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 FDA is taking this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities without diminishing public health concerns.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.


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.

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 refusal 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) (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (21 U.S.C. 387e, 387f, and 387k). 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 refusal 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 rulemaking is withdrawn because of any significant adverse comments. The comment period for the
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 refusal to accept submissions for premarket tobacco product review, including 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>
<thead>
<tr>
<th>Tobacco product category</th>
<th>Tobacco product subcategory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes</td>
<td>Combusted, Filtered.</td>
</tr>
<tr>
<td></td>
<td>Combusted, Non-Filtered.</td>
</tr>
<tr>
<td></td>
<td>Combusted, Other.</td>
</tr>
<tr>
<td></td>
<td>Non-Combusted.</td>
</tr>
<tr>
<td>Roll-Your-Own Tobacco Products</td>
<td>Roll-Your-Own Tobacco Filler.</td>
</tr>
<tr>
<td></td>
<td>Rolling Paper.</td>
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<tr>
<td></td>
<td>Filtered Cigarette Tube.</td>
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<td></td>
<td>Non-Filtered Cigarette Tube.</td>
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<td></td>
<td>Filter.</td>
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<td></td>
<td>Paper Tip.</td>
</tr>
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<td></td>
<td>Roll-Your-Own Co-Package.</td>
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<tr>
<td></td>
<td>Other.</td>
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<tr>
<td>Smokeless Tobacco Products</td>
<td>Loose Moist Snuff.</td>
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<td></td>
<td>Portioned Moist Snuff.</td>
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<td></td>
<td>Loose Snus.</td>
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<tr>
<td></td>
<td>Portioned Snus.</td>
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<td></td>
<td>Loose Dry Snuff.</td>
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<tr>
<td></td>
<td>Dissolvable.</td>
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<tr>
<td></td>
<td>Loose Chewing Tobacco.</td>
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<td></td>
<td>Portioned Chewing Tobacco.</td>
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<td></td>
<td>Smokeless Co-Package.</td>
</tr>
<tr>
<td></td>
<td>Other.</td>
</tr>
<tr>
<td>ENDS (Electronic Nicotine Delivery System)</td>
<td>Open E-Liquid.</td>
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<tr>
<td></td>
<td>Closed E-Liquid.</td>
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<tr>
<td></td>
<td>Closed E-Cigarette.</td>
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<tr>
<td></td>
<td>Open E-Cigarette.</td>
</tr>
<tr>
<td></td>
<td>ENDS Component.</td>
</tr>
</tbody>
</table>
This product-specific informationbreak 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.

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, 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(b) 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 required by statute (i.e., must be a tobacco product). One of the deficiencies is required by 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, 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.
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117
[Docket No. USCG–2016–0747]

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.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>COTP</td>
<td>Captain of the Port</td>
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<td>DHS</td>
<td>Department of Homeland Security</td>
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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 Governor’s 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