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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing 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. 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. By refusing to accept submissions that have the deficiencies identified in the proposed rule, FDA will be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Paul Hart, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Rule

FDA is issuing this refuse to accept rule to identify deficiencies that will result in FDA's refusal to accept certain tobacco product submissions under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (21 U.S.C. 387e, 387j, and 387k).[1] Because these submissions will be refused before they enter FDA's review queue, more resources will be available for submissions that are ready for further review. This rule establishes a refuse to accept process for premarket tobacco product submissions, including premarket tobacco product applications (PMTAs), modified risk tobacco product applications (MRTPAs), substantial equivalence (SE) applications (also called SE reports), and exemption requests (including subsequent abbreviated reports).

B. Summary of the Major Provisions of the Regulatory Action

The rule explains when FDA will refuse to accept a premarket submission, including PMTAs, MRTPAs, SE applications, and exemption requests (including subsequent abbreviated reports). The rule is based on FDA's experience in reviewing these submissions. Under the rule, FDA will refuse to accept a premarket submission that: (1) Does not pertain to a tobacco product; (2) is not in English (or does not include a complete translation); (3) is submitted in an electronic format that FDA cannot process, read, review, or archive; (4) does not include the applicant's contact information; (5) is from a foreign applicant and does not include the name and

[1] FDA has published a final rule extending the Agency's "tobacco product" authorities in the FD&C Act to all categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products (Final Rule Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (81 FR 28974, May 10, 2016) (the Deeming rule)). This rule will apply to all tobacco products FDA regulates under Chapter IX of the FD&C Act.

contact information of an authorized U.S. agent (authorized to act on behalf of the applicant for the submission); (6) does not include a required form(s); (7) does not identify the tobacco product; (8) does not identify the type of submission; (9) does not include the signature of a responsible official authorized to represent the applicant; or (10) does not include an environmental assessment or claim of a categorical exclusion, if applicable. Under the rule, if FDA refuses to accept the submission, FDA will send the contact (if available) a notification. If the submission is accepted for further review, FDA will send an acknowledgement letter.

II. Background

FDA published two rulemaking documents concerning refuse to accept procedures in the Federal Register of August 8, 2016: A direct final rule (81 FR 52329) and a companion proposed rule (81 FR 52371). We published the direct final rule because we believed that the rule was noncontroversial, and we did not anticipate that it would receive any significant adverse comments. As a companion to the direct final rule, we published a proposed rule with the same codified language published in the proposed rules section of the Federal Register. The companion proposed rule provides a procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. We received adverse comment on the direct final rule and withdrew the direct final rule by issuing a notice in the Federal Register of November 16, 2016 (81 FR 80567). We are now finalizing the proposed rule and responding to the comments we received.

III. Purpose and Legal Authority

A. Purpose

FDA is issuing this refuse to accept rule to efficiently handle submissions that do not meet a threshold of acceptability for FDA review (e.g., the submission lacks certain information

FDA needs for substantive review of the submission). Currently, FDA often expends extensive time and resources in attempts to obtain information and resolve the deficiencies identified in the rule simply to begin substantively processing the submission. FDA expects that this rule will enhance the quality of the submissions and that submissions will move expeditiously through the review process. In addition, this rule will help submitters better understand the common hurdles FDA encounters in conducting a substantive review of submissions.

The rule identifies deficiencies that FDA has seen across types of premarket submissions and will result in FDA refusing to accept the submission. This rule applies to all tobacco product applications; we note that there are additional deficiencies that are not covered in this rule that may arise for specific types of premarket submissions that would also result in FDA's refusal to accept that specific type of premarket submission (e.g., omission of labeling for a PMTA that is required under section 910(b)(1)(F) of the FD&C Act).

FDA's refusal to accept a tobacco product submission does not preclude an applicant from resubmitting a new submission that addresses the deficiencies. In addition, acceptance of a submission does not mean that FDA has determined that the submission is complete, rather only that the submission meets the basic, minimum threshold for acceptance. Substantive review of the submission will begin once FDA accepts the submission, and for submissions with filing requirements (i.e., PMTAs and MRPTAs), once filed. This rule establishes a general process for refusing to accept submissions for premarket tobacco review, including PMTAs, MRTPAs, SE applications, and exemption requests (including subsequent abbreviated reports). Because administratively incomplete submissions will be refused before FDA begins substantive review, we will be able to use our resources on submissions that are more complete and better prepared for further review. In addition, FDA intends to determine, as soon as practicable, whether the

