Item descriptor *Note:* The description must match by model number or a broader descriptor that does not necessarily need to be company specific	Date of initial or subsequent BIS classification (ID = initial date; SD = subsequent date)	Date when the item will be designated EAR99, unless reclassified in another ECCN or the 0Y521 classification is reissued	Item-specific license exception eligibility
* * * * * * *			
0E521. Technology.			
No. 1 "Technology" required for the "development" or "production" of 0A521 No. 1 items.	August 8, 2016 (ID) ...	August 8, 2017	License Exception GOV under §740.11(b)(2)(ii) only.

Dated: July 25, 2016.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2016–18070 Filed 8–5–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2016–N–1170]

Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of September 16, 2016, for the final rule that appeared in the **Federal Register** of May 4, 2016. The direct final rule amends the general biological products standards relating to dating periods and removes certain standards relating to standard preparations and limits of potency. FDA is taking this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities without diminishing public health concerns. This action is part of FDA's retrospective review of its regulations in response to an Executive order. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the **Federal Register** of May 4, 2016 (81 FR 26687), confirmed: September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 4, 2016 (81 FR 26687), FDA solicited comments concerning the direct final rule for a 75-day period ending July 18, 2016. FDA stated that the effective date of the direct final rule would be on September 16, 2016, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the biological products provisions of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended. Accordingly, the amendments issued thereby are effective.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18584 Filed 8–5–16; 8:45 am]

BILLING CODE 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: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a 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 rule, FDA will be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions. FDA is issuing this action directly as a final rule because we believe there is little likelihood that we will receive any significant adverse comments opposing the rule given the specific deficiencies identified that will result in FDA's refusal to accept the submission.

DATES: This rule is effective December 21, 2016. Submit either electronic or written comments on this direct final rule by October 24, 2016. If we receive no significant adverse comments during the specified comment period, we intend to publish a confirmation document on or before the effective date by publication of a document in the **Federal Register**.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–1555 for ''Refuse to Accept Procedures for Premarket Tobacco Submissions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 under direct final rule procedures. The rule identifies 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 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. 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. Direct Final Rulemaking

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described the procedures on when and how the Agency will employ direct final rulemaking (this guidance document may be accessed at *http://www.fda.gov/regulatoryinformation/guidances/ucm125166.htm*). We have determined that this rule is appropriate for direct final rulemaking because we believe it is noncontroversial and we anticipate no significant adverse comments. Consistent with our procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule with the same codified language as this direct final rule to add a rule describing when FDA would refuse to accept submissions due to deficiencies. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn because of any significant adverse comments. The comment period for the

[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)). This direct final rule applies to all tobacco products FDA regulates under Chapter IX of the FD&C Act.

direct final rule runs concurrently with the companion proposed rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comments, we intend to withdraw this direct final rule action before its effective date by publication of a notification in the **Federal Register**. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice and comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment provides a reasonable explanation for why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not subject of a significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of this direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual notice and comment procedures. If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a confirmation document, before the effective date of the direct final rule, confirming the effective date.

III. Purpose and Legal Authority

A. Purpose

FDA is issuing this refuse to accept rule as a means of efficiently handling 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 the 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 will also result in FDA's refusal to accept that specific type of premarket submission (*e.g.,* a PMTA fails to contain specimens of the labeling proposed to be used for such tobacco product under section 910(b)(1)(F) of the FD&C Act).

FDA's refusal to accept a tobacco product submission will not preclude an applicant from resubmitting a new submission that addresses the deficiencies. In addition, acceptance of a submission will not mean that FDA has determined that the submission is complete, but rather only that the submission has met 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 MRTPAs), once filed. The rule establishes a general process for refusing to accept submissions for premarket tobacco product 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 expect the amount of time it takes FDA to make this determination to be relatively quick, however, it 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 after the deeming rule becomes effective. FDA expects the performance goals to be generally similar to other Agency performance goals, *i.e.* a certain percentage of RTA 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 authority to issue regulations for the efficient enforcement of the FD&C Act. This rule allows 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. Description of the Direct Final Rule

We are adding part 1105 (21 CFR part 1105) to title 21, specifically § 1105.10. Section 1105.10(a) 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 (10), if applicable:

- Section 1105.10(a)(1) states that FDA will refuse to accept a tobacco product submission that does not pertain to a tobacco product. This provision addresses a submission that refers to a product that does not meet the definition of a ''tobacco product'' under section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) and, therefore, is not subject to FDA's tobacco product authorities.
- Section 1105.10(a)(2) states that FDA will refuse to accept a submission that is not in the English language or does not contain complete English translations of any information included with the submission. FDA is unable to read and process such submissions.
- Section 1105.10(a)(3) provides that FDA will refuse to accept a submission if it is provided in an electronic format that FDA cannot process, read, review, and archive. As with submissions that are not in English (or fail to include an English translation), FDA is unable to read and process such submissions. FDA provides information on the electronic formats that it can read, process, review, and archive at *http://www.fda.gov/tobaccoproducts/*

guidancecompliance regulatoryinformation/manufacturing/default.htm.

