4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0212]

Applications for Premarket Review of New Tobacco Products; Draft Guidance for Industry; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a draft guidance for industry entitled "Applications for Premarket Review of New Tobacco Products." We are withdrawing this guidance because the topics discussed in the draft guidance are addressed in the final rule entitled "Premarket Tobacco Product Applications and Recordkeeping Requirements."

DATES: The draft guidance is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Paul Hart, 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SUPPLEMENTARY INFORMATION: FDA is announcing the withdrawal of a draft guidance for industry entitled "Applications for Premarket Review of New Tobacco Products," the notice of availability for which appeared in the *Federal Register* of September 28, 2011 (76 FR 60055). The draft guidance was intended to assist persons submitting premarket tobacco product applications (PMTAs) for new tobacco products under section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j(b)(1)). The draft guidance discussed, among other things, when and how to submit PMTAs, what information the FD&C Act requires a PMTA to contain, and what information FDA recommends that applicants submit to

demonstrate its new tobacco product should receive a marketing granted order. We are withdrawing this draft guidance and not finalizing it because the final rule entitled "Premarket Tobacco Product Applications and Recordkeeping Requirements" covers the topics described in the draft guidance.

Dated: September 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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