4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1105

[Docket No. FDA-2016-N-1555]

Refuse to Accept Procedures for Premarket Tobacco Product Submissions; Revised Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," this action revises the effective date of the final rule ("Refuse to Accept Procedures for Premarket Tobacco Product Submissions") published December 29, 2016, from January 30, 2017, until March 21, 2017.

DATES: The effective date of the rule that published on December 29, 2016, at 81 FR 95863, is delayed until March 21, 2017.

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

SUPPLEMENTARY INFORMATION: On December 29, 2016, the Food and Drug Administration (FDA or Agency) issued a final rule describing when FDA will refuse to accept a tobacco product submission (or application) because the application has not met a minimum threshold for acceptability for FDA review (81 FR 95863). Under the rule, FDA will refuse to

accept a tobacco product submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the type of submission. The rule was published with an effective date of January 30, 2017.

FDA bases this action on the memorandum of January 20, 2017 (82 FR 8346), from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review." That memorandum directed the heads of Executive Departments and Agencies to temporarily postpone for 60 days from the date of the memorandum the effective dates of all regulations that had been published in the Federal Register but had not yet taken effect, for the purpose of "reviewing questions of fact, law, and policy they raise." FDA, therefore, is revising the effective date of the rule that published on December 29, 2016 (81 FR 95863), to March 21, 2017.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the Agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the Federal Register, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The temporary delay in the effective date until March 21, 2017, is necessary to give Agency officials the opportunity for further review and consideration of the new regulation, consistent with the memorandum described previously. Given the imminence of the effective date and the brief length of the extension of the effective date, seeking prior public comment on this temporary delay would have been impracticable, as well as contrary to the public interest in the orderly promulgation and implementation of

regulations.[1] FDA also believes that affected entities need to be informed as soon as possible of the extension and its length in order to plan and adjust their implementation process accordingly.

Dated: January 27, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[1] In the event that this rule does not publish on or before January 30, 2017, good cause similarly exists to stay the effectiveness of the rule published December 29, 2016, and revise its effective date until March 21, 2017.

[FR Doc. 2017-02174 Filed: 1/30/2017 11:15 am; Publication Date: 2/1/2017]