submission will be accepted. We intend to determine whether we will refuse to accept most premarket submissions under this rule by 21 to 60 days of receipt, with less lengthy submissions, such as some exemption requests, taking closer to 21 days or fewer and other more lengthy submissions taking closer to 60 days or fewer; however, this range is an initial estimate and the actual time required may vary depending on the volume of submissions received at any one time. FDA remains committed to an efficient product review process and intends to establish and implement performance goals for this action once it has experience with the volume of submissions it will receive for newly deemed tobacco products. FDA expects the performance goals to be generally similar to other Agency performance goals, i.e. a certain percentage of refuse to accept determinations made within a defined period of time, and with the percentage rising over time.

B. Legal Authority

Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) provides FDA with the authority to issue regulations for the efficient enforcement of the FD&C Act. This rule will allow FDA to more efficiently use our resources to review premarket submissions under sections 905, 910, and 911 of the FD&C Act. FDA has processed and reviewed many submissions since the enactment of the Tobacco Control Act, and submissions with the deficiencies identified in the rule have been repeatedly identified by FDA as reflecting submissions that are incomplete and not prepared for further review.

IV. Overview of the Final Rule

We are finalizing the proposed rule with only editorial changes. The rule adds part 1105 (21 CFR part 1105) to title 21, specifically § 1105.10. Section 1105.10 provides that FDA will refuse to accept, as soon as practicable, PMTAs, MRTPAs, SE applications, and exemption

requests (including subsequent abbreviated reports) for the reasons listed in paragraphs (a)(1) through (a)(10), if applicable.

V. Comments on the Proposed Rule

We consider any comments that were submitted on the direct final rule to have been submitted on the proposed rule. We received two sets of comments on the proposed rule, one from a tobacco product manufacturer and another from a public health group. In general, one of the commenters expressed strong support for this rule, asking that it be applied to a broader set of applications, while the other commenter identified concerns with the rulemaking, including that "promulgating a direct final rule was procedurally improper." This commenter suggested that FDA withdraw the rule in its entirety and issue any future rule only after engaging in notice and comment rulemaking. This rulemaking, however, did provide both notice and an opportunity for comments. As previously noted, FDA withdrew the direct final rule and is proceeding with the rulemaking under the procedural framework of the proposed rule. FDA has considered the comments submitted to the docket for the rulemaking and responds to the comments in the following paragraphs.

To make it easier to identify comments and our responses, the word "Comment," in parentheses, will appear before each comment, and the word "Response," in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with the comment. We have combined similar comments under one numbered comment.

(Comment 1) One commenter suggested that FDA apply the rule to provisional substantial equivalence applications submitted by manufacturers under section 910(a)(2)(B) of

the FD&C Act for new tobacco products that were first introduced or delivered for introduction into interstate commerce between February 15, 2007, and March 22, 2011.

(Response) FDA disagrees with this comment. We do not believe that this rule should be applied retroactively to refuse to accept submissions submitted before the rule is effective. While the refuse to accept criteria represent a minimum threshold that applications should be able to meet, we believe that applying this rule retroactively would be unfair to applicants because they had no notice that they would be subject to the rule's requirements.

(Comment 2) One commenter suggested that FDA apply this "commonsense regulation" to premarket submissions for newly deemed tobacco products submitted during the compliance period announced in the Deeming rule.

(Response) FDA notes that, as explained in the proposed rule, the rule once effective, will apply to premarket submissions for all tobacco products, including those that are for products covered by the Deeming rule.

(Comment 3) One commenter requested that FDA revise and expand the requirements of the rule to allow FDA to refuse to accept substantial equivalence applications that fail to comply with certain criteria that relate to the substantial equivalence pathway, such as creating product-identifying information requirements for predicate products.

(Response) FDA disagrees with this comment. The rule creates a minimum threshold of acceptability for all premarket submissions, regardless of the type of submission, and is not intended to address content specific to only one type of premarket submission. FDA plans to consider including refuse to accept criteria that are specific to a particular premarket pathway as part of future rulemakings. For example, FDA has already issued one such rule, "Tobacco

Products, Exemptions From Substantial Equivalence Requirements," which contains refuse to accept criteria relating specifically to exemption requests (July 5, 2011, 76 FR 38961).

