



1 December 2023

(23-8175)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>UNITED STATES OF AMERICA</u> 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) [2102] 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): Wound dressings and liquid wound washes containing antimicrobials and/or other chemicals as solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes; Medical equipment (ICS code(s): 11.040); Wound dressings and compresses (ICS code(s): 11.120.20); First aid (ICS code(s): 11.160)
5. Title, number of pages and language(s) of the notified document: Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes; (29 page(s), in English)
6. Description of content: Proposed rule - The Food and Drug Administration (FDA, Agency, or we) are proposing to classify certain types of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals (unclassified, preamendments devices) as solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes. FDA currently regulates these unclassified devices as devices requiring premarket notification (510(k) requirements), with the product codes FRO, GER, MGP, MGQ, and EFQ, but FDA intends to create new product codes for these proposed classifications upon finalization of this classification action. FDA is proposing to classify certain wound dressings and liquid wound washes containing antimicrobials with a high level of antimicrobial resistance (AMR) concern (i.e., medically important antimicrobials) into class III. In addition, FDA is proposing to classify certain wound dressings and liquid wound washes containing antimicrobials with a medium or low level of AMR concern and/or other chemicals, into class II (subject to special controls and 510(k) requirements).
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety

8. Relevant documents:

88 Federal Register (FR) 83774, 30 November 2023; [Title 21 Code of Federal Regulations \(CFR\) Part 878](#):

<https://www.govinfo.gov/content/pkg/FR-2023-11-30/html/2023-26209.htm>

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This proposed rule is identified by Docket Number FDA-2023-N-3392. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2023-N-3392/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](#) by or before [4pm Eastern Time](#) on 28 February 2024. Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders will be shared with the regulator and will also be submitted to the [Docket](#) on Regulations.gov if received within the comment period.

9. Proposed date of adoption: To be determined

Proposed date of entry into force: To be determined

10. Final date for comments: 28 February 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/2023/TBT/USA/23_13920_00_e.pdf