• Section 1105.10(a)(4) provides that FDA will refuse to accept any submission that does not contain contact information, including the applicant's name and address. If a submission omits the contact information, FDA will not be able to contact the applicant regarding the submission, *e.g.,* with questions or followup related to the submission. In this instance, FDA also will likely be unable to provide notice of the Agency's refusal to accept the submission under § 1105.10(c).

• Section 1105.10(a)(5) provides that FDA will refuse to accept a submission from a foreign applicant if the submission does not list an authorized U.S. agent, including the agent's U.S. address. FDA is requiring identification of a U.S. agent for two reasons. First, a U.S. agent is important to help CTP ensure adequate notice is provided to applicants for official Agency communications. FDA may be unable to confirm that adequate notice of Agency action or correspondence concerning premarket submissions is provided to foreign applicants as FDA cannot necessarily confirm receipt of correspondence sent internationally. Accordingly, the designation of a U.S. agent provides an official contact to the Agency who can receive the information or documentation on behalf of the applicant. Providing notice regarding that application to the U.S. agent will constitute notice to the foreign applicant. Second, FDA requires identification of a U.S. agent to assist FDA in communication with the foreign applicant and help the Agency to efficiently process applications and avoid delays. In many instances during the application review process, FDA has reached out numerous times to foreign applicants and has either been unable to speak with the applicant or unable to directly communicate questions and/or concerns. This impediment, which occurs more for foreign applicants than domestic applicants, has resulted in delays or terminations in the review of specific applications and a slowdown of the premarket application process as a whole. A U.S. agent will act as a communications link between FDA and the applicant and will facilitate timely correspondence between FDA and foreign applicants, including responding to questions concerning pending applications and, if needed, assisting FDA in scheduling meetings with the foreign applicants to resolve outstanding issues before Agency action is taken. Additionally, the identified U.S. agent will be authorized to act on behalf of the foreign applicant for that specific application.

• Section 1105.10(a)(6) provides that FDA will refuse to accept the submission if it does not include any required FDA form(s). At the time of this direct final rule, FDA has not yet issued any forms to accompany premarket submissions. In the event that FDA does issue such a form(s), the Agency will give interested parties notice and opportunity to comment on such forms in accordance with rulemaking procedures and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

• Section 1105.10(a)(7) provides that FDA will refuse to accept a submission that does not contain the following product-identifying information (for the product that is the subject of the submission and, if applicable, for the predicate): The manufacturer of the tobacco product; the product name, including brand and subbrand; product category (*e.g.,* cigarette) and subcategory (*e.g.,* combusted, filtered); package type (*e.g.,* box) and package quantity (*e.g.,* 20 per box); and characterizing flavor (*i.e.,* applicants must state the characterizing flavor, such as menthol, or state that there is no characterizing flavor present in the tobacco product). For example, in table 1, FDA has supplied a list of recommended categories and subcategories of some tobacco products to assist applicants in providing product-identifying information in their submissions. Note that there may be other information FDA needs to identify a particular product, *e.g.,* descriptors (such as ''premium'') that are separate from the product name. If this is the case, such information should be provided by the applicant in the initial submission to facilitate FDA's efficient review.

TABLE 1—TOBACCO PRODUCT CATEGORIES AND SUBCATEGORIES

Tobacco product category	Tobacco product subcategory
Cigarettes	Combusted, Filtered.
	Combusted, Non-Filtered.
	Combusted, Other.
	Non-Combusted.
Roll-Your-Own Tobacco Products	Roll-Your-Own Tobacco Filler.
	Rolling Paper.
	Filtered Cigarette Tube.
	Non-Filtered Cigarette Tube.
	Filter.
	Paper Tip.
	Roll-Your-Own Co-Package.
	Other.
Smokeless Tobacco Products	Loose Moist Snuff.
	Portioned Moist Snuff.
	Loose Snus.
	Portioned Snus
	Loose Dry Snuff.
	Dissolvable.
	Loose Chewing Tobacco.
	Portioned Chewing Tobacco.
	Smokeless Co-Package.
	Other.
ENDS (Electronic Nicotine Delivery System)	Open E-Liquid.
	Closed E-Liquid.
	Closed E-Cigarette.
	Open E-Cigarette.
	ENDS Component.

