U.S. Department of Justice
Civil Division, Federal Programs Branch

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March 30, 2020

Via ECF

Hon. Paul W. Grimm
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 465A
Greenbelt, Maryland 20770

Re: *American Academy of Pediatrics v. FDA*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

In accordance with the Court's letter order regarding the filing of motions (ECF No. 15), Defendants respectfully submit this letter describing their planned request for an indicative ruling on a Federal Rule of Civil Procedure 60(b) motion for a 120-day extension of the premarket application deadline imposed in the Court's remedy order (ECF No. 127) in light of the global outbreak of respiratory illness caused by a new coronavirus.

Under the Court's remedy order, the FDA must require that all premarket applications for new products be filed by May 12, 2020, and new products for which applications have been timely filed have a one-year period of enforcement discretion pending FDA review. ECF No. 127 at 12. The global coronavirus outbreak poses unforeseen challenges and has made the May 12 deadline a public health risk to those who cannot comply with the deadline through telework. As a result of the outbreak, many laboratories and contract research organizations, which perform required laboratory and clinical studies for manufacturers' premarket applications, have shut down or suspended in-person work indefinitely. 2d Mitchell Zeller Decl. ¶ 7. Coronavirus-related travel restrictions have hampered travel between offices and factories — in places like Italy, China, Honduras, the Dominican Republic, Nicaragua, and Mexico — to gather information for premarket applications. 2d Zeller Decl. ¶ 9. Factories in countries affected by the outbreak — like China, Honduras, and the Dominican Republic — have been unable to make timely deliveries of the tobacco products that manufacturers need for testing and premarket applications. 2d Zeller Decl. ¶ 9.

Moreover, as a result of the outbreak, some employees from the FDA's Center for Tobacco Products (CTP) have been deployed to work for the U.S. Public Health Service, including many within one of the divisions of CTP's Office of Science, which is responsible for reviewing premarket applications. 2d Zeller Decl. ¶ 13. Also, virtually the entire FDA staff responsible for reviewing premarket applications will be teleworking until further notice. 2d Zeller Decl. ¶ 13. While the FDA has taken steps to enable work to be performed remotely as much as possible, the agency anticipates that it will take additional time for a remote workforce to receive and process applications and conduct scientific review of those applications. 2d Zeller Decl. ¶ 13.

Defendants submit that these exceptional and unforeseen circumstances justify a 120-day extension of the premarket application deadline in the Court's remedy order under Federal Rule of Civil Procedure 60(b), which allows the Court to "relieve a party … from a final judgment [or]

order … for … any other reason that justifies relief."[1] Defendants therefore respectfully request that the Court issue an indicative ruling stating that if the Fourth Circuit were to remand the case, the Court would grant Defendants' Rule 60(b) motion and modify its remedy order to direct the FDA to require that, for new tobacco products on the market as of the August 8, 2016 effective date of the deeming rule ("New Products"), applications for marketing orders must be filed by September 9, 2020.[2] Defendants do not seek to modify any other deadlines in the Court's remedy order.[3]

Defendants seek this extension solely because of the coronavirus outbreak and would not do so but for these highly unusual circumstances. 2d Zeller Decl. ¶ 4. The FDA's current thinking about its enforcement priorities has not changed from the 2020 guidance (ECF No. 174-1), but the agency understands that the exceptional circumstances presented by the coronavirus outbreak warrant the extension. 2d Zeller Decl. ¶ 4.

Defendants consulted with Plaintiffs, who indicated that they do not intend to oppose the motion but wish to express their misgivings about the extension on the record and therefore request leave to file a response. *See* ECF No. 15 (stating that no response to a pre-motion letter should be filed without the Court's approval).

Defendants thank the Court for its attention to this matter.

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[1] Although this case is on appeal, Rule 62.1 allows the Court to issue an indicative ruling in these circumstances. *See* Fed. R. Civ. P. 62.1(a) ("If a timely motion is made for relief that the court lacks authority to grant because of an appeal that has been docketed and is pending, the court may … state … that it would grant the motion if the court of appeals remands for that purpose ….."). If this Court states that it would grant the motion, the court of appeals may remand for further proceedings but would retain jurisdiction over the appeal. *See* Fed. R. App. P. 12.1(b).

[2] If Defendants' motion is granted, the FDA would intend to amend the 2020 guidance accordingly. 2d Zeller Decl. ¶ 15.

