NOTIFICATION

Addendum

The following communication, dated 25 September 2024, is being circulated at the request of the delegation of the United States of America.

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**Title:** Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements; Guidance for Industry; Availability

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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| [ ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |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: Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements |
| [ ] | Other: <https://members.wto.org/crnattachments/2024/TBT/USA/24_06259_00_e.pdf><https://members.wto.org/crnattachments/2024/TBT/USA/24_06259_01_e.pdf> |

**Description:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled "Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements." This guidance describes FDA's enforcement policy for the [final rule](https://www.govinfo.gov/content/pkg/FR-2020-03-18/pdf/2020-05211.pdf), "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," (notified as [G/TBT/N/USA/1519/Add.2](https://eping.wto.org/en/Search?viewData=%20G/TBT/N/USA/1519/Add.2)) which established new required cigarette health warnings for cigarette packages and advertisements. The guidance is intended to assist entities required to comply with the rule.

The announcement of the guidance is published in the Federal Register on 13 September 2024.

89 Federal Register (FR) 74831, [Title 21 Code of Federal Regulations (CFR) Part 1141](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-K/part-1141):

<https://www.govinfo.gov/content/pkg/FR-2024-09-13/html/2024-20850.htm>

<https://www.govinfo.gov/content/pkg/FR-2024-09-13/pdf/2024-20850.pdf>

<https://www.fda.gov/media/181776/download>

Download the final guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-required-warnings-cigarette-packages-and-advertisements>.

This notification of availability is identified by Docket Number FDA-2024-D-3742. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2024-D-3742/document> and provides access to primary documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.

Previous actions notified under the symbol [G/TBT/N/USA/1519](https://eping.wto.org/en/Search?domainIds=1&documentSymbol=usa%2F1519) are identified by Docket Number FDA-2019-N-3065. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2019-N-3065/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.

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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)