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Re: Docket Nos. FDA-2011-P-0512, FDA-2013-P-1079, FDA-2015-N-2002, FDA-2016-N-1149

Dear Mr. Kalb, Ms. Klasmeier, Mr. Guerra, Mr. Griffin, Ms. Combs, Mr. Hallward-Driemeier, Ms. McPhee, Mr. Stansel, Mr. Murphy, and Mr. Florence:

This letter responds to your petition for reconsideration and stay of action received on February 8, 2017 (petition). The petition requests that FDA indefinitely stay its final rule entitled "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products; Amendments to the Regulations Regarding 'Intended Uses'", which was published in the Federal Register on January 9, 2017 (82 FR 2193) (January 2017 Final Rule). The petition also requests that FDA reconsider the January 2017 Final Rule and direct FDA staff to promulgate final definitions of intended use that are consistent with the proposed definitions set out in the notice of proposed rulemaking dated September 25, 2015.

We have carefully considered the issues raised in your petition. For the reasons stated below, your petition is granted in part and denied in part.

## 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 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 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 January 2017 Final Rule.

Your petition, received February 8, 2017, 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 you argue that (1) the January 2017 Final Rule was issued in violation of the fair notice requirement under the Administrative Procedure Act (APA) (petition at pgs. 10–13) and (2) the "totality of the evidence" language in the January 2017 Final Rule is a new and unsupported legal standard (petition at pgs. 10, 13–21).

In the Federal Register of March 20, 2017 (82 FR 14319), we further delayed the effective date of the January 2017 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.

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). In response to the proposed delay, we received nineteen comments, most of which 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 Federal Register of March 16, 2018, FDA published a final rule to delay the effective date of the intended use amendments until further notice.

## II. DISCUSSION

### A. Request for Indefinite Stay of January 2017 Final Rule

The petition requests that FDA issue an indefinite stay of the amendments to the existing medical product intended use regulations. This request is granted. As described in section I above, FDA received numerous comments raising questions about the amendments to the existing medical product intended use regulations, including the concerns noted in your petition. To allow for further consideration of the substantive issues raised in your petition and in the comments received in the docket, FDA published a final rule in the Federal Register of March 16, 2018 that delays the effective date of the amendments until further notice.[1]

### B. FDA Will Consider Petitioner's Requests Concerning the Intended Use Definitions in Connection with the Underlying Rulemaking

The petition requests that FDA reconsider the January 2017 Final Rule and direct FDA staff to promulgate final definitions of intended use that are consistent with the proposed definitions set out in the notice of proposed rulemaking dated September 25, 2015.

The Agency received wide-ranging proposals and recommendations for how we should address issues related to intended use and §§ 201.128 and 801.4. We have delayed the effective date of the amendments to the intended use regulations to allow more time for FDA to consider the feedback we have received, make sure that our approach is guided by our public health mandate, and ensure the clarity of our rules on the subject. Because we intend to consider a variety of possible options and recommendations, we are denying your request that we implement this specific recommendation at this time. We will consider the proposals and recommendations in your petition as we continue to work diligently on the issues relating to intended use raised in the underlying rulemaking.

## III. CONCLUSION

To the extent you are requesting that FDA indefinitely stay the final rule while the Agency considers the issues raised in your petition and in comments submitted to the docket, we grant that request. However, your request that the Commissioner "direct FDA staff to promulgate final definitions of intended use that are consistent with the proposed definitions set out in the notice of proposed rulemaking dated September 25, 2015" (petition at pg. 1) is denied. FDA will

[1] Your petition requests that FDA indefinitely *stay* the January 2017 Final Rule's intended use amendments. Because the intended use amendments were not scheduled to take effect until March 19, 2018, FDA's March 16, 2018 final rule has the effect of delaying, rather than staying, the effective date of the amendments.

consider your 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.

Sincerely,

Leslie Kux
Associate Commissioner for Policy