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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801, and 1100

[Docket No. FDA-2015-N-2002]

RIN 0910-AH19

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Delayed 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 delays the effective date of the final rule ("Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses' "), which published on January 9, 2017, from February 8, 2017, until March 21, 2017.

DATES: The effective date of the rule amending 21 CFR Chapter I published at 82 FR 2193 on January 9, 2017 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 January 9, 2017, the Food and Drug Administration (FDA or Agency) issued a final rule describing the circumstances in which products made or derived from tobacco are regulated as drugs, devices, or combination products. The rule also amended the "intended use" regulations found at 21 CFR 201.128 and 801.4. The rule was published with an effective date of February 8, 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 delaying the effective date of the rule that published on January 9, 2017 (82 FR 2193), 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 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 delay would have been impracticable, as well as contrary to the public interest in the orderly issue and implementation of regulations.

Dated: February 2, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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