under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2014–02–01, Amendment 39–17729 (79 FR 7382, February 7, 2014), and adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2017–1246; Product Identifier 2017–NM–086–AD.

(a) Comments Due Date

We must receive comments by March 2, 2018.

(b) Affected ADs

This AD replaces AD 2014–02–01, Amendment 39–17729 (79 FR 7382, February 7, 2014) (''AD 2014–02–01'').

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial number 10002 through 10344 inclusive.

(2) Bombardier, Inc., Model CL–600–2D15 (Regional Jet Series 705) airplanes and Model CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15397 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by reports that when installing the rudder travel limiter (RTL) return springs, the RTL limiter arm assembly lug can become deformed. We are issuing this AD to prevent deformed RTL limiter arm assembly lugs, which can lead to failure of the limiter arm assembly lug. In combination with failure of the RTL, failure of the limiter arm assembly lug could result in reduced controllability of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections, Modification, and Replacement

(1) For airplanes equipped with RTL return spring part number BA–670–93465–1 or E0650–069–02750S: Within 800 flight hours or 4 months after the effective date of this AD, whichever occurs first, do a detailed visual inspection of the casing of the primary actuator for signs of chafing or missing paint, and all applicable corrective actions; replace the RTL return springs; and do an eddy current inspection of the lugs of the RTL limiter arm assembly for cracks, and modify or replace the RTL limiter arm assembly, as applicable; in accordance with Part A of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–070, Revision B, dated March 31, 2017. Accomplishment of the actions specified in Bombardier Service Bulletin 670BA–27–059 does not meet the requirements of this paragraph.

(2) For airplanes equipped with RTL return spring part number BA–670–93468–1: Within 8,000 flight hours after the effective date of this AD, do a detailed visual inspection of the RTL return springs for signs of chafing, and applicable corrective actions; a detailed visual inspection of the casing of the primary actuator for signs of chafing or missing paint, and all applicable corrective actions; and do an eddy current inspection of the lugs of the RTL limiter arm assembly for cracks, and modify or replace the RTL limiter arm assembly, as applicable; in accordance with Part B of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–070, Revision B, dated March 31, 2017. Accomplishment of the actions specified in Bombardier Service Bulletin 670BA–27–059 does not meet the requirements of this paragraph.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (h)(1) or (h)(2) of this AD.

(1) Bombardier Service Bulletin 670BA–27–070, dated December 17, 2015.

(2) Bombardier Service Bulletin 670BA–27–070, Revision A, dated September 01, 2016.

(i) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2017–19, dated June 6, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1246.

(2) For more information about this AD, contact Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7318; fax: 516–794–5531.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone: 1–866–538–1247 or direct-dial telephone: 1–514–855–2999; fax: 514–855–7401; email: *ac.yul@aero.bombardier.com*; internet: *http://www.bombardier.com*. You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on December 28, 2017.

John P. Piccola, Jr.,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–00340 Filed 1–12–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801, and 1100

[Docket No. FDA–2015–N–2002]

RIN 0910–AH94

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ''Intended Uses''; Proposed Partial Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; partial delay of effective date.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to delay the effective date of certain portions of a final rule published in the **Federal Register** of January 9, 2017. In the **Federal Register** of February 7, 2017, we delayed until March 21, 2017, the effective date of the final rule. In the **Federal Register** of March 20, 2017, we further delayed the effective date of the final rule until March 19, 2018, and invited public comment on the rule. This action, if finalized, will delay until further notice the effective date of the portions of the final rule amending FDA's existing regulations describing the types of evidence that may be considered in determining a medical product's intended uses. FDA received a number of comments on the final rule that raise questions about the amendments to the existing medical product ''intended use'' regulations. FDA is proposing to delay the effective date of the amendments to the existing medical product ''intended use'' regulations to allow further consideration of the substantive issues raised in the comments received. This action, if finalized, will not further delay the effective date of the new regulation that describes the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on this proposed rule by February 5, 2018.

ADDRESSES: You may submit comments on the proposed rule for partial delay as follows. Electronic comments must be submitted on or before February 5, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 5, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. Please note that late, untimely filed comments will not be considered.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2015–N–2002 for ''Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses'; Proposed Partial Delay of Effective Date.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kelley Nduom, Center for Drug Evaluation and Research, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993, 301–796–8597, *kelley.nduom@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 9, 2017 (82 FR 2193), FDA published a final rule entitled ''Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses.' '' The final rule added a new regulation (§ 1100.5) to title 21 of the CFR to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The rule also amended FDA's existing regulations describing the types of evidence that may be considered in determining a medical product's intended uses (21 CFR 201.128 (drugs) and 21 CFR 801.4 (devices)).

