94–853 at 19; 44 FR 29214 at 29215).

If FDA determines that the risk can be corrected through labeling, FDA will notify the responsible person of the required labeling or change in labeling necessary to eliminate or correct such risk (see 21 CFR 895.25). Because FDA is proposing to determine that the risk associated with using ESDs for SIB or AB cannot be corrected or eliminated by labeling, we are not at this time notifying responsible persons regarding labeling. If FDA finalizes this ban as proposed, ESDs intended for SIB or AB

will be adulterated and not legally marketed within the meaning of section 1006 of the FD&C Act when intended for SIB or AB.

To ban a device intended for human use, § 895.21(d) requires that a proposed ban briefly summarize:

- the Agency's findings regarding substantial deception or an unreasonable and substantial risk of illness or injury;
- the reasons why FDA initiated the proceeding;
- the evaluation of the data and information FDA obtained under provisions (other than section 516) of the FD&C Act, as well as information submitted by the device manufacturer, distributer, or importer, or any other interested party;
- the consultation with the classification panel;
- the determination that labeling, or a change in labeling, cannot correct or eliminate the deception or risk;
- the determination of whether, and the reasons why, the ban should apply to devices already in commercial distribution, sold to ultimate users, or both; and
- any other data and information that FDA believes are pertinent to the proceeding.

The previous proposed and final ban on ESDs for SIB or AB describe this information extensively, and we do not repeat that information in full here. Instead, because the primary change in circumstances leading to this rulemaking is of a legal (not scientific) nature, this proposed rule references the information and findings from the previous rulemaking and briefly summarizes that information with reference to the previous proposed rule, final rule, or both, as applicable. In addition, this proposed rule discusses the new data and information that FDA has become aware of since the 2020 Final Rule.

FDA notes that, although a banned device or banned intended use of a device is not barred from clinical study under an investigational device exemption pursuant to section 520(g) of the FD&C Act, any such study must meet all applicable requirements. These include, but are not limited to, requirements for: protection of human subjects (21 CFR part 50), financial disclosure by clinical investigators (21 CFR part 54), approval by institutional review boards (21 CFR part 56), and investigational device exemptions (21 CFR part 812).

V. Evaluation and Discussion of Data and Information

FDA has determined, on the basis of all available data and information, that ESDs for SIB or AB present a substantial and unreasonable risk of illness or injury. Given the relatively short amount of time since the previous ban that we finalized in 2020, there is very little relevant data or information that we have not already considered and discussed in the previous rulemaking. The few publications and other information that have become known to the Agency in the brief interim between the issuance of the previous ban in 2020 and now do not change our conclusions regarding the risks or effects of ESDs for SIB or AB or the state of the art of treatment for this patient population. We are therefore referencing our previous discussion and findings (81 FR 24386 at 24386 through 24412 and 85 FR 13312 at 13312 through 13349) in this rulemaking and supplementing them with an explanation of how since-developed data and information have added to our understanding of the relevant issues. We also are associating with this rulemaking the public dockets created for the previous rulemaking (Docket No. FDA–2016–N–1111) and the Neurological Devices Panel of the Medical Devices Advisory Committee on April 24, 2014 (Docket No. FDA–2014–N–0238) and consider them part of this proposed rule. All of the documents associated with Docket No. FDA–2016–N–1111 and Docket No. FDA–2014–N–0238 are contained in the docket for this proposed rule as well. With regard to the available data and information, this proposed rule therefore focuses on new information and data that we have become aware of since we issued the previous ban.

To identify and assess information that we had not previously considered, we conducted a search for literature on the risks and effects of ESDs for SIB or AB published since our systematic literature review for the 2016 Proposed Rule and again assessed the state of the art for treating SIB or AB.

Our search returned the following new sources: (1) 5 research studies (3 case reports, an open label add-on study, and a retrospective chart review); (2) 4 policy or consensus statements; a task force report; (3) 11 commentaries by researchers, academics, or practitioners; (4) a set of practice guidelines; (5) a followup survey of 88 former patients of JRC that did and did not have ESDs as part of their treatment plans; (6) and a meta-analysis. FDA weighed the new information according to the same factors that we explained in the 2016 Proposed Rule and 2020 Final Rule.

During the development of the 2020 Final Rule, in the form of comments to the docket, JRC provided the Agency with several JRC studies, information, and numerous records of patients with SIB or AB whose treatment plans include ESD use. Of the five new research studies, four are authored or coauthored by JRC staff. The four JRC research studies appear to be based largely on this same information and patient data and, as discussed in sections V.A and B, have many of the same significant limitations identified by FDA as the previously submitted studies, meaning the studies are less likely to support confidence in generalizable results than studies with more scientifically sound designs and methodologies. As a result, while the publication process adds some reassurances to the credibility of the information and data, presenting previously submitted data in a different form does little to add to overall knowledge about the risks and effects of ESDs for SIB or AB.

Generally speaking, little new information or data have developed since our previous consideration of banning ESDs for SIB or AB. Nonetheless, the new material is consistent with the evidence FDA previously considered regarding the risks presented by this device, the lack of evidence of its effectiveness for the treatment of SIB or AB, and the state of the art for treating SIB or AB, which includes successful interventions that are less restrictive and lower risk, as has been the case for decades (85 FR 13312 at 13341). Accordingly, we have again found that the devices present a substantial and unreasonable risk of illness or injury that cannot be corrected or eliminated by labeling or change in labeling.

A. Risks of ESDs for SIB or AB

The new studies and other materials that FDA reviewed are consistent with our previous findings regarding the risks of ESDs for SIB or AB, including likely underreporting of adverse events (AEs). As explained in the 2016 Proposed Rule and 2020 Final Rule, the risks presented by ESDs are both psychological (including suffering) and physical (including pain), each having a complex relationship with the electrical parameters of the shock. The subjective experience of the person receiving the shock can therefore be difficult to predict. Physical reactions roughly correlate with the peak current of the shock delivered by the ESD. However, various other factors such as sweat,

electrode placement, recent history of shocks, and body chemistry can physically affect the sensation. As a result, the intensity or pain experienced by an individual from a particular set of shock parameters can vary greatly from patient to patient and from shock to shock. More information about the relationship between the electrical parameters of the shock and conditions that may affect patient perception can be found in section I.C. of the 2016 Proposed Rule (81 FR 24386 at 24390 through 24391) and Response 14 of the 2020 Final Rule (85 FR 13312 at 13322).