(Comment 4) One commenter argued that FDA lacks the legal authority to implement the rule. The commenter stated that because the Tobacco Control Act does not set forth content requirements for substantial equivalence applications or exemption requests, FDA has no statutory justification for pre-review of those submissions. The commenter further stated that while the Tobacco Control Act does set forth content requirements for premarket tobacco product applications and modified risk tobacco product applications that grant FDA authority to conduct filing reviews of those submissions, FDA lacks the statutory authority to conduct a separate acceptance review as part of the pre-review of an application. In sum, the commenter argued that FDA does not have the statutory authority, either explicit or implicit, to refuse to accept tobacco product submissions.

(Response) FDA disagrees with this comment. As described in section III.B of the rule, section 701(a) grants FDA the authority to issue regulations for the efficient enforcement of the FD&C Act. As also discussed in the proposed rule, this rule will allow FDA to efficiently enforce the premarket review requirements of sections 905, 910, and 911 of the FD&C Act by allowing FDA to refuse to accept submissions that do not meet basic criteria and focus its resources on those submissions that are ready for review.

(Comment 5) One commenter argued that unless FDA establishes a time by which FDA will refuse to accept a premarket submission, the rule is legally problematic for a number of reasons. While two of the specific reasons are discussed in this document in separate comments and responses, overall, the commenter suggested that FDA should, similar to its approach for

new drug applications and premarket approval applications for medical devices, create a limit of 15 days in which to determine whether it will refuse to accept a premarket submission.

(Response) FDA declines the suggestion that FDA adopt a 15-day time limit similar to the refuse to accept review periods for refuse to accept notifications for 510(k) and premarket approval applications established by the Center for Devices and Radiological Health (CDRH). CDRH has had a significantly longer time reviewing such applications and has gained extensive experience doing so. CTP currently lacks sufficient experience reviewing tobacco product submissions to develop specific timeframes. Moreover, there is some uncertainty regarding the types and number of applications that manufacturers will choose to submit for products covered by the Deeming rule and regarding the precise timing of such submissions. Given the size of the industry and the number of newly deemed products on the market, FDA anticipates a large influx of applications, many of which could be at the end of the initial compliance periods for each premarket pathway. It is likely that many applicants will have no experience with the FDA premarket review process, so the quality of the submissions is likewise very difficult to predict. Due to this uncertainty and the difficulty predicting the level of resources FDA will have to expend as a result, FDA is not prepared at this time to commit to a single time limit for all submissions. Instead, FDA is providing an estimated timeframe in which it intends to determine whether to accept submissions: FDA intends to make the determination of whether it will accept an application for review based upon the requirements in the rule by 21 to 60 days of receipt. Further, we intend to establish performance goals or other timeframes once we gain sufficient experience.

(Comment 6) One commenter argues that the absence of a time limit in the rule poses a problem under the First Amendment. Specifically, the commenter alleges that FDA's premarket

review of tobacco product submissions, particularly with regard to MRTPAs, are prior restraints on speech; thus, the lack of a time limit for FDA to make acceptance determinations allows the Agency to delay the applicant's truthful and non-misleading speech indefinitely.

(Response) FDA disagrees with the commenter's assertion that the rule's provisions are problematic under the First Amendment. First, as the commenter acknowledges in a footnote, members of the tobacco industry challenged the MRTP provisions, including the absence of a time limit, on First Amendment grounds, and the Sixth Circuit rejected that challenge and upheld the MRTP provisions (Discount Tobacco v. United States, 674 F.3d 509, 537 (6th Cir. 2012)). Second, the premarket review process is not unique to FDA's regulation of tobacco and in fact is employed widely across most of FDA's product areas. The commenter singles out the MRTP review process as particularly problematic, but they misapprehend the structure of the provision, which imposes no direct restriction on speech. Rather, it requires premarket review before a product may be introduced into interstate commerce and defines such product in part by reference to its promotional claims. Courts have upheld FDA premarket reviews in other product areas based on a similar scheme. See, e.g., United States v. LeBeau, 2016 U.S. App. LEXIS 12375 (7th Cir. 2016); Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004); United States v. Cole, 84 F. Supp. 3d 1159, 1166 (D. Or. 2015). Third, there is a split in authority regarding whether the prior restraint doctrine applies to commercial speech; the Sixth Circuit in Discount Tobacco found that the doctrine did not apply to evaluation of the MRTP provisions (674 F.3d at 532-33). Fourth, even assuming that the marketing of a tobacco product is speech to which the prior restraint doctrine could possibly apply, the process established here would satify the requirements of that doctrine. First, prior restraints are not acceptable where they place "unbridled discretion in the hands of a government official or agency." (FW/PBS, Inc. v. Dallas,

