NOTIFICATION

Corrigendum

The following communication, dated 17 October 2024, is being circulated at the request of the delegation of the United States of America.

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Medical Devices; Quality System Regulation Amendments

The Food and Drug Administration (FDA or Agency) is correcting a [final rule](https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01709.pdf) that appeared in the Federal Register on 2 February 2024 (notified as [G/TBT/N/USA/1839/Add.1](https://eping.wto.org/en/Search?viewData=G/TBT/N/USA/1839/Add.1)). In that final rule, FDA amended the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation to harmonize and modernize the device CGMP. FDA is correcting an editorial error that inadvertently omitted a definition in the codified of the final rule. This action is editorial in nature and is intended to ensure the accuracy and clarity of the Agency's regulations.

Effective 2 February 2026

89 Federal Register (FR) 82945, [Title 21 Code of Federal Regulations (CFR) Part 820](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820):  
<https://www.govinfo.gov/content/pkg/FR-2024-10-15/html/2024-23701.htm>  
<https://www.govinfo.gov/content/pkg/FR-2024-10-15/pdf/2024-23701.pdf>

This action and previous actions notified under the symbol [G/TBT/N/USA/1839](https://eping.wto.org/en/Search?domainIds=1&documentSymbol=usa%2F1839) are identified by Docket Number FDA-2021-N-0507. The Docket Folder is available from Regulations.gov at <https://www.regulations.gov/docket/FDA-2021-N-0507/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number.

<https://members.wto.org/crnattachments/2024/TBT/USA/24_06918_00_e.pdf>

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