In the **Federal Register** of February 7, 2017 (82 FR 9501), in accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' we delayed, until March 21, 2017, the effective date of the final rule. In the **Federal Register** of March 20, 2017 (82 FR 14319), we further delayed the effective date of the final rule until March 19, 2018, and reopened the docket to invite additional public comment on the rule.

The comments we received are summarized below. To allow further consideration of the substantive issues raised in these comments, FDA is proposing to delay the effective date of the amendments to the existing medical product ''intended use'' regulations (§§ 201.128 and 801.4) contained in the final rule of January 9, 2017, until further notice. See 21 CFR 10.35(a) and (b) (stating that FDA ''may at any time stay or extend the effective date of an action pending or following a decision on any matter'' and recognizing that the stay may be ''for an indefinite time period''). The Agency must solicit public comment on this proposed delay, consider the comments submitted, and prepare and publish a final notification of the delay before March 19, 2018, when the final rule is scheduled to take effect. In light of this limited timeframe, it is impracticable to provide 60 days for comment on this proposed delay. Thus, the Commissioner of Food and Drugs finds good cause under 21 CFR 10.40(b)(2) for providing a shortened comment period, ending February 5, 2018. In light of the date on which the current delay of the effective date will expire unless further extended, no extensions on the comment period will be granted.

II. Summary of Comments Received in the Reopened Docket of the Final Rule

Fifteen comments were submitted to the docket for the January 9, 2017 final rule after the docket was reopened on March 20, 2017. These comments were submitted by the drug and device industries, various associations, academia, and individual submitters including a health professional and a consumer. A brief summary of these comments is included below.[1]

Two of the comments submitted to the docket related to the new regulation included in the final rule that describes circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the FD&C Act (§ 1100.5). One comment criticized the modified risk tobacco product provisions of the FD&C Act. The other comment supported the new regulation and criticized the delay in its issuance. Neither comment sought a delay in the effective date of that new regulation.

Thirteen of the 15 comments submitted to the docket related to the amendments to FDA's existing regulations describing the types of evidence that may be considered in determining a medical product's intended use (§§ 201.128 and 801.4). Many of these comments opposed what they described as a broadening from the September 25, 2015, proposed rule (see 80 FR 57756 at 57764 to 57765) of the types of evidence that could be considered in determining intended use, and specifically raised concerns with the ''totality of the evidence'' language included in the final rule. Several of these comments urged a narrowing of the types of evidence that could be considered in determining intended use. Some comments stated that only promotional or external claims should be included in the consideration of intended use, while other comments asserted that scientific exchange, truthful non-misleading communications, and/or mere knowledge of unapproved use should be expressly excluded from consideration. In contrast, a few comments stated that the types of evidence included in the final rule were appropriate at least for certain subsets of medical products, such as wholly unapproved medical products and non-prescription devices.

Several comments raised legal concerns with the final rule, including arguments to the effect that the rule: (1) Violates the First Amendment by regulating truthful speech regarding lawful activity; (2) violates the due process clause of the Fifth Amendment to the extent that the types of evidence to be considered are not clearly defined; (3) unlawfully interferes with the practice of medicine; and (4) departs from relevant statutory text, legislative history, case law, and FDA past practices. Several comments asserted that the January 9, 2017, final rule was issued in violation of the notice requirement under the Administrative Procedure Act (APA) based on the inclusion of the ''totality of the evidence'' language in that final rule.

In addition to these legal concerns, several comments asserted that the final rule could have potentially negative public health implications, including impeding important communications between manufacturers and patients, healthcare professionals, and payors; reducing healthcare options for patients; and harming patient outcomes. In contrast, another comment asserted that narrowing the scope of evidence of intended use could jeopardize the Agency's ability to take enforcement actions against illicit substances, counterfeit products, and synthetic drugs, among other products.

Based on some of the above concerns, several comments urged FDA to stay indefinitely or revoke the final rule. Other comments recommended that FDA adopt the ''intended use'' language proposed in the September 25, 2015, proposed rule, or engage in a new rulemaking.

III. Scope of and Rationale for the Proposed Partial Delay of the Effective Date of the Final Rule

We are proposing to delay the effective date of the portions of the final rule amending the existing medical product ''intended use'' regulations (§§ 201.128 and 801.4) until further notice, to allow for additional consideration of the issues raised in the comments described above. This action should not be construed to indicate that FDA has made any decisions about either the substantive arguments made in these comments or the issues discussed in previous **Federal Register** notifications regarding the amendments to these ''intended use'' regulations.