[3] Thus, under the Court's remedy order, new products for which applications are timely filed in accordance with this extended premarket application deadline would be subject to a one-year period of enforcement discretion while the FDA considers the application. ECF No. 127 at 12.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 8:18-cv-883-PWG

SECOND DECLARATION OF MITCHELL ZELLER

I, Mitchell Zeller, declare as follows:

1. I am the Director of the Center for Tobacco Products ("CTP"), United States Food and Drug Administration ("FDA"), a position I have held since March 2013. In this role, I direct the development and implementation of programs and policies for regulating the manufacture, marketing, and distribution of tobacco products. In my capacity as Director of CTP, I am fully familiar with the instant matter and the facts stated herein.

2. I have dedicated my career to working on issues relevant to FDA (over 37 years), including the last 25 years focused on tobacco regulation. I am a graduate of Dartmouth College and the American University Washington College of Law. I began my career as a public interest attorney in 1982 at the Center for Science in the Public Interest working on FDA food safety and nutrition issues. In 1988, I served as counsel to the Human Resources and Intergovernmental Relations Subcommittee of the House of Representatives Government Operations Committee, where I conducted oversight of enforcement of federal health and safety laws, including human

and animal drugs, dietary supplements, and food policies at FDA. In 1993, I joined the staff of then-FDA Commissioner, Dr. David Kessler, M.D., on a two-week assignment to examine the practices of the tobacco industry. This assignment led to my serving as associate commissioner and director of FDA's first Office of Tobacco Programs where I led FDA's efforts to craft the agency's 1996 tobacco regulations. In this capacity, I represented FDA before Congress, federal and state agencies, and served as an official United States delegate to the World Health Organization Working Group for the Framework Convention on Tobacco Control. In 2000, I left FDA to continue my work in tobacco control as executive vice president of the American Legacy Foundation, where my responsibilities included marketing, communications, strategic partnerships, and creating the foundation's first Office of Policy and Government Relations. I later joined Pinney Associates as senior vice president in 2002, where I remained until I took my current position as Director of CTP. In that role, I provided strategic planning and communications advice on domestic and global health policy issues involving the treatment of tobacco dependence and the regulation of tobacco products and pharmaceuticals.

3. On July 12, 2019, this Court ordered FDA to require submission of applications for premarket review by May 12, 2020, for deemed new tobacco products on the market as of August 8, 2016. The order provided that "new products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application."

4. On January 2, 2020, FDA issued guidance that, among other things, independently concluded that FDA would prioritize enforcement for premarket review requirements for electronic cigarette products on the market as of August 8, 2016, if such products had not submitted an application by May 12, 2020. The guidance also prioritized

earlier enforcement for certain e-cigarette products that are most widely used by youth regardless of whether, or when, submissions for those products are filed.[1] The timeframe set forth in the 2020 guidance continues to reflect FDA's current thinking about its enforcement priorities, and FDA would not be proposing to alter its guidance but for the highly unusual circumstances set out below.

5. As of February 29, 2020, 30 premarket tobacco product applications are pending for electronic cigarette products, 28 substantial equivalence applications are pending for cigars, and 17 substantial equivalence applications are pending for pipes or pipe tobacco products. I understand that many manufacturers intend to file applications by May 12, 2020, for a large number of products but are now facing unforeseen obstacles.

6. On January 31, 2020, the Department of Health and Human Services declared a public health emergency for the novel coronavirus known as SARS-CoV-2, also known by the disease it causes, COVID-19.[2] The U.S. State Department issued a "Do Not Travel" advisory for China on February 8, 2020.[3] On March 11, 2020, the World Health Organization declared the worldwide spread of COVID-19 a pandemic.[4] On March 13, 2020, President Trump declared a national emergency related to the coronavirus.[5] As of March 30, 2020, there are 140,904

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[1] *See* FDA, Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (January 2020), *available at* https://www.fda.gov/media/133880/download.
[2] *See* Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus (Jan. 31, 2020), *available at* https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html.
[3] The U.S. Department of State – China Travel Advisory Level 4 – Do Not Travel (Feb. 8, 2020), *available at* https://china.usembassy-china.org.cn/the-u-s-department-of-state-china-travel-advisory-level-4-do-not-travel/.
[4] *See* WHO characterizes COVID-19 as a pandemic (Mar. 11, 2020), *available at* https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen.
[5] *See* Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Conference (Mar. 13, 2020), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-conference-3/.

confirmed cases in the U.S., and 2,405 deaths.[6] Globally, there are 693,224 confirmed cases and 33,106 deaths, with the number of cases rising rapidly.[7] Many jurisdictions have closed school for extended periods of time, and even for the entire school year.[8] Many international organizations and federal, state, and local governments have taken rapid, unprecedented, and extraordinary measures to address this crisis, including measures that make travel and working on site difficult or infeasible.[9] The CDC has issued a Label 3 Travel Health Notice, recommending that travelers avoid all nonessential travel to international destinations.[10] Travel is currently restricted into the United States for most foreign nationals who have recently visited 27 countries in Europe, most parts of China, and Iran.[11] At least 30 states have shut down nonessential businesses.[12] The 2020 Summer Olympics have been postponed until 2021.[13] The

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[6] *See* Cases in U.S. (Mar. 28, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.