TABLE 1—TOBACCO PRODUCT CATEGORIES AND SUBCATEGORIES—Continued

Tobacco product category	Tobacco product subcategory
	ENDS Co-Package.
	ENDS Other.
Cigars	Filtered, Sheet-Wrapped Cigar.
	Unfiltered, Sheet-Wrapped Cigar.
	Leaf-Wrapped Cigar.
	Cigar Component.
	Cigar Tobacco Filler.
	Cigar Co-Package.
	Other.
Pipe Tobacco Products	Pipe.
	Pipe Tobacco Filler.
	Pipe Component.
	Pipe Co-Package.
	Other.

This product-specific information helps ensure that the product is within CTP's purview and enables FDA to appropriately identify the specific product that is the subject of the submission. Specifically, this information is necessary to both review the submission itself and to issue an order that appropriately identifies the tobacco product that is subject to the order. For example, an SE submission contains a comparison between the predicate and new products. If FDA does not know the exact products that are being compared, FDA will be unable to sufficiently understand and evaluate the comparison to determine whether the products are substantially equivalent. As another example, if an applicant does not specify whether its proposed new product contains a characterizing flavor, FDA will not be able to issue an order as it will not know the specific product for which the applicant is seeking an order (*e.g.,* product X menthol or product X cinnamon.)

- Section 1105.10(a)(8) provides that FDA will refuse to accept a submission if the applicant fails to indicate the type of submission (*i.e.,* PMTA, MRTPA, SE application, or exemption request or subsequent abbreviated report), because that information is necessary to enable FDA to begin an appropriate review of the submission.
- Section 1105.10(a)(9) provides that FDA will refuse to accept a submission if it 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. A signature provides assurance to FDA that the submission is both intended by the applicant and ready for review. Responsible officials also should be aware that under 18 U.S.C. 1001, it is illegal to knowingly and willingly submit false information to the U.S. Government.
- Section 1105.10(a)(10) applies only to PMTAs, MRTPAs, SE applications, and exemption requests (this subsection does not apply to the subsequent abbreviated report). For these submissions, this paragraph provides that FDA will refuse to accept the submission if it does not include an environmental assessment (EA) or a valid claim of categorical exclusion. Under § 25.15(a) (21 CFR 25.15(a)), all submissions requesting FDA action require the submission of either a claim of categorical exclusion or an EA. Because an EA is required for an initial exemption request, it is not also required for an abbreviated report, and thus is not a basis for FDA to refuse to accept an abbreviated report. In addition, § 25.15(a) provides that FDA may refuse to file a submission if the included EA fails to address ''the relevant environmental issues.'' Because the SE and SE Exemption pathways do not include a filing stage, FDA intends to determine such adequacy at the acceptance stage for those pathways.[2] The EA or claim of categorical exclusion must be made for the Agency action being proposed (*e.g.,* issuance of an SE order for introduction of such new tobacco product into interstate commerce for commercial distribution in the United States.). For information on preparing an EA, refer to § 25.40.

Section 1105.10(b) provides that if FDA does not identify a reason under paragraph (a) for refusing to accept a submission, then the Agency may accept it for processing and further review. If FDA does accept the submission, the Agency intends to send the submitter an acknowledgement letter stating that FDA has accepted the submission for processing and further review. This letter will also include a premarket submission tracking number.

[2] The PMTA and MRTPA pathways, by contrast, have a filing stage.

Section 1105.10(c) provides that if FDA identifies a reason under paragraph (a) for refusing to accept a premarket review submission, we will notify the applicant in writing of the reason(s) and that FDA has not accepted the submission for processing and further review. However, FDA will be unable to provide this notification when the contact information is insufficient, for example, has not been provided or is not legible. If FDA refuses to accept the submission for one or more of the reasons stated in § 1105.10, the submitter may revise the submission to correct the deficiencies and resubmit it to FDA as a new submission.

V. Effective Date

This direct final rule will be effective 60 days after the comment period ends.

