of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for website viewing and printing; the address for the Filer Manual is *https://www.sec.gov/info/edgar/edmanuals.htm.* You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

## PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 3. The authority citation for part 274 continues to read in part as follows:

**Authority:** 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l,* 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, 80a–29, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

■ 4. Form ID (referenced in §§ 239.63, 249.446, 269.7 and 274.402 of this chapter) is amended to add in ''PART I—APPLICATION FOR ACCESS CODES TO FILE ON EDGAR'' the following text and checkbox ''Access codes will be used to submit draft registration or draft offering statement. □''

**Note:** The text of Form ID does not, and the amendment will not, appear in the Code of Federal Regulations.

By the Commission.

Dated: March 8, 2018.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2018–05238 Filed 3–15–18; 8:45 am]

**BILLING CODE 8011–01–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''; Partial Delay of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; partial delay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is issuing this final rule to delay the effective date of amendments to the existing medical product ''intended use'' regulations, contained in the final rule published January 9, 2017, until further notice. This final rule delays the effective date of the amendments to allow further consideration of the substantive issues raised in the comments received regarding the amendments. This action does not delay the effective date of the portions of the January 9, 2017, final rule that 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), which remains March 19, 2018.

**DATES:** Effective March 16, 2018, the amendments made to §§ 201.128 and 801.4, revised at 82 FR 2193 (January 9, 2017), delayed at 82 FR 9501 (February 7, 2017) until March 21, 2017, and further delayed at 82 FR 14319 (March 20, 2017) until March 19, 2018, are delayed indefinitely. Section 1100.5, added at 82 FR 2193 (January 9, 2017), delayed at 82 FR 9501 (February 7, 2017) until March 21, 2017, and further delayed at 82 FR 14319 (March 20, 2017) until March 19, 2018, is effective March 19, 2018.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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''' (January 2017 final rule). The final rule added a new regulation (§ 1100.5 (21 CFR 1100.5)) to title 21 of the Code of Federal Regulations (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 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 (§§ 201.128 and 801.4 (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.

On February 8, 2017, various industry organizations filed a petition raising concerns with the January 2017 final rule, requesting reconsideration and a stay pursuant to 21 CFR 10.33(b) and 10.35(b) (see FDA–2015–N–2002–1977). 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 because petitioners argue that (1) the final rule was issued in violation of the fair notice requirement under the Administrative Procedure Act (APA) (petition at pp. 10–13) and (2) the ''totality of the evidence'' language in the final rule is

a new and unsupported legal standard (petition at pp. 10, 13–21).[1]

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. Fifteen comments were submitted to the docket in response. 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). Neither comment requested a delay in the effective date of that new regulation. The remainder of the comments 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.[2]

To allow for further consideration of the substantive issues raised in these comments, in the **Federal Register** of January 16, 2018 (83 FR 2092) (January 2018 proposed rule), we proposed to delay the effective date of the amendments to the existing medical product ''intended use'' regulations contained in the January 2017 final rule, until further notice (§§ 201.128 and 801.4). We did not propose to delay the effective date of the portions of the final rule that issued a new regulation regarding products made or derived from tobacco that are intended for human consumption (§ 1100.5). The Agency received 19 comments to the docket on the proposed delay, which are summarized below.

[1] For a more comprehensive discussion of the arguments raised in the petition, please see the March 2017 final rule (82 FR 14319 at 14320 to 14321) and the January 2018 proposed rule (83 FR 2092 at 2095). Consistent with this rule, FDA is granting in part the petition. Specifically, we are granting petitioners' request for an indefinite stay of the effective date of the amendments to the intended use regulations (see FDA–2015–N–2002).

[2] For a more comprehensive discussion of the comments submitted to the reopened docket, please see the January 2018 proposed rule (83 FR 2092 at 2095).

## II. Comments on the Proposed Rule and FDA Responses

### *A. Introduction*

We received 19 comments on the proposed delay from drug and device industries, various associations and organizations, academia, and individual submitters, including a health professional and consumers. We describe and respond to the comments in sections II.B through II.D of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

### *B. Description of Comments in Support of the Delay and FDA Response*

The majority of comments supported the proposed delay and included specific proposals and recommendations for how FDA should address issues related to intended use, and amendments to §§ 201.128 and 801.4, going forward. In the following paragraphs, we discuss and respond to such comments.