Possible adverse psychological reactions are even more loosely correlated with shock strength or intensity (85 FR 13312 at 13322). To cause such adverse reactions, the shock needs to be subjectively stressful enough to cause trauma or suffering, which does not necessarily require a strong shock. Trauma becomes more likely, for example, when the recipient does not have control over the shock or has developed a fear of future shocks, neither of which is an electrical parameter of the shock. A more detailed explanation of these phenomena can be found in the 2016 Proposed Rule (81 FR 24386 at 24387) and the 2020 Final Rule (85 FR 13312 at 13324 through 13325).

To summarize, FDA found that the medical literature shows ESDs present a number of psychological harms including depression, PTSD, anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage.

FDA also considered risks identified through other sources, such as experts in the field, State agencies that regulate ESD use, and records from the only facility that has recently manufactured and is currently using ESDs for SIB or AB. These sources further support the reports of risks in the literature and indicate that ESDs pose additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling (85 FR 13312 at 13315). For more information about FDA's analysis regarding the risks of ESDs for SIB and AB, see section V.C. of the 2020 Final Rule (85 FR 13312 at 13321 through 13332).

We also concluded that the medical literature likely underreports AEs. This is attributable to several factors including the small number of subjects in the studies, many of whom have impaired ability to demonstrate and communicate AEs; potential attribution by clinicians of adverse effects to the patients' cognitive, intellectual, or psychiatric conditions rather than to the device; methodological limitations such as study design and the lack of a prespecified systematic plan for monitoring AEs; and researcher bias (81 FR 24386 at 24395 through 24396; 85 FR 13312 at 13329 and 13331).

The new sources that are based largely on data and information that FDA previously reviewed when developing the 2020 Final Rule support our previous determinations for the 2020 Final Rule about the types of risks posed by ESDs for SIB or AB. As a result, these new sources do not significantly affect our previous assessment of risks. Specifically, one meta-analysis of 150 reports and studies (Ref. 2) and four commentaries (Refs. 3 to 6), including one by a JRC staff member, report AEs associated with ESDs for SIB or AB. These sources identify the following physical and psychological risks:

- pain (Refs. 2, 3, 5);
- escape or avoidance responses (Refs. 3 and 5);
- extreme anxiety manifesting as screaming, crying, negative vocalizations when ESD was implemented, and attack (Refs. 3 and 5);
- tensing of the body (Ref. 3);
- emotional behavior (Ref. 3);
- fear (Refs. 4 to 6);
- feeling terrorized (Ref. 6);
- panic (Ref. 5);
- ''freezing'' (Ref. 5);
- attempts to remove the device (Ref. 5);
- distress (Refs. 2 and 4);
- burns (Refs. 3 and 6);
- tremor in the thigh during activation (Ref. 3); and
- temporary skin discoloration (Ref. 3).

In addition, the new sources based primarily on data and information that FDA had not previously reviewed for the 2020 Final Rule generally support these risks. A task force of the Association for Behavior Analysis International (ABAI) reports pain and attempts to remove the device (Ref. 7) and two of the studies (Refs. 8 and 9) report pain, escape/avoidance, and/or temporary anxiety, as noted below. While some of these new sources suggest that there is no strong evidence of negative ''side effects'' of ESDs based on research to date (Ref. 7) or no occurrence of AEs (Ref. 8), these conclusions are based on studies that have significant limitations, as discussed below and in the previous rulemaking (81 FR 24386 at 24400 through 24401). During the previous rulemaking, some experts expressed concern about a heightened risk of AEs ''from exposing a member of a vulnerable patient population to continual, painful shocks over a period of years, in many cases several years'' (85 FR 13312 at 13327).

As discussed in section V.B., the new studies continue to demonstrate use of ESDs for lengthy, indefinite periods of time and adaptation of some patients to the shocks (they no longer respond to shocks), even at the strongest level. The use of ESDs for long periods and on patients who have adapted to shocks would provide greater opportunity for AEs to occur, or for existing AEs to get worse due to cumulative effects, in a population largely consisting of vulnerable individuals. A treatment plan that includes use of ESDs for individuals with SIB or AB indefinitely (Ref. 10) would further heighten the concern about the risks of AEs. As explained further in section V.B., a 173-patient retrospective chart review study suggests that JRC attempts ''planned fading'' of ESD use, defined in that study as the removal of all ESD devices for any period, for only a relatively few number of individuals the attending clinician believes are likely to succeed (Ref. 9).[2] Thus, most of the individuals would continue to accumulate exposure to the risks of ESDs for SIB or AB. Further, a decision to use ESDs for ''long-term management'' of SIB or AB (Ref. 10) could suppress behavior in a manner that masks an underlying medical condition (Ref. 7). This in turn can affect access to (or the desire to access) effective treatments, which itself represents a risk to health.

The new sources also add evidence for the likelihood of underreporting of AEs for the same reasons we previously found for the medical literature reviewed for the 2020 ban: the impaired ability of many subjects to demonstrate and communicate AEs, which also increases the risk of harm to these individuals; difficulty of practitioners to recognize feedback from patients indicating that an AE occurred; methodological limitations in the studies; and researcher bias. Thus, while some new sources indicate that research ''does not provide strong evidence that [ESDs are] associated with negative side effects'' and that the ''few studies presenting data on the side effects of [ESDs] have reported only

[2] According to the study, only 23 of 173 individuals were in the planned fading group.

positive collateral changes in responding,'' (Ref. 7), these conclusions need to be viewed with these limitations in mind.

Like the medical literature considered for the 2020 Final Rule, most of the new studies involve a small number of patients, some of whom likely would have difficulty communicating or otherwise demonstrating AEs, including injuries, due to cognitive, intellectual, or psychiatric conditions. As noted in the 2016 Proposed Rule (81 FR 24386 at 24395), this difficulty may prevent providers from recognizing feedback from patients indicating that an AE has occurred.

None of the new studies prospectively planned for the systematic observation and collection of data regarding AEs, and very few AEs are reported. Only one new study on the use of the GED, the only ESD still in use for SIB or AB, identified any AEs (Ref. 9). That study, a retrospective chart review of 173 patients authored by JRC staff, reports only what the authors ''anecdotally'' found were ''the most common side effects'': escape/avoidance responses and temporary anxiety during the period between occurrence of the behavior and the ''programmed consequence,'' *i.e.,* shock (Ref. 9). The study reports that staff members who administered shocks were ''prompted to report any adverse conditions,'' and acknowledges that ''a standardized *a priori* system was not employed'' for monitoring AEs (Ref. 9). Thus, the study does not report systematic, recorded counts of adverse events based on specific identification or followup protocols. Rather, it reports the authors' subjective opinion in hindsight. Three of the other new studies, two of which were authored or coauthored by JRC staff, include no assessment of AEs (Refs. 10 to 12).

