4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1282]

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.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

Instructions: All submissions received must include the Docket No. FDA-2013-N-1282 for "National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions--Small Entity Compliance Guide." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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 and comply with FDA's implementation of NEPA and the Council on Environmental Quality (CEQ) regulations for classes of actions for tobacco products as provided by the final rule. Specifically, this guidance is intended to help small businesses understand

which classes of actions for tobacco products require at least the preparation of an EA, and how to apply for categorical exclusions if they qualify based on their particular circumstance.

NEPA and CEQ regulations require each Federal Agency to assess, as an integral part of its decisionmaking 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 CFR 1506.6). FDA regulations governing its responsibilities under NEPA are codified at 21 CFR part 25, and the CEQ regulations are codified at 40 CFR parts 1500 to 1508.

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

Categorically excluded actions refer to a category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not normally require the preparation of an EA or EIS (40 CFR 1508.4). However, as required under 21 CFR 25.21 and 40 CFR 1508.4, FDA will require preparation of at least an EA for any specific action that normally would be excluded if extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121), FDA is making available this small

entity compliance guide stating in plain language the legal requirements of the September 24, 2015, final rule, set forth in 21 CFR part 25.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on NEPA and environmental assessments for tobacco products including categorical exclusions. 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.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either http://www.regulations.gov or http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.

Dated: October 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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