Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1107

[Docket No. FDA–2016–N–3818]

RIN 0910–AH89

Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule that appeared in the **Federal Register** of April 2, 2019. The Agency is taking this action in response to requests for an extension to allow interested parties additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published April 2, 2019 (84 FR 12740). Submit either electronic or written comments by July 17, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 17, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on July 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2016–N–3818 for ''Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 2, 2019, FDA published a proposed rule with a 75-day comment period that would, if finalized, establish requirements for the content and format of reports intended to establish the substantial equivalence of a tobacco product. The proposed rule, if finalized, would also establish the general procedures that FDA intends to follow when evaluating substantial equivalence reports.

The Agency has received requests for an extension of the comment period for the proposed rule. The requests conveyed concern that the current 75-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until July 17, 2019. FDA believes a 30-day extension is appropriate and would help ensure that interested persons have time to fully consider the proposed provisions, which are detailed and interrelated, as well as to fully consider and develop responses to the Agency's specific requests for comment.

Dated: June 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12478 Filed 6–12–19; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 220

RIN 0596–AD31

National Environmental Policy Act (NEPA) Compliance

AGENCY: Forest Service, USDA.

ACTION: Proposed rule.

SUMMARY: The U.S. Department of Agriculture, Forest Service (Agency) is proposing revisions to its National Environmental Policy Act (NEPA) regulations. The Agency proposes these revisions to increase efficiency in its environmental analysis while meeting NEPA's requirements and fully honoring its environmental stewardship responsibilities. The proposed rule would contribute to increasing the pace and scale of work accomplished on the ground and would help the Agency achieve its mission to sustain the health, diversity, and productivity of the nation's forests and grasslands to meet the needs of present and future generations. Public input has informed the development of the proposed rule, including through an Advance Notice of Proposed Rulemaking. The Agency is now requesting public comment on the revisions in the proposed rule. The Agency will carefully consider all public comments in preparing the final rule.

DATES: Comments must be received in writing by August 12, 2019.

ADDRESSES: Please submit comments via one of the following methods:

1. *Public participation portal (preferred): https://www.regulations.gov/.*

2. *Mail:* NEPA Services Group, c/o Amy Barker; USDA Forest Service, 125 South State Street, Suite 1705, Salt Lake City, UT 84138.

3. *Email: nepa-procedures-revision@fs.fed.us.*

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received online via the public reading room at *https://www.regulations.gov/,* or at U.S. Forest Service, Ecosystem Management Coordination, 201 14th St. SW, 2 Central, Washington, DC 20024. Visitors are encouraged to call ahead to 202–205–1475 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Christine Dawe; Director, Ecosystem Management Coordination; 406–370–8865. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The Forest Service is proposing revisions to its NEPA procedures (36 CFR part 220, which are located at *https://www.fs.fed.us/emc/nepa/nepa_procedures/index.htm*) with the goal of increasing efficiency of environmental analysis while meeting NEPA's requirements. The Forest Service is not fully meeting agency expectations, nor the expectations of the public, partners, and stakeholders, to improve the health and resilience of forests and grasslands, create jobs, and provide economic and recreational benefits. The Agency spends considerable financial and personnel resources on NEPA analyses and documentation. The Agency is proposing these revisions to make more efficient use of those resources. The Agency will continue to hold true to its commitment to deliver to decision makers scientifically based, high-quality analysis that honors its environmental stewardship responsibilities while maintaining robust public participation. These values are at the core of the Forest Service mission and are compatible with gaining efficiency in NEPA analysis and documentation.

Reforming the Forest Service's NEPA procedures is needed at this time for a variety of reasons. An increasing percentage of the Agency's resources have been spent each year to provide for wildfire suppression, resulting in fewer resources available for other management activities, such as restoration. In 1995, wildland fire management funding made up 16 percent of the Forest Service's annual spending, compared to 57 percent in 2018. Along with a shift in funding, there has also been a corresponding shift in staff from non-fire to fire programs, with a 39 percent reduction in all non-fire personnel since 1995.

The Consolidated Appropriations Act of 2018 (2018 Omnibus Bill) included a new budget authority for FY 2020 to FY 2027, which will provide federal agencies with a new budget authority of over $20 billion for fighting wildfires, in addition to regular appropriations. While this budget stability is welcome, the trends discussed above make it imperative that the Agency makes the most efficient use of available funding and resources to fulfill its environmental analysis and decision making responsibilities.

Additionally, the Agency has a backlog of more than 5,000 applications for new special use permits and renewals of existing special use permits that are awaiting environmental analysis and decision. On average, the Forest Service annually receives 3,000 applications for new special use permits. Over 80 million acres of National Forest System (NFS) land are in need of restoration to reduce the risk of wildfire, insect epidemics, and forest diseases.

Increasing the efficiency of environmental analysis would enable the Agency to do more to increase the health and productivity of our national forests and grasslands and be more responsive to requests for goods and services. The Agency's goal is to complete project decision making in a timelier manner, improve or eliminate inefficient processes and steps, and, where appropriate, increase the scale of analysis and the number of activities in a single analysis and decision. Improving the efficiency of environmental analysis and decision making will help the agency ensure that lands and watersheds are sustainable, healthy, and productive; mitigate wildfire risk; and contribute to the economic health of rural communities through use and access opportunities.

Council on Environmental Quality (CEQ) regulations at 40 CFR 1507.3 require Federal agencies to adopt procedures, as necessary, to supplement CEQ's regulations for implementing NEPA (40 CFR parts 1500–1508), and to