ROPES &GRAY

SIDLEY AUSTIN LLP
SIDLEY

April 5, 2017

Via Hand Delivery and Electronic Submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: 82 FR 14319
Docket # FDA-2015-N-2002
Request for Extension of Comment Period on Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments

To Whom it May Concern:

Pursuant to 21 C.F.R. § 10.40(b)(3), the Medical Information Working Group (MIWG), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Biotechnology Innovation Organization (BIO) respectfully request a 90-day extension to the comment period in the above-captioned proceeding. This request follows the Petition To Stay and for Reconsideration (Petition) submitted by these three groups,[1] as well as FDA's delay of the effective date of the Final Rule and request for comments.[2]

Intended use is one of the core operational principles around which the Federal Food, Drug, and Cosmetic Act (FDCA) is organized. In September 2015, when FDA initially proposed to revise the intended use regulations at 21 C.F.R. § 201.128 and 21 C.F.R. § 801.4, the agency sought merely to clarify that FDA would no longer "'regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that such product was being prescribed or used by doctors for such use.'"[3] Although the agency originally established a 60-day comment period for responses to the Proposed Rule, it extended the

---

1 Petition to Stay and for Reconsideration, Docket No. FDA-2016-N-1149-0048 (Feb. 8, 2017) [hereinafter "Petition"].

2 Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments, 82 Fed. Reg. 14319, 14321 (Mar. 20, 2017) (to be codified at 21 C.F.R. §§ 201, 801, and 1100) [hereinafter "Delay and Request for Comment"].

3 Petition at 7 (quoting Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Proposed Rule, 80 Fed. Reg. 57756, 57771 (Sept. 25, 2015) (to be codified at 21 C.F.R. §§ 201, 801, and 1100).

deadline by 30 days in response to a request, to provide "adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues."[4]

When FDA published the Final Rule on intended use, as we explained in the Petition, the agency not only addressed the use of knowledge, but also revised the regulation to add new language—not contemplated in the Proposed Rule—indicating that intended use was to be determined with respect to the "totality of the evidence."[5] Furthermore, in the recent Federal Register notice announcing the delayed effective date, FDA requested public input not just on the use of knowledge, or on the "totality of the evidence" standard, but also on other aspects of intended use, including the forms of evidence that should or should not be considered, the relevant First Amendment considerations, and the public health consequences of various approaches to determining intended use.[6] A 90-day extension to the comment period is necessary given the breadth of the comment request and the significance of the issues at stake.[7]

Granting the extension request would also be appropriate given FDA's decision to connect intended use with the regulation of manufacturer communications in the intended use notice. Until April 19, 2017, FDA is accepting comments to inform its "comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved/cleared medical products."[8] In the notice announcing the delay in effective date for the intended use amendments, FDA "encourag[ed] commenters to submit to this [intended use] docket their feedback on issues addressed in the separate docket to the extent that the feedback may also be pertinent to the final rule (including the preamble), 'intended use,' and/or the specific issues raised herein."[9] Extending the comment period for the intended use docket by 90 days would enable our respective organizations and other stakeholders to review comments

---

4 Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Reopening of the Comment Period, 80 Fed. Reg. 74737 (Nov. 30, 2015).

5 Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Final Rule, 82 Fed. Reg. 2193 (Jan. 9, 2017).

6 Delay and Request for Comment at 14320-22; *see also id.* at 14322 (requesting "any other pertinent comments or information stakeholders would like to share regarding the final rule, including whether there are any other approaches to 'intended use' FDA should consider").

7 Granting the extension would also be consistent with FDA's recent action on January 19, 2017, where the agency *sua sponte* granted a 60-day extension to the comment period involving manufacturer communications regarding unapproved uses of approved or cleared medical products. There, FDA recognized that granting commenters additional time to respond was warranted by the significant issues implicated by its regulation of "off-label" communications. Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Availability of Memorandum; Reopening of the Comment Period, 82 Fed. Reg. 6367 (Jan. 19, 2017).

8 Delay and Request for Comment at 14322.

9 *Id.* at 14321-22.

submitted to the manufacturer communications docket and take those comments into account in our comments on intended use.

Finally, FDA has already decided to delay the effective date of the intended use rule until March 19, 2018.[10] Extending the comment period by 90 days should not interfere with FDA's ability to take action before that date, as the agency would still have seven months to consider comments submitted to the docket and to determine how best to proceed.

We appreciate your consideration and timely response to this request.

Sincerely,

Coleen Klasmeier
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, DC 20001
(202) 736-8000

Kellie Combs
ROPES & GRAY LLP
2099 Pennsylvania Avenue NW
Washington, DC 20006
(202) 508-4600

Counsel to the Medical Information Working Group

James C. Stansel
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street NW, Suite 300
Washington, DC 20004
(202) 835-3400

John A. Murphy
BIOTECHNOLOGY INNOVATION ORGANIZATION
1201 Maryland Avenue, SW Suite 900
Washington, DC 20024
(202) 962-9200

[10] *Id.* at 14319.