世界贸易组织

通报号: G/TBT/N/USA/2071

通报日期: 2023-12-04

贸易技术壁垒委员会

原文: 英语

通 报

以下通报根据 TBT 协定第 10.6 条分发

1.	**通报成员：**美国 **如适用，所涉及的地方政府名称（第 3.2 和 7.2 条）：**
2.	**负责机构：**食品药品监督管理局（FDA）卫生和福利部（HHS）[2102] **处理通知意见的机构或机构的名称和地址（包括电话和传真号码、电子邮件和网站地址，如果有的话）如与上述不同，应注明：** 请将意见提交至:美国 WTO TBT 咨询点，电子邮件：usatbtep@nist.gov
3.	**通报依据的条款：2.9.2[X]，2.10.1[ ]，5.6.2[X]，5.7.1[ ]，3.2[ ]，7.2[ ]，其他：**

4.	**覆盖的产品：**含有抗菌剂和/或其他化学物质的固体伤口敷料和液体伤口清洗剂；配制成凝胶、霜剂或软膏的伤口敷料；以及液体伤口清洗剂；医疗设备（ICS 编码：11.040）；伤口敷料和绷带（ICS 编码：11.120.20）；急救（ICS 编码：11.160） **ICS：　HS：**
5.	**通报标题：**医疗器械；普通和整形外科器械；固体伤口敷料的分类；配制成凝胶、霜剂或软膏的伤口敷料；以及液体伤口清洗剂 **页数：**29 页　**使用语言：**英语　**链接网址：**
6.	**内容简述：**拟议法规-食品药品监督管理局（FDA、“管理局”或“我们”）拟将某些含有抗菌剂和/或其他化学物质的伤口敷料和液体伤口清洗剂（未分类、上市前设备）归类为固体伤口敷料；配制成凝胶、霜剂或软膏的伤口敷料；以及液体伤口清洗剂。管理局目前将这些未分类器械作为需要上市前通知（510(k)要求）的器械进行监管，产品代码为 FRO、GER、MGP、MGQ 和 EFQ，但管理局打算在最终确定该分类行动后，为这些拟议分类创建新的产品代码。管理局拟将某些含有抗菌剂耐药性（AMR）关注度较高的抗菌剂（即医疗上重要的抗菌剂）的伤口敷料和液体伤口清洗剂归入第三类。此外，管理局拟将某些含有抗菌剂耐药性中等或低水平的抗菌剂和/或其他化学物质的伤口敷料和液体伤口清洗剂归入第二类（受特别控制并须遵守 510(k)要求）。
7.	**目的和理由：**保护人类健康和安全
8.	**相关文件：** 2023 年 11 月 30 日《联邦公报》（FR）第 88 卷第 83774 页；《美国联邦法规》（CFR）第 21 编第 878 部分：

	https://www.govinfo.gov/content/pkg/FR-2023-11-30/html/2023-26209.htm https://www.govinfo.gov/content/pkg/FR-2023-11-30/pdf/2023-26209.pdf 该拟议法规的案卷号为 FDA-2023-N-3392。该案卷文件夹可从 Regulations.gov 网站获取，网址为：https://www.regulations.gov/docket/FDA-2023-N-3392/document，并可查阅主要文件和证明文件以及收到的意见。还可以在 Regulations.gov 网站上搜索案卷号获取文件。世贸组织成员国及其利益相关者应在东部时间 2024 年 2 月 28 日下午 4 点或之前向美国 TBT 咨询点提交意见。美国 TBT 咨询点从世贸组织成员国及其利益相关者处收到的意见将与监管机构共享，并且如果在评议期内收到，还将提交至 Regulations.gov 摘要处进行备案。
9.	**拟批准日期：**待定 **拟生效日期：**待定
10.	**意见反馈截至日期：**2024 年 2 月 28 日
11.	**文本可从以下机构得到：[ ] 国家通报机构 [ ] 国家咨询点，或其他机构的联系地址、传真及电子邮件地址（如能提供）：** https://members.wto.org/crnattachments/2023/TBT/USA/23_13920_00_e.pdf

WORLD TRADE ORGANIZATION

G/TBT/N/USA/2071

1 December 2023

(23-8175)

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) [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 https://www.govinfo.gov/content/pkg/FR-2023-11-30/pdf/2023-26209.pdf 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