The remaining new study, a case report coauthored by JRC staff, reports ''no evidence of physical or psychological adverse effects when GED is administered per protocol'' (Ref. 8). Despite that statement, the study lists temporary pain as a ''con'' of GED use. Further, the JRC coauthor of the study, who is also coauthor of three of the other new studies, continues to acknowledge that ''[t]he obvious effect of [the ESD] is pain caused when electrical current stimulates nociceptors and sensory receptors'' (Ref. 3). As explained in the 2016 Proposed Rule and 2020 Final Rule, FDA considers pain to be an AE. Such biases against recognizing and/or recording certain harms as AEs creates doubt that the studies adequately considered AEs and, therefore, the risks of the device. Such biases also would impair an accurate benefit-risk assessment; undesirable effects should not be presumed unavoidable, much less go unaccounted for, even if they ultimately prove to be reasonable. The pain ESDs cause is relevant because, although ESDs are intended to apply an aversive stimulus, the pain they cause to attempt to develop the aversion is nevertheless harmful.

All of the new studies are retrospective reviews of clinical experience, not prospective studies. While retrospective reviews can be informative, creating a plan to identify AEs in a standardized, forward-looking way and ensure a comprehensive record from the outset will generally provide much stronger support for a conclusion that a lack of reported AEs means a lack of AEs to report.

As with the earlier studies, researcher bias and author conflicts of interest also may have contributed to underreporting of AEs. As indicated in section III.D., JRC is the sole manufacturer and only facility to use ESDs for SIB or AB. Four of the five new studies that looked at ESDs for SIB or AB were authored or coauthored by current JRC staff and may have minimized AEs. As noted earlier, only one study reports any AEs experienced by patients and limits reporting only to the ''most common side effects,'' of which pain was not included (Ref. 9).

The other new sources that FDA reviewed also suggest a lack of attention to the careful and systematic assessment of AEs in research involving ESDs, and more generally, in research involving intellectually and developmentally disabled individuals (Refs. 2, 4 to 6, 8, and 13 to 17). For instance, one meta-analysis looking at reporting of AEs in research involving young autistic children notes that ''[s]tudies of effectiveness did not systematically define, monitor, or measure adverse events; instead they were reported in an ad hoc fashion and considered tangential to the studies'' (Ref. 2). Another author discussing research involving autistic individuals opines that the inadequate attention to and examination of harms amounts to ''negligent reporting'' (Ref. 13). While not all individuals with SIB or AB are autistic, this information informs our general understanding of the limitations in research involving individuals with intellectual and developmental disabilities. This information tends to show that research that, in general, involves people who have difficulties communicating and, more specifically, involves the use of ESDs for SIB or AB, often does not provide a complete picture of AEs.

Given the foregoing, FDA has not changed its determination that AEs very likely have been underreported in the literature. More information about FDA's prior conclusion that AEs likely are underreported in the literature can be found in the 2020 Final Rule at Responses to Comments 26–29 of (85 FR 13312 at 13329 through 13332).

Thus, based on the totality of the information available to FDA, our determination regarding the risks posed by ESDs for SIB or AB identified in the 2020 Final Rule has not changed.

B. Effects of ESDs for SIB or AB

The new information that FDA reviewed does not change our previous determinations regarding effectiveness of ESDs for SIB or AB. For the 2020 Final Rule, FDA determined that some individuals subject to ESDs may exhibit an immediate interruption of the targeted behavior if the shock is applied while the behavior is occurring, assuming the individual has not adapted to the shocks (85 FR 13312 at 13333). However, we also determined that the available evidence does not establish that ESDs improve the underlying causative disorder or condition an individual to achieve a durable reduction of SIB or AB for a clinically meaningful period of time (85 FR 13312 at 13333). A durable effect is one where an individual develops a conditioned response, so the target behavior, along with the frequency of shocks, is significantly reduced over a clinically meaningful period of time, either while the individual continues to wear the ESD or after the ESD is removed.

As we discussed in the 2020 Final Rule (see 85 FR 13312 at 13332), FDA found some information in the scientific literature to suggest ESDs may reduce SIB and AB in some individuals. However, as we explained, the evidence cannot be generalized and is insufficient to demonstrate effectiveness because the studies suffer from serious limitations that limit confidence in the results, including weak design, small size, confounding factors, outdated standards for conduct, and study-specific methodological limitations. As discussed in the 2016 Proposed Rule, generally a study's strength or weakness is related to design in a number of ways, particularly through randomization, control, and the number of study subjects. There have been no large, randomized, and controlled trials, or even any large or randomized trials, of

ESDs for SIB or AB.[3] Although there have been some studies with some level of controls, the controls have been inadequate for effectiveness to be demonstrated and they suffer from other significant limitations. For further discussion about the strengths and weaknesses of study designs and the limitations in the literature previously reviewed by FDA, see section II.B.2 of the 2016 Proposed Rule (81 FR 24386 at 24400 through 24401) and responses to Comment 33 of the 2020 Final Rule (85 FR 13312 at 13332 through 13333).

For instance, as discussed in the previous rulemaking, one study used a prospective case-control design. In addition to not being randomized, the study also suffers from significant methodological limitations. The study was not blinded, the sample size was extremely small, and an unvalidated surrogate endpoint (decrease in mechanical restraint rather than a direct measure of SIB) was used as the primary outcome measure (81 FR 24386 at 24400; 85 FR 13312 at 13333). The study also did not systematically assess AEs (85 FR 13312 at 13329).

FDA also reviewed a retrospective chart review during the previous rulemaking. Retrospective reviews are often considered a relatively weaker design because they do not include a control group. The study also suffers from various methodological limitations that affected the weight of the evidence (see 81 FR 24386 at 24401). The bulk of the scientific articles reviewed during the prior rulemaking suggesting effectiveness of ESDs for SIB and AB were case reports or series. Case reports or series are even weaker than retrospective chart reviews because they report on, and attempt to explain, the experiences of very few, or even single, individuals (81 FR 24386 at 24400). Further, designs that take an outcome as given and then work backwards in an attempt to explain it are more vulnerable to bias than prospective designs.

As explained in the 2016 Proposed Rule, conclusions drawn from study designs that are not randomized or controlled are generally considered weaker because they do not rule out other causes for any differences in results, including selection bias, as effectively as other study designs. Many factors contribute to the manifestation or reduction of target behaviors and therefore can be significantly confounding (81 FR 24386 at 24400). It is difficult to draw conclusions regarding the effectiveness of ESDs from a study that does not control for such confounding factors. Studies that do not plan for the systematic observation and collection of data about AEs also may overemphasize benefits, unduly implying greater safety and reasonableness of the risks because such a study would not fully account for the risks. Such studies will yield weaker conclusions with respect to the benefit-risk profile. As noted in the 2016 Proposed Rule, in the case of ESDs used for SIB or AB, randomization, control, large numbers of subjects, and AE reporting are critical to understanding the benefit-risk profile (81 FR 24386 at 24400).