When the Agency proposed amendments to the existing intended use regulations in 2015, the objective was not to reflect a change in FDA's approach regarding evidence of intended use for drugs and devices. These proposed amendments were intended to better reflect FDA's existing interpretation and application of these regulations (see 80 FR 57756 at 57761). Specifically, the amendments were intended to clarify that FDA would not regard a firm as intending an unapproved new use for an approved or cleared drug or device based solely on that firm's knowledge that its product was being prescribed or used by doctors for such use (see 80 FR 57756 at 57761). FDA proposed to delete the last sentence of the intended use regulations to provide this clarification, in addition to some other changes.

In the **Federal Register** of January 9, 2017, we published final regulations adding new § 1100.5 to title 21 of the CFR and amending the intended use regulations found at §§ 201.128 and 801.4. The provisions in the final rule amending the intended use regulations were modified from the proposed rule because of comments we received that

[1] This summary is not intended to be a comprehensive discussion of the comments nor should it be construed to suggest that FDA has made any decisions about the substantive issues raised in the comments.

suggested to us that the proposed changes might not provide adequate clarity to manufacturers (see 82 FR 2193 at 2207). Significant comments were submitted on the proposed rule that indicated misunderstanding of the very limited scope of what FDA intended by the proposed changes to the intended use provisions.

In response to the new language in the final rule, a petition raising concerns with the final language was submitted by various industry organizations on February 8, 2017 (''petition'' and ''petitioners''). The petition requests that FDA reconsider the amendments to the ''intended use'' regulations and issue a new final rule that, with respect to the intended use regulations at §§ 201.128 and 801.4, reverts to the language of the September 25, 2015, proposed rule. The petition also requests that FDA indefinitely stay the rule. Petitioners ask that the final rule be stayed indefinitely and reconsidered for two independent reasons (petition at pg. 10). First, they argue that the final rule was issued in violation of the fair notice requirement under the Administrative Procedure Act (APA) (petition at pgs. 10–13). Second, they argue that the ''totality of the evidence'' language in the final rule is a new and unsupported legal standard (petition at pgs. 10, 13–21). The petitioners contend that the final rule unexpectedly expanded the understanding of intended use, and that adding the new final sentence referencing the ''totality of the evidence'' was a reversal of the proposed rule that violates the APA's notice-and-comment provisions (petition at pg. 11). Petitioners express the view that the wording used in the proposed rule would have helped to address substantial concerns they have regarding FDA's intended use definitions, while the final rule exacerbates those concerns (petition at pg. 11). These concerns include constitutional concerns (petition at pg. 19–21), and public health concerns related to chilling valuable scientific speech (petition at pg. 21). Based in part on the questions raised by the petition, we further delayed the effective date of the final rule until March 19, 2018, and reopened the docket to invite additional public comment on the rule.

The issues raised by the petition, as well as the comments we have received on the 2015 proposed rule, the January 2017 delay of the effective date, and the March 2017 delay of the effective date (discussed above in section II) underscore for FDA the potential for confusion related to the language in the final rule. ''Intended use'' is fundamental to medical product jurisdiction under the FD&C Act (21 U.S.C. 321(g) (definition of ''drug'') and 21 U.S.C. 321(h) (definition of ''device'')). Lack of clarity regarding the text of the final rule might affect FDA's medical product jurisdiction in ways that FDA did not intend when it set out to clarify one point regarding ''intended use.'' Although FDA remains committed to the goal of the intended use rulemaking because it reflects current agency policy, FDA has tentatively concluded, for the reasons set forth above, that the Agency needs additional time for further consideration. FDA continues to work diligently on the issues relating to intended use raised in the underlying rulemaking and remains committed to rulemaking on this issue.

FDA does not propose to further delay the effective date of the portions of the final rule that issued a new regulation that describes the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product (§ 1100.5). As noted, the Agency did not receive any comments requesting that we further delay the effective date of § 1100.5 or that we make any changes to that regulation. The effective date of § 1100.5 remains March 19, 2018.

IV. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. Moreover, this proposed rule is an action that does not impose more than de minimis costs and, consequently, is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we expect the proposed rule to impose negligible costs, if any, we propose to 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 $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in expenditure in any year that meets or exceeds this amount.

In table 1, we provide the Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated Information Center accounting information.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized				2016	7	10	
Monetized $millions/year				2016	3	10	
Annualized				2016	7	10	

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Quantified				2016	3	10	
Qualitative	None						
Costs:							
Annualized				2016	7	10	
Monetized $millions/year				2016	3	10	
Annualized				2016	7	10	
Quantified				2016	3	10	
Qualitative	Negligible costs, if any.						
Transfers:							
Federal				2016	7	10	
Annualized				2016	3	10	
Monetized $/year	From:			To:			
Other				2016	3	10	
Annualized				2016	3	10	
Monetized $/year	From:			To:			

Effects:
State, Local or Tribal Government: None
Small Business: None
Wages: None
Growth: None