VI. Paperwork Reduction Act of 1995

FDA concludes that this direct final 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 direct final 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 direct final 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 direct final 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 final rule establishes a procedure that FDA is responsible for implementing and has the effect of providing entities with useful feedback on the readiness of a submission, we certify that the direct final 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 direct final rule would 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 environmental considerations). 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 will have clarity about basic expectations of the requirements needed for acceptance of premarket applications. In addition, refusing to accept submissions with these deficiencies allows 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 to subchapter K to read as follows:

PART 1105—GENERAL

Subpart A—General Submission Requirements

Sec.

1105.10 Refusal to accept a premarket tobacco product submission.

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

Subpart A—General Submission Requirements

§ 1105.10 Refusal to accept a premarket tobacco product 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 an environmental assessment, or a valid claim of categorical exclusion in accordance with part 25 of this chapter.

(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: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18534 Filed 8–5–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0747]

Drawbridge Operation Regulation; Umpqua River, Reedsport, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US 101 Bridge across the Umpqua River, mile 11.1, at Reedsport, OR. The deviation is necessary to accommodate updating the electric control panels on the bridge. This deviation allows the US 101 Bridge to remain in the closed-to-navigation position during upgrades.

DATES: This deviation is effective from 7 a.m. on August 16, 2016 until 5 p.m. on August 18, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0747] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Oregon Department of Transportation requested that the US 101 Bridge, near Reedsport, Oregon, remain in the closed-to-navigation position to update the electric control panels. The US 101 Bridge crosses the Umpqua River at mile 11.1 and provides 36 feet of vertical clearance above mean high water when in the closed-to-navigation position. This deviation allows the US 101 Bridge to remain in the closed-to-navigation position and need not open for maritime traffic from 7 a.m. on August 16, 2016 until 5 p.m. August 18, 2016. The normal operating schedule of this bridge is detailed at 33 CFR 117.893(a).

Waterway usage on this part of the Umpqua River includes vessels ranging from occasional commercial tug and barge to small pleasure craft. ODOT has coordinated with local mariners in this regard, and no objections have been received. No immediate alternate route is available for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation. Vessels which do not require an opening of the bridge may continue to transit beneath the bridge during this repair period.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 29, 2016.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2016–18709 Filed 8–5–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0670]

RIN 165–AA00

Safety Zones; Marine Events Held in the Sector Long Island Sound Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing nine temporary safety zones for fireworks displays within the Coast Guard Sector Long Island Sound (LIS) Captain of the Port (COTP) Zone. This temporary final rule is necessary to provide for the safety of life on navigable waters during these events. Entry into, transit through, mooring or anchoring within these regulated areas is prohibited unless authorized by COTP Sector Long Island Sound.

DATES: This rule is effective without actual notice from August 8, 2016 through September 03, 2016. For the purposes of enforcement, actual notice will be used July 30, 2016, through August 8, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0670 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Petty Officer Jay TerVeen, Prevention Department, Coast Guard Sector Long Island Sound, telephone (203) 468–4446, email *Jay.C.TerVeen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
LIS Long Island Sound
NPRM Notice of Proposed Rulemaking
NAD 83 North American Datum 1983

II. Background Information and Regulatory History

This rulemaking establishes 9 safety zones for fireworks displays. Each event and its corresponding regulatory history are discussed below.

The Hoffman Wedding Fireworks Display is a first time marine event with no regulatory history.

The Pyro Engineering Inc. Fireworks Display is a first time marine event with no regulatory history.

The Sag Harbor Fire Department Fireworks Display is a recurring marine event with regulatory history. A safety zone was established for this event in 2015 via a temporary final rule entitled, ''Safety Zones; Marine Events held in the Sector Long Island Sound Captain of the Port Zone.'' This rulemaking was published on Friday, August 14, 2015 in the **Federal Register** (80 FR 48692).

The Montalbano Wedding Fireworks Display is a first time marine event with no regulatory history.

The Village of Saltaire Fireworks Display is a recurring marine event with regulatory history. A safety zone was established for this event in 2015 via a temporary final rule entitled, ''Special Local Regulations and Safety Zones; Marine Events held in the Sector Long Island Sound Captain of the Port Zone.'' This rulemaking was published on Monday, May 18, 2015 in the **Federal Register** (80 FR 28176).

The Baker Annual Summer Celebration is a first time marine event with no regulatory history.

The Gestal Wedding Fireworks Display is a first time marine event with no regulatory history.

The Clinton Chamber of Commerce Fireworks Display is a recurring marine event with regulatory history. A safety zone was established for this event in 2015 via a temporary final rule entitled, ''Safety Zones; Marine Events held in the Sector Long Island Sound Captain of