DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Docket No. FDA-2023-N-3902

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This proposed rule, if finalized, would reestablish the ban of electrical stimulation devices (ESDs) for self-injurious or aggressive behavior, following the Agency's now clarified authority to ban devices intended for human use for specific intended uses. 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 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 to read and understand the rule. We estimate that the annualized costs over 10 years would range between $0.00 million and $9.17 million, with a primary estimate of $4.59 million at both a 7 percent and a 3 percent discount rate.

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I. **Introduction and Summary**

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 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 electrical stimulation devices (ESDs) 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 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% and 3% 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 Dollars	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	$0.00	$9.17	2022	7%	10 years	
		$4.59	$0.00	$9.17	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	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	$0.00	$15.74	2022	7%	10 years	
		$7.87	$0.00	$15.74	2022	3%	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.							

II. **Preliminary Economic Analysis of Impacts**

A. Background

FDA previously issued a final rule in 2020 banning ESDs (2020 Final Rule), which was vacated by the United States 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 Food Drug & Cosmetic Act (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 clarify that FDA may issue a ban that applies to specific intended uses, such as the previous ban on ESDs for self-injurious or aggressive behavior. Specifically, section 3306 of Food and Drug Omnibus Reform Act (FDORA), enacted through the Consolidated Appropriations Act of 2023, expressly provides that FDA has the

authority to ban a device for one or more intended uses (see 21 U.S.C. 360f(a)(1) and (2), as amended by section 3306 of FDORA). This proposed rule, if finalized, would reestablish the ban now that FDA's authority to do so has been clarified.

As explained in more detail in the 2020 Final Rule (85 FR, 13312, Ref. 1), some individuals with intellectual or developmental disabilities exhibit self-injurious behavior (SIB) and/or aggressive behavior (AB), while other individuals who exhibit SIB or AB do not have intellectual or developmental disabilities. Examples of SIB include head-banging, hand-biting, excessive scratching or picking of the skin. In addition, some individuals may engage in AB that endangers their families or caregivers. By conservative estimates, there are approximately 330,000 individuals who have intellectual or developmental disabilities and exhibit SIB, AB, or both. The most extreme cases of serious self-injurious behavior afflict an estimated 25,000 or more individuals in the United States.

To protect the individual from injury caused by SIBs and to protect others from injury caused by AB, some form of intervention may be required. There have been existing pharmacological treatments and behavioral interventions for individuals who manifest SIB and AB. Behavioral treatment strategies may employ positive approaches (to reward appropriate behavior) and negative approaches (to discourage inappropriate behavior). Physical measures and protective equipment may also be used to reduce the immediate threat of injury.

There is currently one facility at which electrical stimulation devices (ESDs) are used on some individuals with SIB or AB who reportedly have not responded well to treatments. ESDs allow observers to administer an electric shock to an individual engaging in SIB or AB or engaging in a precursor to SIB or AB. These devices are attached to the individual's body. When the individual engages in the targeted behaviors, an observer using a remote monitor or an

automated mechanism attached to the device will trigger the device, delivering an electric shock to the individual's skin. The device is intended to interrupt the behavior and condition the individual not to engage in such behavior, with the eventual goal of ending SIB and AB in the individual. The devices operate on the principle of aversive conditioning and are sometimes referred to as "aversive." Many individuals prescribed the device, however, may have difficulty communicating about their experience with it and may lack the ability to consent to its use.

This proposed rule, if finalized, would ban ESDs intended for SIB and/or AB. Though similar products may be used for other purposes, we seek only to ban ESDs for SIB and/or AB.

B. Potential Need for Federal Regulatory Action

Individuals who receive shocks from the device do not generally make decisions about their own medical treatment. Instead, decisions about treatment are made by agents of the individual, including guardians and caregivers. From an economic perspective, this may result in a principal-agent problem. A principal-agent problem results from asymmetric information, where one individual (the principal) has information that other individuals (agents) do not have.[1] In this case, guardians and the affected facility may be agents, while the individual experiencing the shock from the device is the principal. The agents do not experience the effects of the device, and many individuals may not be able to communicate effectively about their experience with the device. Though agents can quantify the effect of the device in reducing unwanted behavior, they cannot easily observe the adverse effects of the device on the individual, and the individual may not be able to communicate effectively about their experience. Agents may therefore

[1] The potential market failure due to the principal-agent problem does not depend on the intentions of the agent(s). We do not doubt the intentions of parents or guardians when faced with these most difficult decisions.

recommend or approve the use or continued use of the device even when the individual would not have consented to its use.

