WORLD TRADE ORGANIZATION

G/TBT/N/USA/2108

27 March 2024

(24-2637)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** UNITED STATES OF AMERICA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Food and Drug Administration (FDA), Health and Human Services (HHS) [2140] **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Please submit comments to: USA WTO TBT Enquiry Point, Email: usatbtep@nist.gov
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Electrical stimulation devices intended for self-injurious behavior; Medical equipment (ICS code(s): 11.040); Domestic safety (ICS code(s): 13.120)
5.	**Title, number of pages and language(s) of the notified document:** Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior; (16 page(s), in English)
6.	**Description of content:** Proposed rule - 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.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection; Protection of human health or safety
8.	**Relevant documents:** 89 Federal Register (FR) 20882, 26 March 2024; Title 21 Code of Federal Regulations (CFR) Parts 882 and 895: https://www.govinfo.gov/content/pkg/FR-2024-03-26/html/2024-06037.htm https://www.govinfo.gov/content/pkg/FR-2024-03-26/pdf/2024-06037.pdf This proposed rule is identified by Docket Number FDA-2023-N-3902. The Docket Folder is available on Regulations.gov at https://www.regulations.gov/docket/FDA-2023-N-

	3902/document and provides access to primary and supporting documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number. WTO Members and their stakeholders are asked to submit comments to the USA TBT Enquiry Point. Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders by 4pm Eastern Time on 28 May 2024 will be shared with the FDA and will also be submitted to the Docket on Regulations.gov if received within the comment period. G/TBT/N/USA/1113 and subsequent addenda - Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior, identified by Docket Number FDA-2016-N-1111.
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Final date for comments:** 28 May 2024
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** https://members.wto.org/crnattachments/2024/TBT/USA/24_02292_00_e.pdf