[7] *See* Coronavirus disease (COVID-19) Pandemic, *available at* https://www.who.int/emergencies/diseases/novel-coronavirus-2019.

[8] *See* Map: Coronavirus and School Closures (updated Mar. 26, 2020), *available at* https://www.edweek.org/ew/section/multimedia/map-coronavirus-and-school-closures.html.

[9] *See* Complete Coronavirus Travel Guide—The Latest Countries Restricting Travel (Mar. 17, 2020), *available at* https://www.forbes.com/sites/jamesasquith/2020/03/15/complete-coronavirus-travel-guide-the-latest-countries-restricting-travel/#f5e21c7715b4; *see also* U.S. Centers for Disease Control and Prevention, COVID-19 Travel Recommendations by Country, *available at* https://www.cdc.gov/coronavirus/2019-ncov/travelers/map-and-travel-notices.html#travel-1 (last accessed Mar. 27, 2020); U.S. Dep't of State, Global Health Advisory (Mar. 19, 2020), *available at* https://travel.state.gov/content/travel/en/traveladvisories/ea/travel-advisory-alert-global-level-4-health-advisory-issue.html; NY State On Pause (Mar. 28, 2020) ("All non-essential workers are directed to work from home, and everyone is required to maintain a 6-foot distance in public."), *available at* https://coronavirus.health.ny.gov/home; Coronavirus (COVID-19) ("Stay home. [San Francisco] is requiring people to stay home except for essential needs."), *available at* https://sf.gov/topics/coronavirus-covid-19.

[10] *See* U.S. Centers for Disease Control and Prevention, COVID-19 Travel Recommendations by Country, *available at* https://www.cdc.gov/coronavirus/2019-ncov/travelers/map-and-travel-notices.html#travel-1 (last accessed Mar. 27, 2020).

[11] *See* Proclamation on the Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting Coronavirus (Mar. 14, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-certain-additional-persons-pose-risk-transmitting-coronavirus-2/.

[12] *See* Here are the states that have shut down nonessential businesses (Mar. 29, 2020), *available at* https://abcnews.go.com/Health/states-shut-essential-businesses-map/story?id=69770806.

[13] *See* Joint Statement from the International Olympic Committee and the Tokyo 2020 Organising Committee (Mar. 24, 2020), *available at* https://www.olympic.org/.

President has recently maintained guidance for social distancing through April 30, 2020.[14]

7. I have received numerous communications from industry urging CTP to seek an extension of this Court's May 12, 2020 deadline because of difficulties in completing applications related to the coronavirus disruptions. As of March 25, I have received over 15 emails or letters from e-cigarette and cigar industry members and trade associations, representing thousands of individual entities and a broad swath of the market, including manufacturers, distributors, and retailers. The majority have requested some form of a 180-day extension. I have been informed (with supporting documentation), for example, that many laboratories and contract research organizations within the United States and abroad, including those with which manufacturers contract to conduct important laboratory and clinical studies, are shutting down or suspending in-person work, or reducing it significantly — some as the result of their states' or localities' closures of "non-essential businesses," others as a result of company policies implemented to ensure their employees' health and safety. By its nature, this type of laboratory work must be performed in person, on site.

8. As a further example, I am informed that many clinical studies involving human participants have been suspended to ensure safety. A leading contract research organization halted ongoing clinical studies in one of its facilities due to the COVID-19 pandemic on March 16, 2020, after reviewing public health guidance from federal and state regulatory authorities, given the nature of the clinical studies, the number of personnel and participants in the labs, and the close personal proximity required to conduct the studies. The laboratory postponed testing until the COVID-19 pandemic passes and it can safely resume the studies consistent with

[14] *See* Trump says social distancing should continue to April 30 (Mar. 29, 2020), *available at* https://www.washingtonpost.com/world/2020/03/29/coronavirus-latest-news/?itid=hp_hp-top-table-high_liveblogblurb-740pm%3Ahomepage%2Fstory-ans.

recommendations of relevant health organizations and regulatory authorities. The laboratory also determined that it was unable to continue testing at a reduced rate of participants given current public health guidance.

