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Given the above, you should not use this document as a tool, guide, or manual for the preparation of applications or submissions to FDA. Instead, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. FDA also regularly posts additional resources for applicants, such as webinars and application tips, on CTP's website and social media.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: File

From: Todd Cecil, Ph.D.
Deputy Director, Office of Science, CTP

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.06.01 09:41:23 -04'00'

Through: Matthew Holman, Ph.D.
Director, Office of Science, CTP

Matthew R. Holman -S Digitally signed by Matthew R. Holman -S
Date: 2022.06.01 10:05:28 -04'00'

Subject: Process for implementing new Acceptance and Filing Reviews for premarket tobacco product applications (PMTAs) based on new requirements under 21 CFR 1114

Background

The Agency issued a final rule, Premarket Tobacco Product Applications and Recordkeeping Requirements (PMTA rule[1]), that set forth new requirements for PMTAs received as of November 4, 2021. The rule requires manufacturers to maintain records establishing that their tobacco products are legally marketed and articulates information needed for FDA to make a marketing determination. Specifically, the rule codifies general procedures and requirements that enable FDA to assess whether:

I. There is a showing that permitting the marketing of the new tobacco product would be appropriate for the protection of the public health;
II. the methods used in, or the facilities and controls used for, the manufacture, processing, or packing of the product conform to the requirements of section 906(e) of the FD&C Act (21 U.S.C. 387f(e));
III. the product labeling is not false or misleading in any particular; and
IV. the product complies with any applicable product standard in effect under section 907 of the FD&C Act (21 U.S.C. 387g) or there is adequate information to justify a deviation from such standard.

FDA updated Acceptance and Filing review templates to align with the new requirements set forth in the PMTA rule. This memo describes FDAs general approach and prioritization for Acceptance and Filing of PMTAs received as of November 4, 2021.

Discussion

FDA evaluated review criteria established in the PMTA rule and considered them across phases of Acceptance, Filing, and Scientific review. Based on its experiences with PMTA processing and review, FDA is prioritizing select review criteria across the various phases of review to address requirements in the PMTA rule, while balancing the need for efficient review to address public health goals. FDA also considered our lack of experience implementing these requirements at this time.

Acceptance Review

[1] Premarket Tobacco Product Applications and Recordkeeping Requirements (86 FR 55300)

In general, requirements pertaining to jurisdiction, environmental criteria, administrative content, and format of the application were designated for Acceptance review. As the scope of review is limited to regulatory content, the review will remain within the Division of Regulatory Health Project Management; no changes to the assigned reviewer were made.

Filing Review

Historically, Filing review has been conducted to ensure that PMTAs contain required elements described in section 910(b)(1) of the FD&C Act. Whereas the adequacy of the scientific information and review of whether the tobacco product is appropriate for the protection of the public health (APPH) has been part of Scientific review phase. Using the PMTA rule as a guide, the Filing review was updated to include scientific content necessary for an application to be considered complete and ready for Scientific review. In general, any requirement assessing the adequacy of data will continue to be deferred to Scientific review.

Prior to finalization of the PMTA rule and during the one-year compliance period[2], FDA increased Filing efficiency by streamlining the Filing teams and limiting review to three disciplines: Chemistry, Engineering, and Regulatory (see Filing Efficiency Memo dated February 20, 2020). Because the PMTA rule set forth Filing requirements that require evaluation by more than the three review disciplines employed during the streamlined Filing review, FDA will:

I. Reinstate a more comprehensive Filing team which includes but is not limited to the following disciplines: Behavioral Clinical Pharmacology, Chemistry, Engineering, Epidemiology, Medical, Microbiology, Office of Compliance and Enforcement (OCE), Social Science, and Toxicology;
II. Focus on the presence or absence of those items within section 910(b)(1) of the FD&C Act and requirements outlined in 21 CFR 1114; and
III. Continue to defer request for samples under section 910(b)(1)(E) of the FD&C Act to scientific review.

To gain more experience on new requirements and to give applicants time to become familiar with the PMTA rule, FDA will prioritize Acceptance and Filing criteria that are more immediately apparent, given the public health need for more efficient review. This approach will provide both FDA and the applicant more time to become familiar with new more stringent requirements.

Prioritization of Non-tobacco Nicotine Products (NTN)

On March 15, 2022, the Consolidated Appropriations Act, 2022 (H.R. 2471) was enacted. This amended the tobacco product definition to extend FDA authority to products containing nicotine not made or derived from tobacco (i.e., non-tobacco nicotine [NTN]). The authority is effective 30 days from enactment (April 14, 2022) and requires manufacturers of tobacco products using NTN to submit premarket applications between 30 – 60 days after enactment (April 14, 2022-May 14, 2022). Manufacturers that submit timely applications will receive enforcement discretion for up to 120 days (or until July 13, 2022) unless FDA issues a negative action. To make substantial progress towards final decisions before the end of the enforcement discretion period, FDA will not use the "first in, first reviewed" approach for applications received after the effective date of the PMTA rule. Instead, FDA will prioritize PMTAs for NTN products submitted in accordance with the Consolidated Appropriations Act, 2022.

[2] The United States District Court for the District of Maryland issued an order directing FDA to require that premarket authorization applications for all new deemed tobacco products on the market on August 8, 2016, be submitted to the Agency by September 9, 2020, and providing for a one-year period during which products with timely filed applications might remain on the market pending FDA review.

Conclusion

Promulgation of the final PMTA rule set additional requirements for the Acceptance and Filing review phases. Respective reviews and procedures were updated and will be used to evaluate applications received as of November 4, 2021. Because of the expansion of the tobacco product definition, FDA will prioritize applications for NTN products and implement the updated reviews using the approach outlined in this memo. FDA intends to initiate this review process starting in June 2022 with applications for NTN products, followed by other applications received as of November 4, 2021. The review process and prioritization described in this memo will benefit public health as it will facilitate final decisions for NTN products by July 13, 2022. The processes in this memo will be revisited once FDA gains more experience with new PMTA requirements.