NOTIFICATION

Addendum

The following communication, dated 15 October 2021, is being circulated at the request of the delegation of the United States of America.

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**Title:** Unique Device Identification System

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| **Reason for Addendum:** | |
| [  ] | Comment period changed - date: |
| [  ] | Notified measure adopted - date: |
| [  ] | Notified measure published - date: |
| [  ] | Notified measure enters into force - date: |
| [  ] | Text of final measure available from[[1]](#footnote-1): |
| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [  ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [X] | Interpretive guidance issued and text available from1:  <https://www.govinfo.gov/content/pkg/FR-2021-10-14/html/2021-22308.htm>  <https://www.govinfo.gov/content/pkg/FR-2021-10-14/pdf/2021-22308.pdf>  <https://members.wto.org/crnattachments/2021/TBT/USA/interpretative_guidance/21_6569_00_e.pdf>  The "2020 UDI Compliance Policy Guidance," is available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification>. This draft guidance is not final nor is it in effect at this time. This guidance is being distributed for comment purposes only. |
| [  ] | Other: |

**Description:** Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the draft guidance entitled "Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff." This draft guidance explains that there are certain class I devices for which FDA does not intend to enforce Global Unique Device Identification Database (GUDID) submission requirements and describes how a labeler of a class I device can determine if its device is one of these devices in the revised section III of this draft guidance. When this draft guidance is finalized, the updates in section III of this draft guidance would supersede the recommendations in section III of the guidance "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking" ("2020 UDI Compliance Policy Guidance," available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification>). This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by 13 December 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

This notice of availability is identified by Docket Number FDA-2017-D-6841. The Docket Folder is available on [Regulations.gov](https://www.regulations.gov/) at <https://www.regulations.gov/docket/FDA-2017-D-6841> and provide access to documents associated with the notice. Documents are also accessible from [Regulations.gov](https://www.regulations.gov/) by searching the Docket Number. We note this is a "Nonrulemaking Docket".

WTO Members and their stakeholders are asked to submit comments on the draft guidance to the [USA TBT Enquiry Point](mailto:usatbtep@nist.gov). Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders will be shared with the FDA and will also be submitted to the [Docket](https://www.regulations.gov/docket/FDA-2017-D-6841) on [Regulations.gov](https://www.regulations.gov/) if received within the comment period.

Previous rulemaking and related actions notified under the symbol [G/TBT/N/USA/720](http://tbtims.wto.org/en/Notifications/Search?ProductsCoveredHSCodes=&ProductsCoveredICSCodes=&DoSearch=True&ExpandSearchMoreFields=False&NotifyingMember=United+States+of+America&DocumentSymbol=&DistributionDateFrom=&DistributionDateTo=&SearchTerm=Unique+Device+Identification&ProductsCovered=&DescriptionOfContent=&CommentPeriod=&FinalDateForCommentsFrom=&FinalDateForCommentsTo=&ProposedDateOfAdoptionFrom=&ProposedDateOfAdoptionTo=&ProposedDateOfEntryIntoForceFrom=&ProposedDateOfEntryIntoForceTo=&ReasonForAddendum=) ("Unique Device Identification System") are identified by Docket Number FDA-2011-N-0090. The Docket Folder for the rulemaking is available on [Regulations.gov](https://www.regulations.gov/) at <https://www.regulations.gov/docket/FDA-2011-N-0090/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](https://www.regulations.gov/) by searching the Docket Number.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)