

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

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,

*Plaintiffs,*

*v.*

UNITED STATES FOOD AND DRUG  
ADMINISTRATION, *et al.*,

Defendants,

CIVIL ACTION NO. 6:20-cv-00176

**JOINT MOTION FOR ENTRY OF STIPULATED ORDER TO  
POSTPONE RULE'S EFFECTIVE DATE AND SET BRIEFING SCHEDULE**

In view of the extraordinary disruptions caused by the COVID-19 pandemic, and to facilitate the efficient briefing and resolution of this case, the parties, subject to the Court's approval, HEREBY STIPULATE as follows, and respectfully request that the Court enter the attached order adopting their stipulation:

1. On March 18, 2020, the Food and Drug Administration ("FDA") issued a Final Rule requiring the use of eleven new textual warnings, accompanied by eleven color graphics, on cigarette packages and advertising. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) ("the Rule"). The Rule was promulgated pursuant to the Tobacco Control Act's mandate that FDA "issue regulations that require color graphics depicting the negative health consequences of smoking." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1776, 1845 (2009) (codified at 15 U.S.C. § 1333(d)[1]). The Rule's "effective date" currently is June 18, 2021—*i.e.*, 15 months from the Rule's publication. 85 Fed. Reg. at 15,694.

2. On April 3, 2020, Plaintiffs filed this action seeking an order and judgment holding unlawful, enjoining, and setting aside the Rule in its entirety and the Tobacco Control Act's graphic-warnings requirement. *See* Compl. ECF No. 1. Plaintiffs assert several claims in the complaint, including, *inter alia*, that the Rule and the Act's graphic-warnings requirement violate the First Amendment to the United States Constitution; that FDA violated the Administrative Procedure Act ("APA") by acting arbitrarily and capriciously, failing to provide meaningful notice, and failing to provide a meaningful opportunity to comment; and that the Rule violates the Tobacco Control Act. Plaintiffs included a claim and request for injunctive relief in the complaint as they anticipated the need to file an expedited motion for a preliminary injunction to stay implementation of the Rule to avoid alleged irreparable harm.

3. On April 9, 2020, Plaintiffs' counsel contacted Defendants' counsel for the purpose of conferring in accordance with Local Rule CV-7(h), to discuss, among other issues, Plaintiffs' intention to move on an expedited basis for summary judgment and a preliminary injunction. The parties engaged in extensive discussions regarding both the Rule's effective date and an appropriate schedule for presenting the issues that this case raises to the Court. The parties agree that the proposed schedule outlined herein would facilitate an efficient resolution of this litigation.

4. In light of the disruptive effects of the global outbreak of COVID-19 on both the regulated community affected by the Rule and on FDA, Defendants stipulate that justice requires a 120-day postponement of the Rule's effective date, from June 18, 2021, to October 16, 2021. *See* 5 U.S.C. § 705. Defendants remain fully committed to the Rule, and would not agree to postpone its effective date but for the extraordinary disruptions caused by the COVID-19 pandemic. Defendants do not concede that Plaintiffs will suffer irreparable harm absent this postponement or are entitled to any form of preliminary relief.

5. Congress provided for a 15-month implementation period in Section 201(b) of the

Tobacco Control Act. Plaintiffs R.J. Reynolds Tobacco Company, Santa Fe Natural Tobacco Company, Inc., ITG Brands, LLC, and Liggett Group LLC (collectively, “Manufacturer Plaintiffs”) are in the business of manufacturing cigarettes. The Manufacturer Plaintiffs contend that implementation of the Rule’s requirements would be time-consuming, burdensome, and expensive, and would require them to commence substantial efforts as soon as possible, and throughout the 15-month implementation period, so they could meet the requirements imposed by the Rule prior to the current deadlines. *See* Compl. ¶¶ 117–19. In addition, Plaintiffs state that compliance efforts are now further complicated by the disruptions caused by the COVID-19 pandemic. Plaintiffs further maintain that the expenditures that they incur for the purpose of meeting the Rule’s requirements constitute irreparable harm because none of them will be compensable by money damages should the Rule and/or the graphic-warnings requirement in the Tobacco Control Act be invalidated. If the schedule in this Joint Motion were not granted, Plaintiffs would seek expedited relief from the Court now, by moving for an injunction on an expedited basis to avoid what they maintain would be immediate, costly compliance with the Rule. Plaintiffs also assert their claims present a substantial case on the merits.