The Agency also has had concerns regarding the fact that some of the authors of such studies and a member of one publication's editorial board were affiliated with JRC, which suggests potential researcher bias and conflicts of interest (81 FR 24386 at 24401). For more information on the limitations identified by FDA in the medical literature FDA considered for the 2020 Final Rule, see the 2016 Proposed Rule (81 FR 24386 at 24400 and 24401) and Responses 31 and 33 in the 2020 Final Rule (85 FR 13312 at 13332 and 13333).

As explained in the 2020 Final Rule, the ability to achieve durable effects by aversively conditioning behavior is critical to the evaluation of the effectiveness of ESDs for SIB or AB (see 85 FR 13312 at 13333). In its comments in the previous rulemaking, JRC relied on its fading of some individuals off ESDs to support its arguments regarding the device's ability to condition an individual to achieve a durable reduction in SIB and AB. The gradual reduction in the use of the device is part of ''fading,'' which would presumably be implemented once the individual has associated the target behaviors with the noxious stimulus. However, both the previously reviewed and new evidence indicate that only a small percentage of individuals at JRC (the only facility that applies the devices for SIB or AB) have been completely faded off the ESD—and that the device has been used on some individuals for years and even decades (see 85 FR 13312 at 13335 and 13336; Refs. 7 to 9). While one study suggests that there also are a number of patients who have tolerated some degree of fading with continued availability of the ESD (estimated at 20 percent ranging from hours to months) (Ref. 8), the study acknowledges that the percentage is only an estimate and suffers from a number of the limitations discussed above.

Among the new studies, the 173-patient retrospective review indicates that JRC views fading, defined in that study as the removal of all ESD devices for any period, as likely to succeed in only a small number of individuals. JRC selects for ''planned fading'' only a small percentage of individuals whom JRC assesses to have likely demonstrated low rates of problem behaviors over extended periods of time, higher rates of alternative behaviors, and the acquisition of new skills (23 of 173 patients in the study) (Ref. 9). Also, as has been observed in the literature, once the ESD is removed, SIB and AB can exceed pre-baseline levels (85 FR 13312 at 13335). This evidence undermines the claim that ESDs are effective for durable behavior conditioning for SIB or AB. Further, JRC provided no information regarding clinical protocols, treatment plans, or behavior frequencies for individuals after they stopped use and left JRC. As explained in the 2020 Final Rule, such data are important in order to understand, for example, whether behaviors worsened or improved after discontinuation of ESD use and whether ESDs or other, non-aversive, treatments are responsible for any successes (85 FR 13312 at 13336).

In the previous rulemaking, FDA also discussed evidence indicating that some individuals can experience adaptation to ESD shocks after being shocked for some period of time. This means that, to the extent a patient may have been responding to ESD shocks, the patient no longer responds, at least at the level of shock strength that has been used on them. For these individuals, even immediate interruption of behavior may not result from use of shocks. Experts in the field consider adaptation to be evidence of ineffectiveness (see 85 FR 13312 at 13336 and 81 FR 24386 at 24399). JRC has acknowledged that adaptation may necessitate an alternative method to modify behaviors instead of an ESD (see 85 FR 13312 at 13336). As we stated in the 2020 Final Rule, JRC's Director of Research at the time said JRC had ''a very comprehensive alternative behavior program'' that was ''very effective'' after adaptation to the stronger version of JRC's ESD, even for patients engaging in SIB that could result in serious injury to themselves (85 FR 13312 at 13336). That JRC's own providers ultimately turn to alternative behavioral programs, even for severe behaviors, speaks both to the effectiveness of state-of-the-art approaches and the ineffectiveness of applying electrical shocks for SIB or AB.

[3] A randomized controlled trial is prospective; the researcher creates different conditions across groups at the outset and will observe outcomes in the future. The researcher will eventually compare the outcomes across groups, with the control group providing confidence that the researcher-set conditions were responsible for any differences.

Considering such evidence in the previous rulemaking, FDA concluded that the limited data regarding the effects of ESDs for SIB or AB are inadequate to demonstrate that ESDs are effective for durable behavior conditioning. For more information about FDA's previous determination regarding the effects of ESDs on SIB and AB, see section V.D. of the 2020 Final Rule (85 FR 13312 at 13332 through 13337).

The information in the new sources does not change the Agency's prior determinations about the short- and long-term effects of ESDs on SIB or AB. Most of the new studies are authored or coauthored by JRC staff and appear to be based on much of the same or similar data JRC previously submitted, with similar limitations, albeit presented in a different format. As with the studies FDA reviewed for the 2020 Final Rule, the new studies similarly suggest some immediate effects of ESDs for SIB or AB for some individuals, in particular that the ESDs interrupted the target behavior (Refs. 8 to 12). Some commentaries, consensus statements, the ABAI task force report, and the 88-patient survey also offer some support for the immediate effect of ESDs on targeted behavior (although some individuals may not respond and/or may adapt to the shock intensity and alternative approaches are used) (Refs. 3, 5, 7, 14, 18, and 19). The new studies also conclude that ESDs have some level of durable effectiveness for some individuals with SIB and AB. Relying on information that FDA previously reviewed and some of the new studies discussed in this proposed rule, the ABAI task force similarly states that ESDs ''can be effective in suppressing problem behavior for up to 5 years'' and that ''responding typically remains suppressed under [ESDs] over the long run'' (Ref. 7). However, due to the various limitations of these studies as well as the evidence indicating adaptation to the device and potentially unending ESD use for some individuals, FDA has determined that the evidence still does not demonstrate that the devices are effective for durable behavior conditioning for SIB or AB for a clinically meaningful period of time, much less that they present a favorable benefit-risk profile.

The new studies suffer from many of the same limitations as those studies FDA considered and discussed in the 2016 Proposed Rule and 2020 Final Rule. The three case report studies (Refs. 8, 11, and 12) and one open label add-on trial (Ref. 10) involve a very small number of patients (one to four), which makes generalization of any results difficult. Four of the five new studies were authored or coauthored by JRC staff, which may introduce researcher bias. All of the studies lack robust experimental controls and, as explained above, likely underreport AEs.