493 U.S. 215, 225-226 (1990) (plurality opinion).) Here, however, the rule lays out 10 basic requirements for tobacco product applications which, if not met, will cause FDA to refuse to accept the submission. Further, when assessing whether a submission meets that minimum threshold of acceptability, FDA will look only to whether the submission is facially complete and it will not conduct a substantive review. Second, the prior restraint doctrine requires that decisions "must be issued within a reasonable period of time." (City of Littleton v. Z. J. Gifts D-4, L.L.C, 541 U.S. 774, 780 (2004).) For instance, in a case involving FDA premarket review of health claims for dietary supplements, the Second Circuit held that a 540-day period was permissible "given the need to protect consumers before any harm occurs," to "evaluate the evidence in support of labeling claims," and to develop "a record on the matter so that a court can determine whether the regulated speech is, in fact, truthful and non-misleading." (Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998).) Furthermore, as the district court in the Discount Tobacco case noted, the Administrative Procedure Act (APA) "imposes a general but nondiscretionary duty upon an administrative agency to pass upon a matter presented to it 'within a reasonable time,' 5 U.S.C. 555(b), and authorizes a reviewing court to 'compel agency action unlawfully withheld or unreasonably delayed,' 5 U.S.C. 706(1)." (Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 533 (W.D. Ky. 2010).) The APA requirement that the Agency act on matters before it "within a reasonable time," in conjunction with FDA's estimated timeframes and the performance goals for refuse to accept review that FDA intends to establish, indicate that FDA will not leave applications "in limbo," as claimed by the commenter, but will act on them in a reasonable amount of time. For all of these reasons, the rule's provisions do not constitute an unconstitutional prior restraint.

(Comment 7) One commenter argued that implementing the rule would allow FDA to deprive manufacturers of the valuable substantive right to market their products during the compliance period for deemed products with no hearing and no substantive review, which is contrary to Congress' intent in the Tobacco Control Act. The commenter further argued that the Tobacco Control Act allows FDA to require certain tobacco products to be taken off of the market only upon making a substantive determination that the action is warranted under statutory standards, and thus FDA cannot require that products be removed from the market without any such substantive review.

(Response) FDA disagrees with this comment. Under the FD&C Act, generally, a new tobacco product may not be introduced or delivered for introduction into interstate commerce unless it is subject to a marketing order under section 910(c)(1)(A)(i), FDA has issued an order finding the new tobacco product substantially equivalent to a predicate product, or FDA has issued an exemption from the requirements of substantial equivalence. The final Deeming rule, issued with notice and an opportunity for comment, extends this requirement to newly regulated products that are not grandfathered (i.e., marketed as of February 15, 2007). Thus, as of August 8, 2016, marketing these products without FDA authorization is prohibited by statute. However, FDA is affording staggered compliance periods during which FDA does not intend to enforce the premarket review requirements. These compliance periods are general statements of policy that do not establish any rights for any person, and are not binding on FDA or the public. (See e.g., Professionals and Patients for Customized Care v. Shalala, 56 F.3d 592 (5th Cir. 1995).) The commenter gives a vague reference to the rule depriving manufacturers of a "substantive right" to market with no hearing or substantive review, but without citing any authority for such a right.

Irrespective of the rule, a manufacturer does not have a right to market a product that is in violation of the FD&C Act because it does not have a required premarket authorization.

(Comment 8) One commenter stated that FDA should allow manufacturers to amend applications that FDA finds to be deficient and consider the amended applications to be received as of their original submission dates. The commenter explained that this approach would not tie up Agency resources because FDA could simply notify an applicant of any deficiencies and suspend substantive review until the applicant resolves those issues and, as such, there is no valid reason for requiring that applications be resubmitted rather than amended.

(Response) FDA disagrees with this suggestion. Creating a queue of deficient premarket submissions that FDA must track and manage is the type of inefficient process that FDA seeks to eliminate from the premarket submission review process with the rule. A queue for plainly deficient submissions will require a redirection of FDA resources away from more complete, quality submissions. Additionally, we disagree with the suggestion that we should consider amended submissions to have been received by the original submission date. This would allow manufacturers to submit woefully deficient premarket submissions and rely on FDA to identify deficiencies to be resolved.