9. In addition, testing labs and consultants preparing Environmental Assessment reports can no longer guarantee timely results because employees are now working at home and cannot access testing facilities or primary source materials. I also understand that restrictions on travel within the United States and internationally have hampered necessary travel between factories and offices preparing applications. Many of the suppliers are located in places such as Honduras, the Dominican Republic, Italy, Nicaragua, Mexico, and China, where information related to premarket review applications resides. I am also informed that industry members are experiencing disruptions in receiving finished product and packaging on samples from overseas sources. For example, factories in China have not been able to make timely deliveries of e-cigarette products, and many cigar factories across Honduras and the Dominican Republic are closed, depriving industry members of the physical product needed to test and support premarket applications.

10. Industry and contractors affected by the Court's order are located all over the country, including in locations like New York and Washington State with a large number of affected residents. As of March 30, 2020, there were over 4,500 reported cases in Washington State.[15] As of the same date, New York State reported over 59,000 known cases, and over 5,000 hospitalizations, with over 1,200 in intensive care, numbers that threaten to strain the capacity of

[15] *See* Cases in U.S. (Mar. 30, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.

the health care system.[16] New York Governor Cuomo recently stated that the state had not yet even reached the "apex" of its hospitalizations, which is still estimated to be weeks away.[17] Residents in these and several other jurisdictions are subject to indefinite stay-home orders to reduce the spread of illness. Public health officials recently warned, "no state, no metro area, will be spared."[18] In other locations, like Alabama, California, Kansas, Nebraska, New Jersey, New Mexico, North Dakota, Oklahoma, Vermont, and Virginia,[19] where schools have closed until further notice or for the duration of the year, parents of school-aged children will be under increased strain well into June to balance telework and childcare responsibilities, and may not be able to meet the same demands at work for some time. We also know that many working adults are currently struggling with elder care responsibilities as their parents and loved ones of a more vulnerable age self-quarantine to reduce the risk of exposure, and many other working adults have underlying co-morbidities that make self-quarantine prudent as well.

11. FDA remains acutely aware of the recent surge in youth use of e-cigarettes and the public health imperative to ensure that these and other deemed new tobacco products undergo premarket review. The Agency is committed to implementing and enforcing the premarket requirements of the statute, consistent with this Court's order. The Agency also notes that manufacturers of deemed tobacco products have had years to prepare submissions, and indeed

[16] *Id.; see also* Video, Audio, Photos & Rush Transcript (Mar. 26, 2020), *available at* https://www.governor.ny.gov/news/video-audio-photos-rush-transcript-amid-ongoing-covid-19-pandemic-governor-cuomo-announces-3.

[17] *See* Press Release, Amid Ongoing COVID-19 Pandemic, Governor Cuomo Announces Completion of First 1,000-Bed Temporary Hospital at Jacob K. Javits Convention Center (Mar. 27, 2020), *available at* https://www.governor.ny.gov/news/amid-ongoing-covid-19-pandemic-governor-cuomo-announces-completion-first-1000-bed-temporary.

[18] *See* Dr. Deborah Birx: "No metro area will be spared" of the coronavirus outbreak (Mar. 29, 2020), *available at* https://www.nbcnews.com/meet-the-press/video/dr-deborah-birx-no-metro-area-will-be-spared-of-the-coronavirus-outbreak-81346629552.

[19] *See* Map: Coronavirus and School Closures (updated Mar. 26, 2020), *available at* https://www.edweek.org/ew/section/multimedia/map-coronavirus-and-school-closures.html.

several have already submitted applications on which the Agency is conducting scientific review.

12. However, given the severe, unforeseen disruptions that are affecting this industry and the world, I believe it is appropriate for applicants to have an additional 120 days, until September 9, 2020, to submit their applications to FDA for premarket review. The requests we have received generally ask for an extension between 8 weeks and 180 days, with the majority of requests for 180 days. At this point, we do not believe that an extension at the upper end of that range is appropriate given FDA's countervailing critical public health priority in promptly requiring submission of applications. At the same time, the coronavirus has significantly disrupted life globally and we believe that an extension of 120 days is necessary to prevent firms compromising their employees' health or taking actions that could risk further disease transmission to meet the current deadline. Given all of the factors described above, I believe that 120 days is an appropriate length of time to extend the current deadline for industry to complete applications.[20] This period is less than what many manufacturers have requested, but substantial enough to provide a significant measure of relief in these extraordinary circumstances. Manufacturers that would submit applications have been impacted by coronavirus delays since as early as January 2020 due to travel restrictions and business slow-downs in China; a 120-day extension accounts for the months of delay that have already impacted some manufacturers. A

