



9 November 2015

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Page: 1/1

Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

### *Addendum*

The following communication, dated 30 October 2015, is being circulated at the request of the delegation of the United States of America.

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TITLE: National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions – Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of availability

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions – Small Entity Compliance Guide." This guidance is intended to help small businesses understand the recent changes to FDA's National Environmental Policy Act (NEPA)-implementing regulations, which will allow certain classes of actions on tobacco product marketing applications to be excluded from the requirements to prepare an environmental assessment (EA) or an environmental impact statement (EIS). This will decrease the amount of time required for industry to complete, and for FDA to review, applications.

DATES: Submit either electronic or written comments on Agency guidances at any time.

[https://members.wto.org/crnattachments/2015/TBT/USA/15\\_4416\\_00\\_e.pdf](https://members.wto.org/crnattachments/2015/TBT/USA/15_4416_00_e.pdf)

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