C. Purpose of the Proposed Rule

Under this proposed rule, we are banning these devices for SIB or AB, because we have 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. Experiences with these devices vary between individuals and within individuals over time. Labeling cannot adequately define how providers could overcome this variability in individual experience, especially when many of these individuals have difficulty communicating information about their physical or psychological state. Part V of the Preamble contains further discussions of the unreasonable and substantial risks from the device, the lack of evidence on long-term effects and why labeling cannot correct or eliminate the risks posed by this device.

D. Baseline Conditions

This proposed rule, if finalized, would ban ESDs intended to treat patients with SIB or AB, and so would affect all entities that manufacture, distribute, or use these devices. In this case, the proposed rule would affect one firm. This firm is currently the only manufacturer and user of ESDs for self-injurious or aggressive behavior. There are no other firms at this time that use EDSs for SIB or AB, and we do not expect that new devices would enter the market in absence of the rule. A comment submitted by the affected entity in July 2016 reported that the device was court-approved for use in 54 individuals, with 51 currently subject to the device (Ref. 2). We use a range of 51 to 54 as the number of individuals affected by the proposed rule, which captures those currently subject to the device and those at the facility who could potentially use

the device under court approval. According to a report by the Association for Behavior Analysis International (ABAI) in 2022, there are 52 individuals approved for ESDs (Ref. 3). Therefore, we do not expect that the number of individuals subject to ESDs would significantly increase or decrease in absence of the rule. We request comment on the number of individuals currently subject to the device.

The ban is only for electrical stimulation devices that deliver a noxious shock to cause a reduction or cessation in aggressive or self-injurious behavior. ESDs that are intended for other purposes, such as smoking cessation, would not be affected by the proposed rule if finalized.

E. Benefits of the Proposed Rule

The potential benefits of the proposed rule are unquantified and include possible benefits to individuals and to society.

Individuals who manifest SIB or AB are a vulnerable population. Often, individuals with these conditions are nonverbal and may not be able to communicate effectively to their caregivers about how they experience either their conditions or the use of the device. In addition to any adverse physical effects of the ESD, such as pain and skin burns, individuals may experience cumulative psychological effects from the ongoing use of ESDs that result in posttraumatic stress disorder. For other individuals using similar devices for other indications (e.g., smoking cessation), individuals may be able to avoid these risks by discontinuing or reducing the use of those products. Individuals with SIB or AB cannot give or withdraw consent for the use of the device, so these individuals cannot choose to avoid these risks. Therefore, the proposed rule, if finalized, would benefit the affected individuals through preventing adverse physical and psychological effects and through preventing unfavorable experiences that are associated with using the device. As discussed in the Preamble, adverse effects documented in

the literature are likely to be underreported, and one of the reasons is that the individual may not be able to communicate these adverse effects. As we described in the Baseline Section (Section D), we use a range of 51 to 54 as the number of individuals that would be affected under the proposed rule to account for those currently subject to the device and those at the facility who could potentially use the device under court-approval. We assume that the affected individuals experience adverse effects; thus, the proposed rule, if finalized, would provide benefits to between 51 to 54 individuals. Because we do not have sufficient data on the magnitude and frequency of adverse effects on individuals, we cannot quantify the benefits of removing ESDs. We request data on this matter. There could be other potential benefits based on individuals' preferences, which we cannot quantify because individuals with SIB or AB often cannot express their preferences about the device and are not the ones deciding whether to use it.

In addition to the individuals currently subject to the device, society may benefit from banning the device because we have determined that ESDs for self-injurious and aggressive behavior present an unreasonable and substantial risk of illness or injury for this indication. We do not currently foresee that society has an interest in banning this device for other indications in which individuals can give or withdraw consent for its use. For example, individuals can consent to use a technologically similar device for the purpose of smoking cessation. In that case, there is no principal-agent problem because individuals can reduce or stop the use of the device if they experience adverse effects. However, society does have an interest in protecting vulnerable populations from harm. That is, society has an interest in solving this principal-agent problem for the use of this device for SIB or AB in individuals (principals) who do not consent to use of this device, which poses unreasonable and substantial risks, and do not decide whether to discontinue

use. We do not know how much society values the ban of this device. We request comment on this matter.