6. Plaintiffs assert that the Rule will cause irreparable harm even if this postponement is granted. Plaintiffs have stipulated to the agreed-upon schedule in light of the circumstances arising from the COVID-19 pandemic; Plaintiffs do so stipulate without prejudice to their motion or claims for injunctive relief which they intend to brief in accordance with the schedule in paragraph 9, below.

7. The parties request that the Court issue an order, pursuant to this stipulation and 5 U.S.C. § 705, that the effective date of the Rule is postponed until October 16, 2021, and that any obligation to comply with other deadlines tied to the issuance of the Rule is also postponed for 120

days.<sup>1</sup> Given that the circumstances surrounding the COVID-19 pandemic are in flux, each party reserves the right to seek additional relief from the Court, including further extensions of any dates or deadlines requested herein. All agreements made in this motion are without prejudice for Plaintiffs to move for additional relief at a later date, including a motion for an injunction requesting a further or permanent postponement of the Rule's effective date, or for Defendants to oppose any such relief.

8. Defendants agree that, within a reasonable amount of time after entry of such an order, and no later than two weeks after such an order is issued, FDA shall post notice on its public-facing website that the Rule's effective date is postponed until October 16, 2021.

9. Subject to the Court's approval of the foregoing effective-date postponement, the parties respectfully request that the Court adopt the following briefing schedule, format, and page limits:

<b>Event</b>	<b>Deadline</b>	<b>Page Limit<sup>2</sup></b>
Plaintiffs' Combined Motions for Summary Judgment and Preliminary Injunction	May 8, 2020	65
Any Amicus Briefs in Support of Plaintiffs	May 22, 2020	25
Defendants' Combined (i) Opposition to Plaintiffs' Motions and (ii) Cross-Motion	June 26, 2020	75
Any Amicus Briefs in Support of Defendants	July 10, 2020	25
Plaintiffs' Combined (i) Reply in Support of Their Motions and (ii) Opposition to Defendants' Cross-Motion	August 7, 2020	40

<sup>1</sup>The Tobacco Control Act imposes several additional labeling requirements, *see* 15 U.S.C. § 1333(a)(1), 21 U.S.C. §§ 387c(a)(2), 387t(a), tied to the effective date of the graphic-warnings Rule, *see* Pub. L. No. 111-31, § 201(b) (setting the effective date for the textual and graphic warnings in 15 U.S.C. § 1333); *id.* § 103(q)(5) (using identical text to set the effective date for the related requirements in 21 U.S.C. § 387c(a)(2)); *id.* § 301 (using identical text to set the effective date for the related requirement in 21 U.S.C. § 387t(a)). If this Court postpones the effective date of the Rule by 120 days, the parties agree that any obligation to comply with these additional requirements would be postponed by 120 days. The Rule also recommended (but did not require) that manufacturers submit compliance plans "as soon as possible . . . , and in any event within 5 months after the publication of th[e] final rule." 85 Fed. Reg. at 15,694. If the Court grants the relief sought in this motion, both parties would understand that language to recommend submission of the plans as soon as possible, and in any event within 5 months and 120 days after the Rule's publication.

<sup>2</sup>The page limits do not include exhibits or attachments.

Defendants' Reply in Support of Their Cross-Motion	September 4, 2020	30
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10. Pursuant to Local Rule CV-7(g), the parties respectfully request an oral argument on their dispositive motions and Plaintiffs' motion for a preliminary injunction at the Court's earliest convenience following the completion of briefing. The parties believe an oral argument would make sur-reply briefs unnecessary.