(Comment 1) Many of the comments expressed support for the delay based on legal concerns with the January 2017 final rule. Among these legal concerns were arguments that the final 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; (4) departs from relevant statutory text, legislative history, case law, and FDA past practices, and/or (5) was issued in violation of the notice requirement under the APA based on the inclusion of the ''totality of the evidence'' language in that final rule. Many of these arguments were based, at least in part, on what commenters 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 January 2017 final rule.

(Response) We agree that it is appropriate to delay the effective date of the final rule and we will consider the legal concerns raised regarding the January 2017 final rule as we continue to work diligently on the issues relating to intended use raised in the underlying rulemaking.

(Comment 2) Several of the comments supporting the delay also included specific proposals and recommendations for how FDA should address issues related to intended use, and specifically amendments to §§ 201.128 and 801.4, going forward. For example, these comments stated that FDA should:

a. Adopt the approach set forth in the September 2015 proposed rule preamble and codified—including deletion of the ''knowledge'' sentences in §§ 201.128 and 801.4—and ensure that all guidance and policy documents are aligned with that approach;

b. Withdraw the January 2017 final rule and the ''totality of the circumstances'' test included in that rule;

c. Revise §§ 201.128 and 801.4 to make them ''more consistent with applicable law''; and/or

d. Clarify that certain types of evidence, such as the following, do *not* constitute evidence of intended use: (i) Scientific exchange, (ii) truthful, non-misleading communications, and/or (iii) mere knowledge of unapproved use by third parties, including when in combination with non-promotional communication.

(Response) The wide-ranging proposals and recommendations for how FDA should address issues related to intended use and §§ 201.128 and 801.4 in these and other comments underscore the complexities of the issues involved. We believe these comments provide additional support for the delay of the effective date of amendments to the existing medical product ''intended use'' regulations. The Agency needs more time to consider the feedback we received, make sure that our approach is guided by our public health mandate, and ensure the clarity of our rules on the subject. We will consider these proposals and recommendations as we continue to work diligently on the issues relating to intended use raised in the underlying rulemaking.

(Comment 3) One comment stated that the proposed rule should be delayed due to several Federal lawsuits involving FDA and vaping firms. That comment further asserted that FDA acted deceptively and violated the Constitution, that FDA should provide clear rulemaking procedures, that the

tobacco and medical products parts of the rule both should not be addressed piecemeal and should be cleanly split, and that the docket should be closed.

(Response) To the extent the comment intended to support the delay of the effective date of the medical product portions of the January 2017 final rule, we agree. However, to the extent the comment intended to assert that the effective date of new § 1100.5 should likewise be delayed, the comment is outside the scope of this rulemaking. In any event, we disagree that there is any reason to delay the effective date of § 1100.5. As noted in the January 2018 proposed rule, when FDA reopened the docket for the January 2017 final rule, 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. This comment likewise did not suggest any changes to the substance of that regulation. To the extent the comment can be understood to relate to the substance of the amendments to the intended use regulations, we will consider them as we continue to work diligently on the issues relating to intended use raised in the underlying rulemaking.

*C. Description of Comment in Opposition to the Delay and FDA Response*

(Comment 4) One comment opposed the proposed delay and asked that FDA not further delay implementation of the January 2017 final rule. The comment expressed support for the January 2017 final rule, stating that (1) the ''totality of evidence'' language does not lower the relevant evidentiary standard and (2) there has been adequate notice and opportunity to be heard regarding the final rule. The comment recommended that FDA build on the approach it has adopted in the past several years to address intended use issues and argued against the removal of the ''knowledge'' sentences in §§ 201.128 and 801.4.