F. Costs of the Proposed Rule

The proposed rule, if finalized, would ban electrical stimulation devices for self-injurious and aggressive behavior and require that the facility stop using the devices at the effective date of the rule, except for those devices currently in use and have a physician-directed transition plan, for which the facility would have until 180 days after publication of the rule to comply. As discussed in the Baseline Section (Section D), we use a range of 51 to 54 as the number of individuals that would be affected under the proposed rule to account for those currently subject to the device and those at the facility who could potentially use the device under court-approval. These individuals could either move to a different facility where the device is not used or transition to an alternative therapy at the affected facility.

1. Switching to Alternative Care

The incremental switching costs of the proposed rule is the difference in the cost of using the device and the cost of alternative care. Similar to Section E, we use a range of 51 to 54 as the number of individuals that would be affected under the proposed rule. If affected individuals move to a different facility for alternative care, then the switching cost would equal the difference between the cost of enrolling at the affected facility and the cost of enrolling at the new facility. Massachusetts publishes its annual reimbursement for special education residential facilities, including the affected entity. For fiscal year 2023, the reimbursement for the affected

entity is around $291,415 per individual[2]. We looked at Massachusetts' reimbursement rates for other residential facilities that appear to serve similar individuals, including in-state and out-of-state facilities. Annual rates for fiscal year 2023 for these facilities ranged from about $165,000 to about $460,000 per year. To calculate the upper-bound costs associated with transferring to a different facility, we consider the case that all 54 individuals are transferred to the most expensive facility reimbursed by Massachusetts that treats SIB or aggressive behaviors, which would result in incremental treatment costs of up to $9.2 million per year (54*($461,262 - $291,415)).[3] For the lower bound, we assume that individuals are transferred to a facility with similar costs to the affected entity, which would be equivalent to $0 in incremental cost. We request comments on this assumption.

2. Impact on the Affected Entity

The affected entity could keep individuals at its own facility and move them to alternative therapy. According to the 2022 report by ABAI, two-thirds of enrollees are enrolled in programs that do not use the device. Based on the information from the State of Massachusetts, we anticipate that the reimbursement received by the affected entity for each individual who stays at the facility would remain unchanged. However, we lack information about the cost to provide alternative care to the 51 individuals currently subject to the device. Providing alternative therapy is not necessarily more costly than the existing option at the affected facility. Although we do not know what alternative therapies the affected entity would offer, one study found that Dialectical Behavioral Therapy, a potential alternative therapy, costs about $219,918 per year in

[2] Massachusetts publishes budget details on its website (www.mass.gov). Fiscal year 2023 runs from 07/01/2022 to 06/30/2023.
[3] This facility is located in New Hampshire.

2022 dollars, with the most expensive treatment costing around $239,994 per year (Ref. 4).[4] Nevertheless, the affected facility would likely incur some transition costs as they move residents to alternative care. These transition costs could include additional professional expertise, training for existing staff, the administration of additional drugs, and possibly the hiring of additional staff.

The compliance period of 180 days for those devices currently in use may reduce some of the incremental costs of this rule by a modest amount.

3. Impact on Individuals

For the 51 individuals currently subject to the device, costs to them would vary, depending on how quickly they adjust to an alternative care program and whether for the individual, the alternative care program provides equivalent outcomes to the device. If, for example, self-injurious behavior changes with an alternative therapy, an individual may incur some cost for the alternative treatment. For these individuals, it is impossible to say how much their utility would change when they switch to other care programs at a result of the rule.

4. Cost to Government

Many of the individuals have the cost of care paid by their state or local government. Although uncertain, the ban of this device could affect the expenditure of governments that pay for the care of the affected individuals. If the cost of treating each individual without the device is higher than the cost of using the device on each individual, government expenditures could rise, and if the cost of treating each individual without the device is lower than the cost of using

[4] These costs range from $482 to $526 per day, or $175,930 to $191,990 per year, in 2013 dollars. We update to 2022 dollars using the GDP deflator.

the device on each individual, government expenditures could fall. We do not have payment data to determine the cost burdens for each individual. We request data and comment on this matter.

