

National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions

Small Entity Compliance Guide

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2013-N-1282.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

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Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to help small businesses understand and comply with FDA's implementation of the National Environmental Policy Act (NEPA) and the Council on Environmental Quality (CEQ) regulations for classes of actions for tobacco products as amended by this final rule. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

NEPA and the CEQ Regulations require each Federal Agency to assess, as an integral part of its decision-making process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed (42 U.S.C. 4332(2); 40

¹ This guidance was prepared by the Office of Science and Office of Regulations in the Center for Tobacco Products at FDA.

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38 CFR 1506.6). FDA regulations governing its responsibilities under NEPA are codified at 21
39 CFR part 25, and the CEQ regulations are codified at 40 CFR parts 1500 to 1508.

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41 CEQ oversees FDA's compliance with NEPA. For major Federal actions that may have a
42 significant environmental impact, FDA can prepare either an environmental impact statement
43 (EIS) or an environmental assessment (EA). An EA provides sufficient information and analysis
44 for FDA to determine whether to prepare an EIS or issue a finding of no significant impact
45 (FONSI) (21 CFR 25.20; 40 CFR 1501.4). FDA is responsible for the scope and content of an
46 EA and generally requires an applicant to prepare an EA and make necessary corrections to it (21
47 CFR 25.40(b)).

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49 Categorically excluded actions refer to a category of actions that have been found not to
50 individually or cumulatively have a significant effect on the quality of the human environment
51 and which do not normally require the preparation of an EA or EIS (40 CFR 1508.4). However,
52 as required under 21 CFR 25.21 and 40 CFR 1508.4, FDA will require preparation of at least an
53 EA for any specific action that normally would be excluded if extraordinary circumstances are
54 present such that the specific proposed action may have the potential to significantly affect the
55 quality of the human environment.

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57 In the Federal Register of January 23, 2014 (79 FR 3742), FDA issued a notice of proposed
58 rulemaking (NPRM) to amend 21 CFR part 25 to provide categorical exclusions for certain
59 actions related to substantial equivalence (SE) reports, SE exemption requests, and tobacco
60 product applications, and the rescission (order withdrawing an order) or suspension of orders
61 regarding the marketing of tobacco products under the Family Smoking Prevention and Tobacco
62 Control Act (Tobacco Control Act). FDA also proposed to amend its NEPA-implementing
63 regulations to include tobacco products, where appropriate, in light of its new authority under the
64 Tobacco Control Act. In the Federal Register of September, 24, 2015 (80 FR 57531), FDA
65 published the final rule, codified at 21 CFR part 25.

66 67 **III. QUESTIONS AND ANSWERS**

68 69 **A. What are the specific sections of the Code of Federal Regulations (CFR)** 70 **which are impacted by this rule?**

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72 This rule amends §§ 25.15, 25.20, 25.30, 25.35, 25.50, and 25.52 of title 21 of the CFR.

73 74 **B. How does this rule affect part 25 of title 21 of the CFR?**

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76 Part 25 of title 21 provides that all applications or petitions requesting agency action require the
77 submission of an EA or a claim of categorical exclusion. It also clarifies that FDA may refuse to
78 file or approve an application or petition if an applicant provides an insufficient EA. This final
79 rule (1) expands the list of actions that ordinarily require at least the preparation of an EA, to
80 include certain orders relating to tobacco product applications; (2) creates categorical exclusions
81 for certain classes of actions involving tobacco products; and (3) requires applicants to submit an
82 EA or claim of categorical exclusion with their tobacco product applications.

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C. What classes of actions for tobacco products ordinarily require at least the preparation of an EA?

Section 25.20 lists the following classes of actions that ordinarily require at least the preparation of an EA, unless categorically excluded under § 25.35 (see III. D. for those classes of actions for tobacco products that are categorically excluded):

- Issuance of an order finding a tobacco product substantially equivalent under the Federal Food, Drug, and Cosmetic Act, or granting of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence.
- Issuance of an order authorizing marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act or an order authorizing marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act.

D. What classes of actions for tobacco products qualify for a categorical exclusion?

Section 25.35 lists the following classes of actions that are categorically excluded and, therefore, normally do not require the preparation of an EA or an EIS:

- Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the FD&C Act (provisional SE order);
- Denial of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence;
- Issuance of a not substantially equivalent (NSE) order under section 910(a) of the FD&C Act;
- Issuance of an order finding that a product may not be introduced or delivered for introduction into interstate commerce under section 910(c) of the FD&C Act;
- Issuance of an order finding that a modified risk tobacco product may not be introduced or delivered for introduction into interstate commerce under section 911 of the FD&C Act;
- Rescission (order withdrawing an order) or temporary suspension of an order authorizing the marketing of a new tobacco product;
- Rescission of a modified risk tobacco product (MRTP) authorization order; and
- Rescission of an order granting an exemption from the requirement of demonstrating substantial equivalence.

E. What information must be provided to FDA to request a categorical exclusion?

A claim of categorical exclusion must be submitted in accordance with 21 CFR 25.15. Section 25.15 requires that the claim of categorical exclusion include: (1) A statement of compliance with the categorical exclusion criteria and (2) a statement that, to the submitter's knowledge, no extraordinary circumstances exist.

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F. What if I qualify for a categorical exclusion but I have already submitted my application and CTP has not yet made a determination?

You may amend your application. Contact the assigned regulatory health project manager for your application for further details.

G. Under what circumstances is an application prohibited from requesting categorical exclusion?

If extraordinary circumstances exist, such that the specific proposed action may have the potential to significantly affect the quality of the human environment, an EA must be submitted for that particular application. To learn more about what qualifies as an extraordinary circumstance, refer to CEQ's, "Final Guidance for Federal Departments and Agencies on Establishing, Applying, and Revising Categorical Exclusions Under the National Environmental Policy Act," 76 FR 3843, January 21, 2011.

H. When will applicants have to submit an EA

Section 25.15 requires that all applications or petitions requesting agency action include the submission of an EA or a claim of categorical exclusion. Thus, applicants must include an EA in their applications seeking the actions listed in III.C or a claim of categorical exclusion. The EA must be prepared in accordance with 21 CFR 25.40, unless the action qualifies for a categorical exclusion. Under § 25.15, an applicant's failure to submit an adequate EA for an application or petition requesting agency action of a type specified in § 25.20, unless the agency can determine that the action qualifies for exclusion under § 25.35, is sufficient grounds for FDA to refuse to file or approve the application or petition. Per § 25.15, an EA adequate for filing is one that addresses the relevant environmental issues and an EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment. More information on environmental assessments can be found in 21 CFR part 25.

I. Will FDA provide assistance for small businesses seeking additional information regarding this rule?

FDA's Center for Tobacco Products (CTP) has established an Office of Small Business Assistance in an effort to help small businesses access up-to-date information and comply with the requirements of the Tobacco Control Act. CTP's Office of Small Business Assistance can be reached at SmallBiz.Tobacco@fda.hhs.gov or at 1-877-CTP-1373 (1-877-287-1373) Monday–Friday, 9:00 a.m. – 4:00 p.m. EDT.

J. When does this rule become effective?

This rule becomes effective on October 26, 2015, which is 30 days after the rule published in the Federal Register. See 80 FR 57531.

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