(Response) With respect to the request not to delay implementation of the January 2017 final rule, under FDA regulations, the Commissioner of Food and Drugs (Commissioner) is authorized to stay, including for an indefinite time period, the effective date of any action if the stay is in the public interest and the interest of justice (see § 10.35(a) to (b), (e) to (f) (21 CFR 10.35(a) to (b), (e) to (f))). We believe that the delay is reasonable and appropriate in light of the complex issues under consideration and the wide range of concerns, proposals, and recommendations we have received in comments from stakeholders on these issues. In addition to these comments, the Agency received a petition specifically requesting that the Commissioner ''indefinitely stay the Final Rule'' (petition at p. 1). The petition raised a number of concerns with the January 2017 final rule, including constitutional concerns and public health concerns related to what the petition stated could be a chilling of valuable scientific speech. While the Agency remains committed to providing clarity on issues relating to intended use, we have determined that it best serves the public health for the Agency to take additional time to carefully consider all of these concerns and delay the effective date of the January 2017 final rule. The petitioners raised significant concerns with the text of the ''intended use'' amendments, which were echoed by several additional commenters. The Agency does not believe that indefinitely delaying the effective date of the January 2017 final rule to consider these issues will create a public health risk. To the contrary, the potential for confusion and uncertainty regarding the text of the January 2017 final rule might affect FDA's medical product jurisdiction in ways that FDA did not intend when it set out to clarify the ''intended use'' regulations.

Accordingly, the Commissioner has concluded that the delay is warranted because it is in the public interest and the interest of justice (see § 10.35(e)). As noted above, we will consider the concerns, recommendations, and proposals set forth in these comments as we continue to work diligently on the issues relating to intended use raised in the underlying rulemaking.

*D. Description of Comments Outside the Scope of This Rulemaking and FDA Response*

(Comment 5) Several comments supported FDA suspending rulemaking and closing the docket to address issues related to a specific drug product.

(Response) These comments appear to concern product-specific issues that are outside the scope of this rulemaking.

## III. Effective/Compliance Date(s)

This rule is effective March 16, 2018. As provided at 82 FR 14319, March 20, 2017, the amendments to FDA's existing regulations describing the types of evidence that may be considered in determining a medical product's intended uses (§§ 201.128 (drugs) and 801.4 (devices)) will take effect on March 19, 2018. In order to delay that effective date, this final rule needs to be effective on or before March 19, 2018, and therefore it is not possible for this rule delaying that effective date to take effect 30 days from publication in the **Federal Register**. Thus, the Commissioner finds good cause under 21 CFR 10.40(c)(4)(ii) to make this rule effective on the day of publication.

## IV. Economic Analysis of Impacts

We have examined the impacts of the final 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 final rule is not a significant regulatory action as defined by Executive Order 12866. The final rule 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 this final rule will impose negligible costs, if any, we certify that the 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 issuing ''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 final rule would not result in an expenditure in any year that meets or exceeds this amount.

We received no comments on the proposed rule that specifically addressed our preliminary regulatory impact analysis. Therefore, we retain our preliminary estimate that the final rule will maintain the status quo for the medical product industries and impose no additional burden on affected entities. In table 1, we provide the costs

and benefits of the final rule in 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 FINAL RULE

| Category | Primary estimate | Low estimate | High estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|
| | | | | Year dollars | Discount rate (percent) | Period covered (years) | |
| Benefits: | | | | | | | |
| Annualized | | | | | 7 | 10 | |
| Monetized $millions/year | | | | | 3 | 10 | |
| Annualized | | | | | 7 | | |
| Quantified | | | | | 3 | | |
| Qualitative | Avoid potential unintended consequences | | | | | | |
| Costs: | | | | | | | |
| Annualized | | | | | 7 | 10 | |
| Monetized $millions/year | | | | | 3 | 10 | |
| Annualized | | | | | 7 | | |
| Quantified | | | | | 3 | | |
| Qualitative | Negligible costs, if any | | | | | | |
| Transfers: | | | | | | | |
| Federal | | | | | 7 | | |
| Annualized | | | | | 3 | | |
| Monetized $millions/year | | | | | | | |
| From/To | From: | | | To: | | | |
| Other | | | | | 7 | | |
| Annualized | | | | | 3 | | |
| Monetized $millions/year | | | | | | | |
| From/To | From: | | | To: | | | |

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

## 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

This 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 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. Consultation and Coordination With Indian Tribal Governments

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 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

Dated: March 12, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–05347 Filed 3–15–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2018–0070]**

### Drawbridge Operation Regulation; St. Johns River, Jacksonville, FL

**AGENCY:** Coast Guard, DHS.