5. Administrative Costs

The affected entity would incur costs to learn about the rule. These costs include time to read and interpret the rule. Based on the effort from the one affected entity to read and respond to the 2016 Proposed Rule, we estimate that several employees at the affected facility would each spend between 5 hours and 10 hours reviewing the rule. In valuing this time, we use average wages from the Bureau of Labor Statistics (BLS) national industry-specific occupational employment and wage estimates for NAICS 623210 and NAICS 623220 (Ref. 5).[5] The average hourly wage rate ranges from $43.34 to $51.53 for management occupations (average wage data for occupation codes 11-1000, 11-3031 and 11-9111), from $31.69 to $32.17 for healthcare occupations (occupation code 29-0000) and is $89.59 for legal occupations (occupation code 23-1000).[6]

For the low estimate, we also assume that one manager, one legal professional, and one healthcare professional would spend five hours each to read and understand the rule; and for the high estimate, we assume that two managers, one legal professional, and one healthcare professional would spend ten hours each to read and understand the rule. We calculate the fully-loaded wages by doubling the wage estimates to account for benefits and other indirect costs. We

[5] We use data from the May 2022 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 623210 – Residential Intellectual and Developmental Disability Facilities and NAICS 623220 – Residential Mental Health and Substance Abuse Facilities <http://www.bls.gov/oes/>

[6] The BLS did not publish wage estimates for legal occupations within NAICS 623210 or NAICS 623220 in 2022. We use instead the legal occupation wage reported in NAICS 623000.

estimate that it would cost between $1,646 and $6,745 for the affected entity to read and understand the rule. In Table 2, we list details of costs to read and understand the rule.

Table 2. Costs to Read and Understand the Rule

	Low	High
Manager (fully-loaded wage)	$86.67	$103.07
Legal professional (fully-loaded wage)	$179.18	$179.18
Healthcare professional (fully-loaded wage)	$63.38	$64.34
Hours to read and understand the rule	5	10
People to read the rule	1 manager, 1 legal professional, 1 healthcare professional	2 managers, 1 legal professional, 1 healthcare professional
Cost to read the rule	$1,646	$6,745

6. Summary of the Quantified Costs of the Rule

We estimate that one-time costs of the rule range from around $1,600 to $6,700; the annual incremental costs of the rule range from about $0 per year to about $9.2 million per year.[7] The lower bound cost estimate assumes that there are costs to the affected entity to read and understand the rule, but no change in the costs for changing to alternatives or moving to a different facility. For the upper bound cost, we assume that all 54 individuals would transfer to the most expensive facility. Table 3 shows the annual breakdown of quantified costs over 10 years, and Table 4 reports the present value and annualized values of total costs associated with the proposed rule. Our primary estimate of the present value of the total incremental costs of the proposed rule over 10 years equals $34.47 million with a 7 percent discount rate and $40.30

[7] These estimates assume that, without the rule, the number of individuals who would have been subject to the device would be constant over time.

million with a 3 percent discount rate. The annualized costs of the present value of total costs range from $0.00 million to $9.17 million at both a 3 percent and 7 percent discount rate. The primary estimate of annualized costs over 10 years is $4.59 million at both a 3 percent and 7 percent discount rate.

Table 3. Annual Breakdown of Quantified Costs in Millions of 2022 Dollars

	Low	Primary	High
Costs Incurred in Year 1	$0.00	$4.59	$9.18
Annual Costs Incurred from Year 2 to Year 10	$0.00	$4.59	$9.17

Table 4. Present Value and Annualized Costs over 10 Years in Millions of 2022 Dollars

	Discount Rate	Low	Primary	High
Present Value of Total Costs	7%	$0.00	$34.47	$68.93
	3%	$0.00	$40.30	$80.59
Annualized Value of Total Costs	7%	$0.00	$4.59	$9.17
	3%	$0.00	$4.59	$9.17

G. Transfers Caused by the Proposed Rule

If individuals move to another facility for alternative care, there would be a transfer from the affected entity to the facility to which the individual would move. The amount of the transfer is equal to Massachusetts' reimbursement rate to the affected entity if the new facility has a larger (or equal) reimbursement rate. If all affected individuals were to move to a different facility, between $14.9 million and $15.7 million in revenue from those individuals would be transferred to another entity providing alternative care (=51*$291,415 and =54*$291,415). If individuals enroll in a lower-cost facility, transfers would be lower, and if all individuals stay at the affected entity and enroll in an alternative program, then the transfer would be zero. We

present the present and annualized values of total transfers in Table 4. The present value of our primary estimates for transfers is $59.13 million at a 7% discount rate and $69.13 at 3% discount rate. The annualized value of the primary estimate for transfers is $7.87 million at both 7% and 3% discount rates.