[20] Other agencies have taken coronavirus-related action with similar timeframes. *See* HHS, Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures Under Executive Order 13910 and Section 102 of the Defense Production Act of 1950 (Mar. 25, 2020) (designating scarce or threatened materials subject to hoarding prevention measures for 120 days), *available at* https://www.hhs.gov/sites/default/files/hhs-dfa-notice-of-scarce-materials-for-hoarding-prevention.pdf; IRS, Coronavirus Tax Relief (extending deadline to file and pay federal income taxes by three months), *available at* https://www.irs.gov/coronavirus; Orders Limiting Operations at John F. Kennedy International Airport and New York LaGuardia Airport; High Density Traffic Airports Rule at Ronald Reagan Washington National Airport, 85 Fed. Reg. 16,989 (Mar. 25, 2020) (tentative FAA determination to extend certain coronavirus-related waivers for flight requirements from May, 31, 2020 until October 24, 2020); *cf.* No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. 16,623 (Mar. 24, 2020) (suspending most cruise ship operations until further notice); Acting Secretary Chad Wolf Statement on the REAL ID Enforcement Deadline (Mar. 26, 2020) (extending REAL ID deadline one year until October 1, 2021 due to concerns resulting from the COVID-19 pandemic), *available at* https://www.dhs.gov/news/2020/03/26/acting-secretary-chad-wolf-statement-real-id-enforcement-deadline.

shorter extension could put pressure on manufacturers to put their employees' health and safety at risk to make up for that lost time. And, while paragraph 4 of this Court's remedy order allows FDA to exempt new products from filing requirements for good cause on a case-by-case basis, the challenges are widespread and the requests have come from numerous manufacturers and trade organizations representing thousands of individual entities. Thus, any extension should more equitably apply to all manufacturers.

13. Moreover, as a result of the outbreak, a number of CTP personnel have been deployed to work on outbreak issues for the U.S. Public Health Service, including many within one of the divisions in CTP's Office of Science, which is responsible for reviewing applications. In addition, the available FDA staff responsible for reviewing and processing premarket applications will be teleworking until further notice. While the FDA has taken steps to enable work to be performed remotely as much as possible, it anticipates that receiving and processing applications, and then conducting scientific review of the applications with a remote workforce, will take additional time. The requested extension would allow FDA staff to continue reviewing the premarket applications that have been submitted to date, and when new premarket applications are submitted before the proposed new deadline, FDA staff could then devote its attention to those new applications. It is not clear at this point what the precise impact of the COVID-19 outbreak will be on the scope of FDA's ability to complete application reviews within the 12-month period of time once applications are filed.

14. On March 10, 2020, FDA issued 22 Warning Letters to e-cigarette retailers and manufacturers consistent with its January 2, 2020 enforcement priorities guidance.[21] These

[21] *See* FDA Warns Retailers, Manufacturers to Remove Unauthorized E-Cigarette Products from Market (Mar. 10, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-warns-retailers-manufacturers-remove-unauthorized-e-cigarette-products-market.

warning letters are the first of what are expected to be a series of ongoing actions to protect youth from the dangers of tobacco use. FDA will continue to monitor any available data about youth usage trends and take appropriate action.

15. If this Court were to grant a 120-day extension for submission of applications by May 12, 2020, FDA would intend to revise the January 2020 guidance to be consistent with the new deadline pursuant to its procedures for Level 2 Guidance in 21 C.F.R. § 10.115(g)(4).

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Dated: Silver Spring, Maryland

March 30, 2020

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Mitchell Zeller
Director, Center for Tobacco Products
United States Food and Drug Administration

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 8:18-cv-883-PWG

[PROPOSED] INDICATIVE RULING

Upon consideration of Defendants' request for an indicative ruling on a motion under Federal Rule of Civil Procedure 60(b) for a 120-day extension of the premarket application deadline imposed by the Court's remedy order [ECF No. 127] in light of the global outbreak of respiratory illness caused by a new coronavirus, the Court hereby **STATES** that

The Court would **GRANT** the motion if the case were remanded for that purpose; and

The Court would **MODIFY** paragraph 1 on page 12 of the remedy order to read as follows: "1. the FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed by September 9, 2020;" and

The Court would **MODIFY** all other references in the remedy order to the "ten-month deadline for submissions" to the "September 9, 2020 deadline for submissions."

Dated: _____

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PAUL W. GRIMM
United States District Judge