(Comment 9) One commenter argued that FDA should withdraw the rule and instead issue rules specifying the content that must be contained in each type of application because without such application-specific rules, the rule is unconstitutionally vague. The commenter further explained that without the promulgation of such content regulations, it considers the rule to violate the Due Process Clause of the 5th Amendment as well as the APA because it would allow FDA to deny applications without fully explaining application content requirements to applicants. Additionally, the comment asserts that the rule is unduly vague under the Due

Process Clause and the APA on the basis that some of the criteria are either "ill-defined or entirely undefined."

(Response) FDA disagrees with this comment. The rule is not impermissibly vague as it provides applicants with fair notice of 10 criteria by which FDA will refuse to accept a premarket submission. These criteria are not specific to the requirements of any one premarket pathway but instead include basic parameters that apply to all premarket submissions. Detailed criteria that are specific to each premarket pathway are not necessary to implementing a rule that applies to all types of premarket submissions generally without any consideration of content specific to each premarket pathway. Any additional grounds for which FDA may refuse a premarket submission exist independently from this rulemaking; therefore, the vagueness of such grounds, if any, is not attributable to the rule and does not cause it to violate the Due Process clause of the 5th Amendment or the APA. Further, the comment incorrectly asserts that some of the criteria required by the rule are unduly vague under the Due Process Clause and the APA. A law is impermissibly vague if it does not give "a person of ordinary intelligence a reasonable opportunity to know what is prohibited." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972). To the extent that the commenter identifies concerns with specific requirements of the rule, we address them in the responses to comments 10-14; however, FDA believes that the requirements of this rule are sufficiently clear to give submitters a reasonable opportunity to be aware of what information must be included with a tobacco product application.

(Comment 10) One commenter argued that FDA must edit the rule so that it comprehensively states all potential refuse to accept criteria for each premarket pathway and commit to accepting all submissions that meet those specific criteria because granting FDA

discretion to refuse to accept submissions on the basis of criteria not specified in this rule violates the principles of fair notice embodied in the Constitution and the APA.

(Response) FDA disagrees. Under § 1105.10(b), FDA "may accept the submission" if it "finds that none of the reasons in paragraph (a) of this section exists for refusing to accept a premarket submission." The use of the word "may" in this section reflects the fact that this rule addresses the basic threshold of acceptability that all premarket submissions must meet; however it does not address other grounds on which FDA could refuse to accept a specific type of premarket submission, such as the omission of labeling from a PMTA that is required by section 910(b)(1)(F) of the FD&C Act. Any additional grounds on which FDA may refuse to accept a premarket submission exist independently from this rulemaking and are outside of its scope.

(Comment 11) One commenter argues that FDA's discussion in the preamble of the proposed rule regarding "other information" that FDA recommends be included as part of the product-identifying information submitted under § 1105.10(a)(7) should either be deleted or modified to provide a full and complete description of what "other information" applicants should provide. The commenter also suggests that FDA must state whether failure to provide such information would be grounds for FDA to refuse to accept a submission.

(Response) FDA disagrees with this comment. Section 1105.10(a)(7) specifically lists the product-identifying information that is required under the rule: The manufacturer of the tobacco product; the product name, including the brand and subbrand; the product category and subcategory; package type and package quantity; and characterizing flavor. The preamble of the proposed rule notes that other information may be needed to identify the product, such as product descriptors that are not a part of the product name (e.g., premium), but it merely requests such information be submitted to facilitate FDA's review. Failure to include additional product-

identifying information beyond those specifically listed in § 1105.10(a)(7) is not grounds for FDA to refuse to accept a submission under the rule.

(Comment 12) One commenter argued that FDA must either remove the requirement in § 1105.10(a)(7) that applicants specify the category and subcategory of the tobacco product or provide a list of all potential categories and subcategories. The commenter further noted that FDA could require a uniform system of product identification under 21 U.S.C. 387e(e) (section 905(e) of the FD&C Act), but it has not yet issued a regulation doing so.