The new studies also include significant confounding factors, such as the presence of concurrent treatments or changes in other treatments over a period of time. The JRC 173-patient retrospective chart review acknowledges that, ''[d]uring treatment, a given participant may have received additional treatments including psychotherapy, psychopharmacology, and/or various behavioral interventions.'' The ABAI task force report describes one example of an additional treatment, a ''holster program,'' used by JRC in some cases where a patient adapts or does not respond to the GED–4 to decrease problem behavior (see also Ref. 8). Individuals in the program receive continuous access to a positive reward (preferred videos, music, etc.) for keeping their hands in a holster for increasing amounts of time. If they remove their hands, the reward will stop, and a shock will be administered. Once the individuals can keep their hands in the holsters for 10 minutes, they continue to receive regular ''practice sessions'' to ''maintain the effectiveness of holster-wearing to decrease problem behavior throughout the remainder of the day.'' While wearing the holster during the day, if a target behavior occurs, the individual receives a shock and a 10-minute holster session (Ref. 7). The description of the holster program, while unclear in some particulars, suggests that increasing opportunities for positive reinforcement supports any reduction of target behaviors. The use of this positive reinforcement method introduces a confounding factor in the determination of the effectiveness of ESDs; the reward system, rather than the ESD, may have induced or helped induce any desirable effects on behavior. Alternatively, or perhaps as a complement to the reward system, use of the holster may have controlled or helped control the behavior. Other concurrent treatments or changes to treatments may have similar confounding effects.

Another limitation of some of the new studies stems from the fact that the behaviors targeted for ESD use are not consistent across the studies, and they were not limited to SIB or AB. Target behaviors spanned a wide range, such as ''members of a chain of behaviors (*e.g.,* posturing and threats) that consistently led to the ultimate behavior, attempts to engage in the behavior, and vestigial versions of the behavior'' (Ref. 9). Thus, vaguely described improvements that may, for example, include reductions in ''vestigial versions of the behavior'' are not obviously evidence of effectiveness for treating SIB or AB. Such claims also speak to a vulnerable population being subject to invasive behavioral control techniques; that is, such claims may also speak to an increased risk of AEs from an overly broad set of targeted behaviors. The sources also indicate that ESDs may be used for other categories of behavior such as noncompliant, destructive, and major disruptive behaviors as well as attempts to remove the device (Refs. 7, 9, and 11). Delivering an electric shock, for instance, for disruptive behavior is not clearly addressing self-injury or aggression. In the same vein, use of the device in an attempt to prevent its removal is not only difficult to rely on as evidence of effectiveness for SIB or AB, but such use also underscores that vulnerable patients are unable to avoid the risks presented by the device, such as pain. This in turn can increase other risks, such as the risk of learned helplessness (Ref. 20). Such broad target behaviors also suggest that a population broader than individuals exhibiting SIB and AB may be subject to the invasive behavioral control of ESDs and the risks they present.

Some studies acknowledge these methodological limitations. The JRC 173-patient retrospective chart review (Ref. 9) explains that ''a wide range of behavior topographies [were] targeted'' because they ''were associated with aggression and self-injury,'' and the ''participants lacked homogeneity outside of the uniting factor of behavior problem severity and refractory nature.'' In other words, the study included participants with widely differing behavioral characteristics, although their severity was considered similar. The study also recognizes, ''[t]he participants carried a variety of diagnoses and may have responded differently because of their diagnostic classification'' and ''[v]arious pathophysiological and environmental determinants may lead to such behaviors.'' This study also noted, ''the frequency data lacks interobserver reliability,'' meaning it did not account for or address variability between different observers' subjective judgments. The open label add-on trial (Ref. 10) identifies some of the same limitations that make it difficult to conclude that any observed reductions in target behavior are evidence of effectiveness of ESDs for SIB or AB.

New evidence regarding the lengthy, often indefinite, time periods that ESDs have been used on individuals and the adaptation of some individuals to the shocks further supports our determination that ESDs have not been demonstrated to be effective. For example, a four-patient case report study suggests that, for some patients, ESDs would be indicated indefinitely, similar to insulin for diabetes or antiarrhythmic and antihypertensive drugs for cardiovascular disease (Ref. 8). The ABAI task force reports that JRC's approach is that ''most clients will need to receive treatment [with ESDs] for lengthy periods of time (5 to 20 years)'' and that ''this does not appear to be a treatment that can be effectively faded or discontinued quickly'' (Ref. 7). This suggests that the device is not effective for durable behavior conditioning for SIB or AB, and is, therefore, not effective for its intended use.

The new sources also support FDA's previous finding that ESDs may even lose any immediate effect for some individuals exhibiting SIB or AB. The 173-patient retrospective chart review from JRC reports that for some participants the ''GED lost efficacy or was only partially effective and was substituted for [sic] a more intense stimulus (GED–4)'' (Ref. 9). The authors note that adaptation was consistent with earlier studies that identified habituation to shock intensity by some patients and the need for more-intense shocks to eliminate targeted behavior. The JRC four patient case report study noted this effect in one patient (Ref. 8). The ABAI task force also reported adaptation to the ESD based on a visit by members spanning 2 full days in July 2022 to assess JRC's use of ESDs. The report states that ''[i]n some cases, the intensity of the shock must be increased to improve and/or maintain its efficacy'' and ''a [JRC] client will be moved from the GED–3 to the GED–4 if the GED–3 does not reduce the behavior sufficiently or if the client's behavior begins to show habituation to the GED–3'' (Ref. 7). According to the report, patients can even habituate, or may not respond to, shocks from the GED–4, which provides shocks that are significantly stronger than those provided by the GED–3 (41 milliampere (mA) vs. 15 mA).

As a result of such weaknesses and limitations, the available data, including the data and information in the new studies and other materials, are not sufficient to demonstrate that ESDs for SIB or AB are effective for durable behavior conditioning or that they have a favorable benefit-risk profile.

Based upon all available information and data, FDA continues to find that while ESDs may result in the interruption and immediate cessation of SIB and AB for some individuals if the individual has not adapted to the shocks, ESDs have not been demonstrated to be effective at improving the underlying condition or conditioning an individual to achieve a durable reduction of SIB or AB for a clinically meaningful period of time. The evidence does not establish a favorable benefit-risk profile, and the newer evidence suggesting indefinite use of the devices for ongoing management of symptoms may indicate a worse benefit-risk profile.