On January 9, 2017, we published the final rule ''Clarification of When Products Made or Derived from Tobacco are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses'.'' We refer to this final rule as the Clarifications Final Rule in this section of the preamble. The Clarifications Final Rule included changes to the ''intended uses'' provisions for medical products. In the **Federal Register** of March 20, 2017, we further delayed the effective date of the final rule—we extended the effective date of the Clarifications Final Rule to March 19, 2018 and reopened the docket to invite public comments on the medical products ''intended uses'' provisions. Comments submitted to the docket revealed a number of stakeholders had questions and concerns about possible implications of our revised ''intended uses'' provisions for medical products. Thus, the proposed rule would delay until further notice the changes to the ''intended uses'' provisions in the Clarifications Final Rule, and give all stakeholders and FDA sufficient time to consider the substantive issues raised by the comments to the docket.

When we conducted our economic analysis of the final rule that published on January 9, 2017, we expected that the benefits and costs of the rule for drug sponsors and for device manufacturers would be negligible, if any, because we anticipated that the final rule would leave the existing policies for these industries unchanged. As discussed in section II, we revised the intended use provisions for medical products in the final rule to clarify our position that the intended use of a medical products can be based on any relevant source of evidence, including a variety of direct and circumstantial evidence. Thus, we expected that the final rule would maintain the status quo and not impact current business practices.

Comments submitted to the reopened docket for the January 9, 2017, final rule indicate that at least some of the medical products industries believe that the final rule would change current practices and impose new burdens not captured in our final regulatory impact analysis. By delaying the final rule's intended use provisions for medical products, this proposed rule would maintain the status quo for medical products.

We judge that the proposed rule, if finalized, would thus avoid any potential unintended burden caused by the final rule. Moreover, drug sponsors and medical device manufacturers would likely learn about the proposed rule through industry news sources and not incur one-time costs to learn about the rule. We request comment on our assumptions.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.20(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.

VI. Paperwork Reduction Act of 1995

FDA has determined that this proposed rule contains no collection of information as defined by 5 CFR 1320.3(c). 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 proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed 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. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

IX. Other Issues for Consideration

This proposed rule would only delay the effective date of the portions of a final rule amending the ''intended use'' regulations for medical products (§§ 201.128 and 801.4), published in the **Federal Register** of January 9, 2017. Therefore, comments to this proposed rule should pertain to this delay of the effective date only with respect to such provisions.

X. Request for Comments

FDA is proposing to delay, until further notice, the effective date of the amendments to §§ 201.128 and 801.4 that were published at 82 FR 2193 on January 9, 2017. FDA had previously delayed the effective date on February 7, 2017 (82 FR 9501), and on March 20, 2017 (82 FR 14319). FDA requests comment on this proposal to further delay the effective date of the amendments to §§ 201.128 and 801.4.

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00555 Filed 1–12–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2017–0697; FRL–9972–98–Region 1]

Air Plan Approval; Connecticut; Revision of the Low Emission Vehicles Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Connecticut on December 14, 2015. This SIP revision includes Connecticut's revised regulation for new motor vehicle emission standards. Connecticut has updated its rule to be consistent with various updates made to California's low emission vehicle (LEV) program. The Connecticut LEV regulations also include updates to the zero emission vehicle (ZEV) provision. Connecticut has adopted these revisions to reduce emissions of volatile organic compounds (VOC), particulate matter (PM), and nitrogen oxides (NO_X) in accordance with the requirements of the Clean Air Act (CAA), as well as to reduce greenhouse gases. The intended effect of this action is to propose approval of Connecticut's December 14, 2015 SIP revision. This action is being taken under the CAA.

DATES: Written comments must be received on or before February 15, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2017–0697 at *www.regulations.gov,* or via email to *rackauskas.eric@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Eric Rackauskas, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05–2), Boston, MA 02109–3912, telephone number (617) 918–1628, fax number (617) 918–0628, email *rackauskas.eric@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Background and Purpose

On December 14, 2015, the Connecticut Department of Energy and Environmental Protection (DEEP) submitted a revision to its SIP consisting of the amended Section 22a–174–36b ''Low Emission Vehicle II Program'' (LEV II) and the newly adopted Section 22a–174–36c ''Low Emission Vehicle III Program'' (LEV III) of the Regulations of Connecticut State Agencies (RCSA). This SIP revision proposes to adopt regulations to mirror the California Air Resources Board (CARB) emission limits for new passenger cars, light-duty trucks, and medium-duty passenger vehicles sold, leased, imported, delivered, purchased, rented, acquired, or received in the State of Connecticut. Connecticut's amended LEV II and adopted LEV III programs were submitted as part of an overall revision to their ''infrastructure SIP'' for the 2012 Fine Particle ($PM_{2.5}$) National