(Response) FDA disagrees with this comment. The rule requires applicants to describe the category and subcategory of the tobacco product that is the subject of the premarket submission. This is a requirement to provide basic product-identifying information, such as describing the product category as "Smokeless Tobacco Product" and the subcategory as "Dissolvable," which in no way creates a rigid system of product identification with which an applicant must comply.[2] Creating an exhaustive product categorization system is not necessary for applicants to describe the product's category and subcategory and in some cases may not allow applicants to accurately describe new tobacco products that fall into novel categories or subcategories. Table 1 in the preamble of the proposed rule provides some recommendations on how an applicant may satisfy this requirement, but it is not intended to be an exhaustive list (for example, although recommendations for waterpipes were not included in table 1, submissions on waterpipes should include similar information). While the table is not an exhaustive list of every tobacco product category and subcategory that exists, manufacturers have enough information to reasonably understand how to comply with the requirement and can provide information based

[2] Applicants should note that some categories are defined in section 900 of the FD&C Act (e.g., cigarette (900(3)), cigarette tobacco (900(4)), roll-your-own tobacco (900(15)), smokeless tobacco (900(18))).

on internal classifications. Applicants unable to identify the category or subcategory of the tobacco product that will be the subject of a premarket submission are encouraged to contact FDA prior to submission.

(Comment 13) One commenter argued that FDA should not require an applicant to identify the submission type as part of a premarket submission because the list of submission types provided to implement § 1105.10(a)(8) is incomplete. To support this statement, the commenter notes that the list in the preamble of the proposed rule does not mention Product Quantity Change SE Reports as a potential premarket submission type.

(Response) FDA disagrees with the suggestion that manufacturers should not be required to identify the type of application they are submitting and that the list of submission types described in the preamble of the proposed rule is incomplete. Identifying the type of submission is necessary for FDA to review a premarket submission because it enables FDA to determine the appropriate decisional standard to apply to a submission (e.g., whether it is a PMTA subject to the requirements of section 910 of the FD&C Act or an MRTPA subject to the requirements of section 911 of the FD&C Act). The commenter is also incorrect in its assertion that the proposed rule's discussion of the types of premarket submissions is incomplete. The only example the commenter provides to support this assertion is the Product Quantity Change SE Reports, which are SE applications. The preamble of the proposed rule described the types of premarket submissions, which are PMTAs, MRTPAs, SE applications, and exemption requests (and subsequent abbreviated reports). Applicants are welcome to provide additional information regarding their submission type, such as specifying that their SE application is being submitted for a product quantity change, provided that the basic submission type remains clear. Applicants

unsure of how to identify the type of application that they are submitting are encouraged to contact FDA prior to submission.

(Comment 14) One commenter argued that FDA should remove the requirement that a premarket submission be accompanied by required forms because FDA has yet to require any forms and it is unclear what those forms may eventually require. The commenter stated that if and when FDA creates required forms, it can issue regulations providing how and when the forms must be submitted.

(Response) We disagree with the suggestion that this requirement should be removed from the rule. As described in section IV of the proposed rule, if and when FDA issues any forms it would need to do so in accordance with applicable requirements, e.g., notice and opportunity to comment on such forms in accordance with rulemaking procedures and the Paperwork Reduction Act of 1995 and rulemaking under the APA. We have chosen to include the form submission requirement in this rule to provide notice that the failure to submit any required forms, if and whenever they are issued, will be grounds for refusing to accept a premarket submission.

(Comment 15) One commenter argued that FDA should not require applicants to identify whether a product has a characterizing flavor until FDA has issued a full explanation of what it considers to be a characterizing flavor and how it expects manufacturers to determine what the characterizing flavor of a tobacco product is. The commenter also argued that the requirement to identify a characterizing flavor has no statutory basis and is not necessary to identify a product in light of all other information FDA is requiring, such as the product name, brand, subbrand, category, and subcategory.

(Response) FDA disagrees with this comment. This requirement, along with the other product-identifying information in § 1105.10(a)(7), will identify to FDA the specific tobacco product that is the intended subject of the application. As explained in the preamble to the proposed rule, FDA is requiring this product-identifying information under section 701 of the FD&C Act to efficiently enforce premarket review requirements for tobacco requirements. For example, FDA needs to be able to distinguish between products that have the same brand and subbrand, but different flavors (e.g., brand X menthol or brand X cinnamon). This also helps ensure that FDA ultimately issues an order that addresses the intended tobacco product. For the purposes of the refuse to accept process and to appropriately identify the specific product that is the subject of the submission, FDA is solely looking to see how the applicant identifies the tobacco product as having no characterizing flavor or having a particular characterizing flavor. Thus, for example, a firm would give "menthol" as the characterizing flavor a tobacco product it identifies as "Brand A menthol". At the acceptance stage, FDA would not review beyond how the product is identified, such as to determine whether the product contains a different or additional characterizing flavor. Applicants that have questions regarding how to describe their product's characterizing flavor are encouraged to contact FDA prior to submission.