C. State of the Art for Treating SIB or AB

In determining whether a device presents an unreasonable and substantial risk of illness or injury, FDA analyzes the risks and benefits that the device poses to individuals relative to the state-of-the-art of treatment for the intended population—that is, the current state of technical and scientific knowledge and medical practice, and the potential hazard to patients and users. As explained in the 2020 Final Rule, FDA found that scientific and medical advances, concerns for ethical treatment, and a desire to create generalizable interventions that work in community settings led behavioral scientists to develop treatments for SIB and AB that are low risk and have generally been successful. The available information indicated that state-of-the-art treatments of SIB or AB are multielement positive interventions (*e.g.,* paradigms such as PBS or DBT), sometimes in conjunction with pharmacological treatments, as appropriate (85 FR 13312 at 13341; 81 FR 24386 at 24410). When restrictive elements or punishment techniques were used, they supplemented other behavioral intervention elements, were much less intrusive, and were not painful; they were considered both compatible with PBS and beneficial (see 85 FR 13312 at 13341).

As we said in the 2020 Final Rule, the use of ESDs does not teach a person new skills or replacement behaviors, does not mitigate the underlying cause of their SIB or AB, and has not been demonstrated to be effective for behavioral conditioning, which is especially difficult to achieve for those who have conditions that impair their ability to understand consequences and react by changing their behaviors. These are some of the reasons that the field of applied behavior analysis (ABA) as a whole moved away from highly intrusive physical aversive conditioning techniques such as ESDs decades ago (85 FR 13312 at 13340).

FDA determined that although positive behavioral interventions may not always be completely successful in all patients, positive-only approaches have low risk and are typically successful, on their own or in conjunction with pharmacotherapy, regardless of the severity of the behavior targeted or the setting, and can achieve durable long-term results while avoiding the risks posed by ESDs (85 FR 13312 at 13315). As noted above, when practitioners felt punishment techniques were helpful, such techniques were much less intrusive than the use of ESDs; for example, they included timeouts, holds, and facial screening (85 FR 13312 at 13341). For a detailed description of FDA's assessment of state-of-the-art treatments for SIB and AB for the 2020 Final Rule, see section V.E. of the 2020 Final Rule (85 FR 13312 at 13337 through 13344) and section II.C. of the 2016 Proposed Rule (81 FR 24386 at 24403 through 24410).

The evidence still indicates that positive-only approaches, such as approaches based on differential reinforcement and skill-based instruction, have been shown to be highly successful in treating many types of severe problem behaviors (Ref. 7). Even when ESDs are used for SIB or AB, they generally are supplemented by state-of-the-art and/or other less intrusive approaches even for severe cases (Ref. 9). An example of an alternative treatment that practitioners may turn to if an individual habituates to the strongest ESD available is the holster program, which is a less intrusive paradigm that increases the use of positive rewards. In short, to the extent new information and data bear on the state of the art, they underscore why the field as a whole has, for decades (81 FR 24386 at 24387), moved away from ESDs and turned toward less intrusive techniques to treat SIB or AB effectively (Ref. 21). Further, the newer information and data emphasize that ESDs are not in fact treatments of last resort, even at the facility that has previously made such claims. As discussed further in section V.C., the ABAI task force reports that JRC rarely conducts analogue functional analyses (FAs), despite the fact that experts consider FA the ''gold standard'' assessment strategy for problem behavior (Ref. 7). This practice suggests that individuals may not experience the ''almost unlimited'' range of alternative treatments available (Ref. 7) based on an up-to-date, location-specific, comprehensive FA prior to JRC

incorporating ESDs into their treatment plan. This failure to systematically identify and exhaustively implement alternatives undercuts the certainty that JRC's patients would not respond to less intrusive treatment, are uniquely refractory, and that the devices are applied as a last resort, as is suggested by the device labeling.[4]

Thus, FDA concludes that state-of-the-art treatment for SIB and AB involves positive behavioral techniques, with or without pharmacotherapy, and that positive-only approaches have low risk and are generally successful even for challenging SIB and AB, in both clinical and community settings. Moreover, when punishment techniques are used in state-of-the-art behavior modification plans, they are not painful and are much less intrusive.

D. Labeling and Correcting or Eliminating Substantial and Unreasonable Risks

After considering all available data and information for the 2020 Final Rule, FDA determined that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury of ESDs for SIB or AB (85 FR 13312 at 13344 and 13345). FDA further determined that labeling cannot limit the risks to only the most refractory patients. The only ESDs for SIB or AB that are currently in use, two models of GED manufactured and used by JRC, are labeled for use only in individuals refractory to other treatments. Such a subpopulation is difficult or impossible to define (85 FR 13312 at 13332). Further, FDA found the available evidence casts doubt on whether the devices are in fact applied as a last resort after attempting all other approaches as indicated in the labeling (and as claimed by one commenter on the previous proposed rule (JRC)) (Ref. 22). These determinations remain true after FDA's updated review of the available literature.

More importantly, no subpopulation has been identified in which ESDs are effective for SIB or AB or do not pose the risks identified in the previous rulemaking and discussed earlier in this document. There are also no data suggesting ESDs are more likely to be effective for SIB or AB or less likely to pose these risks in a subpopulation that is refractory to other treatments or in any other subpopulation. Regardless of how the device is labeled, the individual subject to it will receive shocks intended to be painful and thereby be subject to the physical and psychological risks described in section V.A above, without demonstrated effectiveness (see also 85 FR 13312 at 13344).

Further, individuals with intellectual or developmental disabilities may not communicate or be able to communicate information for the device user to change the manner in which the device is used to correct or eliminate the risks (81 FR 24386 at 24412; 85 FR 13312 at 13344). Impaired communication of the effects of the device further prevents labeling from reducing risks. Accordingly, we concluded that no manner of labeling will correct or eliminate the substantial and unreasonable risks of these devices (see 81 FR 24386 at 24411 and 24412; 85 FR 13312 at 13344).

No additional information has come to FDA's attention indicating that labeling or a change in labeling can correct or eliminate the substantial and unreasonable risks of these devices. As noted in section V.C., the new evidence indicates that JRC rarely conducts FAs of patients. This absence of FAs conducted by JRC suggests that the existing limiting language in the labeling has little effect on mitigating risks by focusing on refractory cases. Indeed, as discussed more in section V.B. above, refractory cases at JRC are ultimately treated with less invasive approaches suggesting that as used, ESDs are not a treatment of last resort. This reinforces our prior determinations that labeling specifying a refractory population would not correct or eliminate the substantial and unreasonable risk, and that there are no labeling changes that would mitigate the risks posed by these ESDs.

Finally, as explained above and in the 2020 Final Rule, no manner of labeling will correct or eliminate the risks for patients receiving shocks, many of whom may not communicate or be able to communicate information about AEs as a result of intellectual or developmental disabilities (85 FR 13312 at 13344). The device will continue to present the same unreasonable and substantial risk of illness or injury for these individuals regardless of the labeling. Based on this information and data, FDA concludes that labeling, or a change in labeling, cannot correct or eliminate the unreasonable and substantial risk of illness or injury of ESDs for SIB or AB.