11. To aid in the efficient implementation of the foregoing schedule, the parties further stipulate and request that, if this Motion is granted, the deadline for responding to the Complaint (June 8, 2020) be extended to June 26, 2020, when Defendants' Combined Opposition and Cross-Motion is due.

12. Defendants agree to serve a copy of the administrative record on Plaintiffs the same date they file their Combined Opposition and Cross-Motion.

13. The parties agree to file a joint appendix, containing copies of those portions of the administrative record that are cited or otherwise relied upon in any memorandum in support of or in opposition to any dispositive motion, within two weeks of the conclusion of briefing on their dispositive motions. The parties further agree that their dispositive motions need not include a statement of undisputed material facts under Local Rule CV-56(a). *See* Rules of the United States District Court for the District of Columbia LCvR 7(h)(2) (providing that summary judgment motions need not include a statement of undisputed material facts in cases where "judicial review is based solely on the administrative record").

14. The parties believe that no discovery is likely to be necessary in this case, and that no discovery is needed prior to this Court's resolution of the Parties' respective dispositive motions. The parties therefore propose that any applicable discovery-related obligations be tolled until at least 30 days after this Court's ruling on their dispositive motions. *See* Fed. R. Civ. P. 26(a)(1)(B)(i) (exempting

“an action for review on an administrative record” from initial disclosure obligations); Fed. R. Civ. P. 26(f)(1)–(3) (exempting such actions from the requirement to confer and develop a proposed discovery plan).

15. Due to the time-sensitive nature of these proceedings, the Parties respectfully request expedited consideration of this Joint Motion.

WHEREFORE, the parties respectfully request that the Court enter the attached proposed order adopting their stipulation.

Respectfully submitted,

May 6, 2020

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*v.*

UNITED STATES FOOD AND DRUG  
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CIVIL ACTION NO. 6:20-cv-00176

**[PROPOSED] ORDER**

The parties’ Joint Motion for Entry of Stipulated Order to Postpone Rule’s Effective Date and Set Briefing Schedule is GRANTED. Pursuant to the parties’ stipulation and 5 U.S.C. § 705, the effective date of the challenged rule, Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141), is postponed for 120 days, until October 16, 2021.<sup>1</sup>

It is FURTHER ORDERED that the parties shall comply with the following briefing format, schedule, and page limits:

<b>Event</b>	<b>Deadline</b>	<b>Page Limit<sup>2</sup></b>
Plaintiffs’ Combined Motions for Summary Judgment and Preliminary Injunction	May 8, 2020	65
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<sup>1</sup> Any obligation to comply with the Tobacco Control Act’s warnings requirements, 5 U.S.C. § 1333(a)(1) and (b)(1), and the additional requirements in 21 U.S.C. § 387c(a)(2) and § 387t(a), is also postponed for 120 days.

<sup>2</sup> The page limits do not include exhibits or attachments.

Plaintiffs' Combined (i) Reply in Support of Their Motions and (ii) Opposition to Defendants' Cross-Motion	August 7, 2020	40
Defendants' Reply in Support of Their Cross-Motion	September 4, 2020	30
Joint Appendix containing copies of those portions of the administrative record that are cited or otherwise relied upon in the parties' briefs.	September 18, 2020	N/A

It is FURTHER ORDERED that the deadline for responding to the Complaint (June 8, 2020) is extended to June 26, 2020, when Defendants' Combined Opposition and Cross-Motion is due.

It is FURTHER ORDERED that the parties' dispositive motions need not include a statement of undisputed material facts under Local Rule CV-56(a).

It is FURTHER ORDERED that the parties are exempted from any applicable discovery-related obligations until at least 30 days after the Court's ruling on the parties' dispositive motions.

It is FURTHER ORDERED that oral argument on the parties' dispositive motions and Plaintiffs' motion for a preliminary injunction is scheduled for \_\_\_\_\_.

It is SO ORDERED.