(Comment 16) One commenter argued that FDA should either modify the rule so that it contains procedures to resolve disputes regarding whether FDA should have refused to accept an application, or it should specify whether the procedures for internal Agency review of decisions specified in § 10.75 (21 CFR 10.75) applies.

(Response) The procedures for internal Agency review of decisions in § 10.75 apply to a decision of an FDA employee, other than commissioner, on a matter. Applicants seeking review of a refuse to accept decision may use this mechanism or consider other mechanisms set out in

part 10. FDA expects, however, that most applicants will find that addressing any deficiencies in the application will quickly resolve issues.

VI. Paperwork Reduction Act of 1995

FDA concludes that this rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VIII. Tribal Consultation

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that would have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order; consequently, a tribal summary impact statement is not required.

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Economic Analysis of Impacts

We have examined the impacts of the rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule establishes a procedure that FDA is responsible for implementing and has the effect of providing all entities useful feedback on the readiness of a submission, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross

Domestic Product. This rule does not result in expenditure in any year that meets or exceeds this amount.

This rule identifies 10 significant and common deficiencies in premarket tobacco submissions that will cause FDA to refuse to accept them. Encouraging submissions that are free of the deficiencies listed in this rule does not represent a change in Agency expectations. One of the 10 deficiencies is required by statute (i.e., must be a tobacco product). One of the deficiencies is required by another regulation (i.e., must comply with requirements related to environmental assessments or exclusions from such assessments). The remaining eight deficiencies are basic expectations for an application to enter the review process. Therefore, this rule clarifies these expectations. This clarification will result in cost savings for both the applicant and FDA as less time is spent by FDA working with applicants to address these significant deficiencies. Applicants have clarity about basic expectations regarding requirements for acceptance of premarket applications. In addition, refusing to accept submissions with these deficiencies will allow Agency staff to more efficiently process submissions and quickly move those submissions without these deficiencies into review of substantial scientific issues.

List of Subjects in 21 CFR Part 1105

Administrative practices and procedures, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended by adding part 1105, consisting of § 1105.10, to read as follows:

PART 1105--GENERAL

Authority: 21 U.S.C. 371(a), 387e, 387j, and 387k.

Subpart A--General Submission Requirements

§ 1105.10 Refusal to accept a premarket submission.

(a) FDA will refuse to accept for review, as soon as practicable, a premarket tobacco product application, modified risk tobacco product application, substantial equivalence application, or exemption request or subsequent abbreviated report for the following reasons, if applicable:

(1) The submission does not pertain to a tobacco product as defined in 21 U.S.C. 321(rr).

(2) The submission is not in English or does not contain complete English translations of any information submitted within.

(3) If submitted in an electronic format, the submission is in a format that FDA cannot process, read, review, and archive.

(4) The submission does not contain contact information, including the applicant's name and address.

(5) The submission is from a foreign applicant and does not identify an authorized U.S. agent, including the agent's name and address, for the submission.

(6) The submission does not contain a required FDA form(s).

(7) The submission does not contain the following product-identifying information: The manufacturer of the tobacco product; the product name, including the brand and subbrand; the product category and subcategory; package type and package quantity; and characterizing flavor.

(8) The type of submission is not specified.

(9) The submission does not contain a signature of a responsible official, authorized to represent the applicant, who either resides in or has a place of business in the United States.

(10) For premarket tobacco applications, modified risk tobacco product applications, substantial equivalence applications, and exemption requests only: The submission does not include a valid claim of categorical exclusion in accordance with part 25 of this chapter, or an environmental assessment.

(b) If FDA finds that none of the reasons in paragraph (a) of this section exists for refusing to accept a premarket submission, FDA may accept the submission for processing and further review. FDA will send to the submitter an acknowledgement letter stating the submission has been accepted for processing and further review and will provide the premarket submission tracking number.

(c) If FDA finds that any of the reasons in paragraph (a) of this section exist for refusing to accept the submission, FDA will notify the submitter in writing of the reason(s) and that the submission has not been accepted, unless insufficient contact information was provided.

Dated: December 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31370 Filed: 12/28/2016 8:45 am; Publication Date: 12/29/2016]