VI. Description of the Proposed Rule

We are proposing to amend part 895 by adding § 895.105 to ban ESDs for SIB or AB. The proposed rule would ban ESDs intended to treat patients with SIB or AB and would cause ESDs intended for these uses not to be legally marketed devices, for example, under section 1006 of the FD&C Act. We are also proposing conforming edits to § 882.5235 to exclude ESDs for SIB or AB from the class II designation for aversive conditioning devices and instead to indicate that ESDs for SIB or AB are banned devices.

A. Applicability (Proposed § 895.105)

FDA is proposing to ban ESDs that apply a noxious electrical stimulus to a person's skin to reduce or stop aggressive or self-injurious behavior. FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. FDA is not proposing to ban ESDs intended for other purposes, such as smoking cessation. ESDs are not used in electroconvulsive therapy, sometimes called electroshock therapy or ECT, which is unrelated to this rulemaking.

1. Distinguishing Technologically Similar Devices With Different Intended Uses

Note that, although ESDs for SIB or AB may have parallels in technology and behavior modification strategy as ESDs for other intended uses, ESDs for SIB or AB are distinguishable from other ESDs based on several factors. These factors include device design; whether patients have control over the shocks and what level of control they have; the power output and resulting intensity of the electric shock; and how the electric shock affects the patient, target behavior, and underlying conditions. For example, a smoking cessation device would generally have different output characteristics, resulting in a less noxious (perhaps non-painful) shock, where the person affected by the shock retains complete control of application of shocks (or could immediately revoke consent to the application of shocks). Use of such a device without modification for SIB or AB would not be expected to induce a response for SIB or AB.

In contrast, patients exhibiting SIB or AB have no control over devices intended for these uses and these devices often deliver a painful or very painful shock, strong enough to induce fear and other reactions, as opposed to a milder shock from other ESDs. The SIB or AB patient is made to carry a stimulus generation module in a waist-pack or backpack 24 hours a day, 7 days a week, except during attempts to ''fade'' the device (although the user,

[4] The labeling of GED devices includes the statement that ''[t]he device should be used only on patients where alternate forms of therapy have been attempted and failed'' (81 FR 24386 at 24412).

not the patient, still decides whether to apply and trigger the device). Depending on the targeted behavior, ESDs for SIB or AB use up to five electrodes strapped to the arms, legs, torso, and/or feet simultaneously, but the locations are not of the patient's choosing (see Ref. 7). Shocks are from one electrode at a time, and the electrodes are rotated every hour or after discharge, but the patients are not able to dictate the rotation for themselves (see Ref. 7). Patients subject to ESDs for SIB or AB also have no control over whether to withdraw from treatment. Even for patients with mild to no intellectual disabilities, evidence indicates that assent from the patient is not sought (see Ref. 7). As explained in the 2020 Final Rule, lack of control over multiple shocks is an additional risk factor because learned helplessness may be more likely when the recipient does not have control over the shocks and has previously received multiple shocks (85 FR 13312 at 13326). When the recipient does not have control over the shocks and has previously received multiple such shocks, psychological trauma such as an anxiety or panic reaction can result even when the strength is relatively modest (see 85 FR 13312 at 13324 through 13327).

Moreover, as explained in the 2020 Final Rule, devices with similar technology intended for other uses address different conditions or behaviors in different patient populations, and as a result, they present different benefit-risk profiles. A device that presents certain risks or benefits for one population may not present the same risks or benefits, or present them to the same degree, or may present different risks or benefits, for a different population. An important consideration in the benefit-risk profile of a device is the intended patient population and their vulnerabilities. The intended use population for ESDs for SIB or AB includes a significant number of individuals who have disabilities that present vulnerabilities, such as difficulty communicating pain and other harms caused by ESDs. As a result of these vulnerabilities, the individual may not communicate or be able to communicate information for the device user to change the manner in which the device is used to correct or eliminate the risks (85 FR 13312 at 13344). In addition, people who exhibit SIB or AB may not be able to associate cause and effect or, as with some people with an autism spectrum disorder (ASD), they may express pain atypically or not at all (85 FR 13312 at 13317). These vulnerabilities are not likely to be present in people who use ESDs for other purposes. As a result, individuals subject to shocks from an ESD for SIB or AB would bear a higher risk of injury or illness from the shock than, for example, smokers who choose to use an ESD to help quit smoking (81 FR 24386 at 24395). Smokers can immediately communicate pain to the device's controller or remove the device themselves. They can communicate symptoms of other harms that may be caused by ESDs to their healthcare provider, which may lead to discontinuation of the device's use, or they can decide to stop using the device (85 FR 13312 at 13317).

2. Banning ESDs for SIB or AB That Are Already in Commercial Distribution

FDA is proposing that the ban apply to devices already in commercial distribution and use, as well as devices sold or commercially distributed in the future (see § 895.21(d)(7)). This means ESDs for SIB or AB currently in use on individuals would be subject to the ban and thus, upon the effective date of the final rule, adulterated under section 501(g) of the FD&C Act and subject to potential FDA enforcement action. FDA is proposing this because the risk of illness or injury to individuals on whom these devices are already used is just as unreasonable and substantial as it is for future individuals on whom these devices could be used. Indeed, as the development of more beneficial, lower-risk alternative treatments continues, the ban's mitigation of the substantial and unreasonable risk may be greatest for the individuals on whom ESDs are currently used.

However, as explained in the 2020 Final Rule, for devices already in use for SIB or AB, in light of concerns about thorough assessments of the behaviors' functions and corresponding development of appropriate treatment plans, FDA recognizes that affected parties may need some period of time to establish or adjust treatment plans (85 FR 13312 at 13349). FDA believes that transition off ESDs should occur under the supervision of a physician and that the transition should occur as soon as possible for the individual. FDA is proposing, for devices in use on specific individuals as of the date of publication of any final rule based on this proposal, and subject to a physician-directed transition plan, compliance would be required 180 days after the date of publication of any final rule. We welcome comment on how long transitions may take.

B. Proposed Conforming Amendment (§ 882.5235)

We are proposing conforming edits to paragraph (b) of § 882.5235 to exclude ESDs for SIB or AB from the classification of aversive conditioning devices into class II. This amendment would indicate that ESDs for SIB or AB are banned devices rather than class II devices.

VII. Proposed Effective and Compliance Dates

FDA proposes that any final rule based on this proposed rule be effective 30 days after its date of publication in the **Federal Register**.

