

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

R.J. REYNOLDS TOBACCO COMPANY;
SANTA FE NATURAL TOBACCO
COMPANY, INC.; ITG BRANDS, LLC;
LIGGETT GROUP LLC; NEOCOM, INC.;
RANGILA ENTERPRISES INC.; RANGILA
LLC; SAHIL ISMAIL, INC.; and IS LIKE
YOU INC.;

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION;

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;

ROBERT CALIFF,
in his official capacity as Commissioner of the
United States Food and Drug Administration;
and

XAVIER BECERRA,
in his official capacity as Secretary of the United
States Department of Health and Human
Services;

Defendants.

CIVIL ACTION NO. 6:20-cv-00176

**PLAINTIFFS' FOURTH MOTION TO EXTEND
POSTPONEMENT OF RULE'S EFFECTIVE DATE**

Plaintiffs respectfully request that the Court grant an additional 90-day extension of the initial 120-day postponement of the Rule's effective date, without prejudice to Plaintiffs' ability to seek additional relief if it becomes necessary. In support of this request, Plaintiffs state as follows:

1. On May 6, 2020, Plaintiffs and Defendants filed a joint motion requesting that the Court postpone for 120 days the effective date of a Final Rule issued by the Food and Drug

Administration (“FDA”), which would require the use of eleven new graphic warnings on cigarette packages and advertisements, *see Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (codified at 21 C.F.R. pt. 1141) (“the Rule”). *See* Joint Mot., ECF No. 30, ¶¶ 1, 4, 7 (May 6, 2020). Defendants stipulated that, “[i]n light of the disruptive effects of the global outbreak of COVID-19 on both the regulated community affected by the Rule and on FDA, . . . justice require[d] a 120-day postponement of the Rule’s effective date, from June 18, 2021, to October 16, 2021.” *See id.* ¶ 4. Plaintiffs explained that the Rule would cause irreparable harm, including substantial compliance costs for the Manufacturer Plaintiffs. *See id.* ¶¶ 5–6. Plaintiffs further noted that they would need to seek expedited relief from the Court if the joint motion were not granted. *See id.* ¶ 5.

2. On May 8, 2020, the Court granted the parties’ joint motion. *See* Order, ECF No. 33 (May 8, 2020) (“Postponement Order”). The Court agreed that Plaintiffs would suffer “irreparable injury absent postponement of the rule’s effective date” because they “would face imminent compliance costs” and “those costs would not be reimbursed by the government if plaintiffs prevail[ed] on the merits.” *See id.* at 1–2. The Court thus postponed the Rule’s effective date for 120 days—from June 18, 2021, to October 16, 2021. *See id.* It also ordered that “[a]ny obligation to comply with a deadline tied to the effective date of the rule [be] similarly postponed.” *Id.* at 2.

3. Following the Court’s 120-day postponement, Plaintiffs have moved on three previous occasions to extend the postponement for an additional ninety days. Plaintiffs noted in each case that, due to the impending expiration of the applicable postponement period, Manufacturer Plaintiffs were facing the same imminent compliance costs that the original postponement was designed to address. *See* Pls.’ Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 76, ¶ 4 (Nov. 23, 2020); Pls.’ Second Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 86, ¶ 7 (Feb. 26, 2021); Pls.’ Third Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 90, ¶ 8 (May 21, 2021). Plaintiffs explained that “the Manufacturer Plaintiffs would have to redesign packaging, modify the printing process, purchase and engrave printing cylinders, print compliant packages, and redesign, modify, and replace point-of-sale advertisements at hundreds of thousands of retailers.” Pls.’ Third

Mot. to Extend Postponement ¶ 4; *see also* Pls.’ Mot. to Extend Postponement ¶ 4; Pls.’ Second Mot. to Extend Postponement ¶ 4. Plaintiffs further noted that “these steps would cost millions of dollars and thousands of employee hours, which would be unrecoverable if Plaintiffs prevailed, and that the balance of equities strongly favored granting a stay.” Pls.’ Third Mot. to Extend Postponement ¶ 4; *see also id.* ¶ 8; Pls.’ Mot. to Extend Postponement ¶¶ 4–6; Pls.’ Second Mot. to Extend Postponement ¶¶ 4, 7.

4. In each instance, Defendants have opposed, or stated their opposition to, the motion. *See* Defs.’ Opp. to Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 79 (Nov. 25, 2020); Defs.’ Opp. to Pls.’ Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 88 (Mar. 1, 2020); Pls.’ Third Mot. to Extend Postponement ¶ 10. And in each instance, the Court has granted the motion and extended the postponement of the Rule’s effective date, along with any obligation to comply with related requirements in 15 U.S.C. § 1333(a)(1), (b)(1), and 21 U.S.C. §§ 387c(a)(2) and 387t(a), and “any other obligation to comply with a deadline tied to the effective date of the rule.” Order, ECF No. 80 (Dec. 2, 2020) (“Extension Order”); Order, ECF No. 89 (Mar. 2, 2021) (“Second Extension Order”); Order, ECF No. 91 (May 21, 2021) (“Third Extension Order”).