Table 5. Present Value and Annualized Value of Transfers over 10 Years in Millions of 2022 Dollars

	Discount Rate	Low	Primary	High
Present Value of Total Transfers	7%	$0.00	$59.13	$118.26
	3%	$0.00	$69.13	$138.26
Annualized Value of Total Transfers	7%	$0.00	$7.87	$15.74
	3%	$0.00	$7.87	$15.74

H. Analysis of Regulatory Alternatives to the Proposed Rule

This proposed rule would require that the use of the device cease by the effective date or, for devices currently in use and may need a physician-directed transition plan, by 180 days after publication of the final rule. One alternative would be to keep the effective date of 30 days in the proposed rule and not allow for an extended compliance date. This alternative would move up incremental costs related to shifts in treatment and could increase the costs of the proposed rule by a modest amount.

This alternative may make some individuals worse off if they would experience more self-injurious or aggressive behavior with an abrupt change in behavioral modification plans than they would experience with an extended compliance period. Other individuals may benefit, as they may experience more adverse effects of the device with a longer transition period than if the device was removed immediately. Thus, a shorter transition would move up potential benefits, as individuals would be exposed to the risks of the device for a shorter period.

Alternatively, we could extend the effective date or compliance date beyond the dates in the proposed rule. This would have opposite effect of shortening the effective date or compliance date that we discussed above. A more extended compliance date would delay incremental costs related to shifts in treatment. However, as part of a longer compliance period, the affected entity may develop a longer or more complex transition plan, which would require additional resources and add to the costs of the proposed rule. A longer compliance period may benefit individuals who would experience more self-injurious or aggressive behavior with an abrupt change in treatment than they would experience with an extended compliance period. (Note that comments on the 2016 Proposed Rule indicate to FDA that a 180-day transition would not be abrupt.) Other individuals may be worse off with an extended compliance period, as they may experience more adverse effects of the device. Thus, a longer transition period would delay potential benefits, as individuals would be exposed to the risks of the device for a longer period.

I. Distributional Effects

We do not expect significant distributional effects across income groups, ethnic groups, geographical regions, gender, and age groups in the general population as a result of this proposed rule. The report by ABAI shows that the percentages of individuals enrolled at the affected entity and the percentages of individuals approved for the device for each racial/ethnicity group are comparable. The proposed rule, however, would benefit a number of individuals with disabilities.

J. International Effects

We do not expect an international effect associated with the proposed rule.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The small business cutoff from the Small Business Administration is $19 million for NAICS 623210 – Residential Intellectual and Developmental Disability Facilities or NAICS 623220 – Residential Mental Health and Substance Abuse Facilities (Ref. 6). The entity affected by the proposed rule reported revenues of about $87.6 million in 2020, which exceeds the size threshold for small entities in this industry. Thus, we propose to certify that the rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. **References**

1. Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior. Docket No. FDA–2016–N–1111.

2. JRC, Inc., public docket comment (attachment 11), FDA-2016-N-1111 (1k0-8reg-jdp8). Received July 25, 2016.

3. Perone, M., Lerman, D., Peterson, S., & Williams, D. C. (2022). Report of the ABAI Task Force on Contingent Electric Skin Shock.

4. Brown, J.F., M.Z. Brown and P. DiBiasio. 2013. "Treating Individuals with Intellectual Disabilities and Challenging Behaviors with Adapted Dialectical Behavior Therapy." Journal of Mental Health Research in Intellectual Disabilities 6: 280-303.

5. U.S. Bureau of Labor Statistics, “Occupational Employment Statistics: May 2022 National-Industry Specific Occupational Employment and Wage Estimates.” <http://www.bls.gov/oes/> April 2023.

6. U.S. Small Business Administration, 2023, Table of Size Standards. <http://www.sba.gov/content/table-small-business-size-standards> March 2023.