FDA proposes that, for devices in use on specific individuals as of the date of publication of the final rule and subject to a physician-directed transition plan, compliance be required 180 days after the date of publication of the final rule in the **Federal Register**. For all other devices, FDA proposes that compliance be required 30 days after publication in the **Federal Register**.

VIII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options

that would minimize any significant impact of a rule on small entities. Because the proposed rule would only affect one entity—one that is not classified as small—we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The 2022 threshold after adjustment for inflation is $177 million, using the 2022 Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits, Costs, and Transfers

The proposed rule, if finalized, would ban ESDs used for self-injurious or aggressive behavior. FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. The proposed rule would apply to devices already in distribution and use, as well as to future sales and commercial distribution of these devices. The costs associated with this proposed rule include costs of individuals who are subject to the device if they move to another facility or another program within the affected entities. Affected entities, who use the device on such individuals, would also incur costs from reading and understanding the rule. The present value of total estimated costs range between $0.00 million and $68.93 million at a 7 percent discount rate, with a primary estimate of $34.47 million. At a 3 percent discount rate, the present value of costs range between $0.00 million and $80.59 million, with a primary estimate of $40.3 million. We estimate that the annualized costs over 10 years would range from $0.00 million to $9.17 million with a primary estimate of $4.59 million at a 7 percent discount rate and a 3 percent discount rate.

The benefits would include avoided negative physical and psychological effects from using ESDs on individuals and benefits to society in terms of protecting vulnerable populations, which we are not able to quantify. We estimate that between 51 to 54 individuals would be affected by the proposed rule, if finalized, and benefit from avoided adverse effects associated with using ESDs. Any transfers associated with the rule would occur if individuals enroll at facilities other than the affected entities. The present value of total transfer ranges between $0.00 million and $118.26 million at a 7 percent discount rate, with a primary estimate of $59.13 million. At a 3 percent discount rate, the present value of transfers ranges between $0.00 million and $138.26 million, with a primary estimate of $69.13 million. The annualized value of transfers range between $0.00 million and $15.74 million, with a primary estimate of $7.87 million, at both 7 percent and 3 percent discount rates. We provide a summary of the benefits, costs, and transfers of the proposed rule, if finalized, in table 1. We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

[Millions of 2022 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollar	Discount rate	Period covered	
Benefits:							
Annualized Monetized ($m/year)	.....	.....	.....	.....	7% 3%		
Annualized Quantified	.....	.....	.....	.....	7% 3%		
Qualitative	Reduction in injuries or adverse psychological effects of ESDs on individuals subject to the device.						
Costs:							
Annualized Monetized ($m/year)	$4.59 $4.59	$0.00 $0.00	$9.17 $9.17	2022 2022	7% 3%	10 years 10 years.	
Annualized Quantified	.....	.....	.....	.....	7% 3%		
Qualitative	Transition costs to affected entities and individuals for transitioning to alternative treatments.						
Transfers:							
Federal Annualized Monetized ($m/year)	.....	.....	.....	.....	7% 3%		
Other Annualized Monetized ($m/year)	$7.87 $7.87	$0.00 $0.00	$15.74 $15.74	2022 2022	7% 3%	10 years 10 years.	
	From: Affected entities that currently use the device			*To:* Other facilities that treat aggressive or self-injurious behavior			
Effects:	*State, Local, or Tribal Government:* State expenditures may rise or fall if individuals move across state boundaries						
	Small Business: No effect						
	Wages: No effect *Growth:* No effect						

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 23) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

IX. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this proposed rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused ESDs that will need to be handled after the effective date of the final rule.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste at municipal solid waste (MSW) facilities. The proposed action will result in an initial batch disposal of used and unused ESDs primarily at a single geographic and affiliated locations followed by a gradual, intermittent disposal of a small number of remaining devices in this and other affected communities where these devices are used. The total number of devices to be disposed is small, *i.e.,* approximately less than 300 units. Overall, given the limited number of ESDs in commerce, the proposed action is expected to have no significant impact on MSW and landfill facilities and the environment in affected communities.

The Agency has concluded that the proposed rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA invites comments and submission of data concerning the EA and FONSI.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain State requirements ''different from or in addition to'' certain Federal requirements applicable to devices (see section 521 of the FD&C Act (21 U.S.C. 360k); *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic,* 128 S. Ct. 999 (2008)). If this proposed rule is made final, it would create a Federal requirement under section 521 of the FD&C Act that bans ESDs for SIB or AB.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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List of Subjects

21 CFR Part 882

Medical devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 882 and 895 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. In § 882.5235, revise paragraph (b) to read as follows:

§ 882.5235 Aversive conditioning device.

* * * * *

(b) *Classification.* Class II (special controls), except for electrical stimulation devices for self-injurious or aggressive behavior. Electrical stimulation devices for self-injurious or aggressive behavior are banned. See § 895.105 of this chapter.

PART 895—BANNED DEVICES

■ 3. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 4. Add § 895.105 to subpart B to read as follows:

§ 895.105 Electrical stimulation devices for self-injurious or aggressive behavior.

Electrical stimulation devices for self-injurious or aggressive behavior are aversive conditioning devices that apply a noxious electrical stimulus to a person's skin to reduce or cease self-injurious or aggressive behavior.

Dated: March 12, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–06037 Filed 3–25–24; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. PTO–T–2022–0034]

RIN 0651–AD65

Setting and Adjusting Trademark Fees During Fiscal Year 2025

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO) proposes to set and adjust trademark fees, as authorized by the Leahy-Smith America Invents Act (AIA), as amended by the Study of Underrepresented Classes Chasing Engineering and Science Success Act of 2018 (SUCCESS Act). The proposed fee adjustments will provide the USPTO sufficient aggregate revenue to recover the aggregate costs of trademark operations in future years (based on assumptions and estimates found in the agency's Fiscal Year 2025 Congressional Justification (FY 2025 Budget)), including implementing the USPTO 2022–2026 Strategic Plan (Strategic Plan).

DATES: The USPTO solicits comments from the public on this proposed rule. Written comments must be received on or before May 28, 2024 to ensure consideration.

ADDRESSES: Written comments on proposed trademark fees must be submitted through the Federal eRulemaking Portal at *https://www.regulations.gov.*

To submit comments via the portal, commenters should go to *https://www.regulations.gov/docket/PTO-T-2022-0034* or enter docket number PTO–T–2022–0034 on the homepage and select the ''Search'' button. The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this notice and select the ''Comment'' button, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe portable document format (PDF) or Microsoft Word format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic