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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.
Associate Director, Division of Product Science
Office of Science, CTP

Todd L. Cecil -S
Digitally signed by Todd L. Cecil -S
Date: 2020.02.20 08:18:27 -05'00'

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

Digitally signed by Matthew R. Holman -S
Date: 2020.02.20 10:06:07 -05'00'

Subject: To support the efficient filing review of premarket tobacco product applications (PMTAs)

Background

Effective August 8, 2016, deemed tobacco products that were not on the market as of February 15, 2007, ('grandfathered' tobacco product) are required to submit a premarket application prior to marketing their tobacco product. Currently, however, deemed tobacco products that were on the market as of August 8, 2016, are under a compliance policy and may remain on the market without FDA authorization until May 12, 2020. A deemed tobacco product that is on the market because of the current compliance policy must submit an application by May 12, 2020, and may remain on the market during a one-year compliance period (May 12, 2020 to May 12, 2021). Because deemed tobacco products encompass a wide variety of tobacco products including waterpipes and waterpipe tobacco, nicotine dissolvables, nicotine gums, ENDS, pipes and pipe tobacco, and cigars, OS expects that we may receive a large number of premarket applications by May 12, 2020. Because deemed products may not be grandfathered or have grandfathered predicates, we expect to receive a large volume of premarket tobacco product application (PMTA) submissions.

As part of our considerations for how to manage of the potentially large numbers of submitted premarket applications under the PMTA pathway on or near the May 12, 2020 deadline, we considered how to most effectively and efficiently move through each phase of application review i.e., acceptance, filing, and then substantive scientific review of the filed PMTAs within 180 days. In examining efficiencies at each phase of review, we determined that the current filing review is a relatively lengthy process, usually taking several weeks to complete, generally necessitating most, if not all, review disciplines to complete a filing review and including a level of substantive scientific review prior to the filing of the application. Because we would want to increase efficiencies in each phase of review, we intend to reduce the amount of time and review disciplines necessary to file a PMTA application and intend to begin substantive scientific review immediately after filing a PMTA.

Discussion

Based on OS' concerns with the high volume of PMTA submissions on or near May 12, 2020, and the need to efficiently 'move' these received PMTAs into substantive scientific review, we have evaluated the current state of the PMTA filing review. In general, the filing review is conducted to ensure that the PMTA is administratively complete and contains the factors described in section 910(b)(1). The adequacy of the scientific information and review of whether the tobacco product is appropriate for the protection of public health is part of the substantive scientific review and not the filing review of the PMTA.

The evaluation of the filing review focused on preserving the effectiveness and increasing the efficiency of PMTA filing and reducing the need for substantive scientific review during the filing review phase. We intend to reduce the length of time for the filing review phase from approximately 38 days to seven days to complete the review and issue the filing letter, and reduce the number of reviewer disciplines who perform the filing review.

The reduction in the length of time to review and the number of reviewer disciplines necessary for completing a PMTA filing review is intended to allow reviewers to focus on those issues that would clearly be a filing issue and limit the initiation of substantive scientific review prior to an application being filed. Additionally, limiting the number of assigned disciplines at the filing phase of review allows for efficient and effective allocation and use of review resources to assignments such as PMTAs currently in the substantive scientific review phase.

Those review disciplines assigned to filing review would rapidly review the application, focusing on those items within section 910(b)(1) that are immediately apparent, legally supportable, and raise to the level of being a filing review issue and are not an issue for substantive scientific review. This more focused filing review preserves the intent of filing a PMTA, but reduces the expenditure of time and resources before the application is either refused to file or filed; if filed, the application moves to the substantive scientific review phase. We acknowledge that filing issues which are less apparent may be inadvertently overlooked during the filing review, and those filing issues that are overlooked could be requested during the substantive scientific review phase.

OS would also defer their request for samples under section 910(b)(1)(E) to the substantive scientific review phase. Many of these products are likely to be novel tobacco products that have not been reviewed by FDA and as such a more comprehensive evaluation of the tobacco product may be necessary to determine what testing should be performed and the number of samples that would be necessary to accomplish that testing. Deferring the samples request until substantive scientific review would allow for evaluation of the tobacco product and if there would be a need for specific independent testing of the product. Additionally, the applicant would not be required to submit their samples until such time as FDA determined these were necessary for submission and testing; thus, reducing the need for FDA to store those samples and for the applicant to submit samples that may not be necessary.

General Approach

Before or at the onset of the influx of large numbers of PMTA applications, OS intends to implement a seven-calendar day filing review. The filing review team may include, at most, the following review disciplines: Chemistry, Engineering, and Regulatory Project Management.

The assigned reviewers will perform a focused filing review of premarket tobacco product applications looking for those elements under section 910(b)(1) that are readily identifiable as filing issues. Such identifiable issues under 910(b)(1) might include for example: a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product (section 910(b)(1)(B)), a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such tobacco product (section 910(b)(1)(C)), or proposed specimens of labeling to be used for such tobacco product (section 910(b)(1)(F)). Additionally, under 21 C.F.R. part 25, the reviewers would evaluate any claims of categorical exclusion under section 25.35 or the adequacy of an environmental assessment (EA) as required under section 25.40. This list is not an exhaustive list of the elements listed under 910(b)(1) but provides examples of issues which may be readily observed by the filing reviewers during the seven-day filing review phase without the need for substantive scientific review.

Such samples of such tobacco product and of components thereof as the Secretary may reasonably be required (section 910(b)(1)(E)), in general, will not be requested during filing and requests for samples will be deferred to the substantive scientific review phase.

The filing reviewers would provide their reviews to a single filing review template as opposed to the current process of each filing reviewer providing their individual filing reviews on individual templates. This consolidation

of review at the filing stage increases communication among the reviewers at the filing stage and allows further streamlining of the review process.

If any of the elements as required under section 910(b)(1) are determined to be missing, then we would refuse-to-file the PMTA by calendar day 14 of the review process.

If the PMTA is filed, a letter is issued by calendar day 14 after application receipt. Within 30 days after filing an application, the applicant should be notified if and how many samples are necessary for FDA testing.

Conclusion

Because OS is expecting a large number of marketing applications to be submitted on or near the May 12, 2020, deadline for deemed tobacco product submissions, we are evaluating filing phase of PMTA review to increase efficiencies in filing review, eliminate inefficiencies, for example, overlap with substantive scientific review and preserve the effectiveness of the filing review. We intend to initiate this filing review process as new PMTAs are submitted to FDA, and re-evaluate the process as part of OS' continuing quality improvement plan.