5. Subsequently, the Court four times acted *sua sponte* in extending the postponement of the Rule’s effective date for an additional 90 days. *See* Order, ECF No. 92 (Aug. 18, 2021) (“Fourth Extension Order”); Order, ECF No. 93 (Nov. 12, 2021) (“Fifth Extension Order”); Order, ECF No. 94 (Feb. 10, 2022) (“Sixth Extension Order”); Order, ECF No. 96 (May 10, 2022) (“Seventh Extension Order”). In all four instances, it also ordered that “[a]ny obligation to comply with the Tobacco Control Act’s warning requirements, 15 U.S.C. § 1333(a)(1) and (b)(1), and the additional requirements in 21 U.S.C. §§ 387c(a)(2) and 387t(a),” and “any other obligation to comply with a deadline tied to the effective date of the rule,” be postponed for an additional 90 days. Fourth Extension Order at 1; Fifth Extension Order at 1; Sixth Extension Order at 1; Seventh Extension Order at 1. Under the Court’s most recent order, the effective date of these requirements and the Rule has been postponed until July 8, 2023. Seventh Extension Order at 1.

6. Ninety days have passed since this Court's most recent extension order. The Manufacturer Plaintiffs are once again on the verge of incurring the same irreparable and imminent compliance costs that were identified in the previous joint motion for a stay, the previous motions to extend postponement of the Rule's effective date, and the merits briefs and supporting declarations, and that the previous postponement orders were designed to address. *See* Joint Mot. ¶¶ 5–6; Pls.' Mot. to Extend Postponement ¶¶ 4–5; Pls.' Second Mot. to Extend Postponement ¶ 7; Pls.' Third Mot. to Extend Postponement ¶ 8; Pls.' Mot. for Summ. J. and Prelim. Inj. at 59–64; Decl. of Lamar W. Huckabee, ECF No. 34-5 (May 15, 2020) (attached as Exhibit A); Decl. of Kim Reed, ECF No. 34-6 (May 15, 2020) (attached as Exhibit B); Decl. of Francis G. Wall, ECF No. 34-7 (May 15, 2020) (attached as Exhibit C); Pls.' Combined Reply and Resp., ECF No. 59, at 39–40. The legal analysis and balance of the equities are indistinguishable from the previous extension motions and orders. *See* Extension Order at 1; Pls.' Mot. to Extend Postponement ¶¶ 5–6; Second Extension Order at 1; Pls.' Second Mot. to Extend Postponement ¶¶ 6–7; Third Extension Order at 1; Pls.' Third Mot. to Extend Postponement ¶ 8; Fourth Extension Order at 1; Fifth Extension Order at 1; Sixth Extension Order at 1; Seventh Extension Order at 1. Another extension is therefore warranted under 5 U.S.C. § 705.

7. Accordingly, Plaintiffs request an additional 90-day extension of the postponement of the Rule's effective date and related requirements, from July 8, 2023, to October 6, 2023. Plaintiffs further request that the additional 90-day extension be granted without prejudice to Plaintiffs' right to move for additional relief at a later date, including another motion requesting a further postponement of the Rule's effective date, and without prejudice to Plaintiffs' pending motions.

8. As detailed in the certificate of conference, counsel for Plaintiffs and Defendants have discussed Plaintiffs' intention to file this motion, and Defendants' counsel has informed Plaintiffs' counsel that Defendants oppose this motion for substantially the same reasons set forth in Defendants' oppositions to Plaintiffs' previous motions for a 90-day extension.

Respectfully submitted,

August 8, 2022

/s/ Ryan J. Watson

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CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2022, a true and correct copy of the foregoing was electronically filed with the clerk of court for the U.S. District Court for the Eastern District of Texas, using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Ryan J. Watson

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CERTIFICATE OF CONFERENCE

I hereby certify, pursuant to Local Rule CV-7(i), that (1) I complied with the meet and confer requirement in Local Rule CV-7(h), and (2) this motion is opposed.

I have conducted the personal conference required by Local Rule CV-7(i). Specifically, I emailed Defendants' counsel on August 2, 2022, to inform him of Plaintiffs' intention to seek an additional postponement of 90 days. On August 4, 2022, I, along with Alex Potapov, had a telephone conference with Garrett Coyle (U.S. Department of Justice) to discuss Plaintiffs' request for an additional postponement of the Rule's effective date, as well as Defendants' position with respect to that motion. After a collegial discussion where both sides discussed the issues in good faith, Defendants' counsel stated that Defendants oppose the motion for substantially the same reasons that Defendants opposed Plaintiffs' previous motions to extend the postponement. The conference participants then concluded that the discussion had ended in an impasse, leaving an open issue for the Court to resolve.

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