UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN KRATOM ASSOCIATION, 5501 Merchants View Square #202 Haymarket, VA 20169, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of the DEPARTMENT OF HEALTH AND HUMAN SERVICES; DEPARTMENT OF HEALTH AND HUMAN SERVICES; JANET WOODCOCK, M.D., in her official capacity as Acting Commission of Food and Drugs; FOOD AND DRUG ADMINISTRATION, Defendants.	Civil Action No. 21-2118

MEMORANDUM IN SUPPORT OF EMERGENCY MOTION
FOR A TEMPORARY RESTRAINING ORDER

Plaintiff, American Kratom Association, moves for a temporary restraining order against the defendants to extend the comment period on a submission to the World Health Organization (WHO) Expert Committee Pre-Review of a substance known as kratom from August 9 to August 30, 2021. This emergency relief is necessary because Defendants Xavier Becerra ("Secretary Becerra"), in his official capacity as Secretary of the Department of Health And Human Services; Department of Health And Human Services ("HHS"); Janet Woodcock, M.D., in her official capacity as Acting Commissioner of Food and Drugs; and the Food and Drug Administration ("FDA") (collectively referred to as "Defendants") failed to provide a sufficient opportunity to allow interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking,

and impact of scheduling changes on availability for medical use of seven drug substances, one of which is kratom. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO). The FDA received notice of the proposed WHO Expert Committee Pre-Review of kratom on June 10, 2021, but deliberately delayed the required Federal Register Notice soliciting public comments until July 23, and then required public comments to be submitted no later than August 9. That period provides AKA, scientists and the public only 17 days – 11 business days – to prepare and submit comments. That is unreasonable, violates requirements of the Controlled Substances Act, and the procedural safeguards of the Administrative Procedures Act.

AKA's request for a very brief extension of the comment period – from August 9 to August 30 – is imminently reasonable and will allow for further substantive and helpful comments to be provided from AKA and the public, including the scientific community, on the benefits of kratom to consumers.

FACTS

AKA brings this action against Defendants for a temporary restraining order and injunctive relief.[1] Defendants have provided an insufficient opportunity to allow "interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of seven drug substances, one of which is kratom. These comments will be considered in preparing a response from the United States to the WHO regarding the abuse liability and

[1] This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1346, and 5 U.S.C. §§ 701-06. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a) and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06. Complaint ¶ 9.

diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. This notice requesting comments is required by the Controlled Substances Act (CSA)." 86 Fed. Reg. 39038 (July 23 2021). Verified Complaint Ex. 1 (Dkt. No. 1-1). The government received the notice from WHO on June 10, 2021. Notice and opportunity to comment in this situation is **required** by the Controlled Substances Act. *See* 21 U.S.C. § 811(d)(2)(a). The Federal Register Notice was published on **July 23**, 2021 and required comments to be submitted by **August 9**, 2021 – only 17 calendar days and 11 business days. Complaint ¶¶ 1, 2, 32.[2] AKA respectfully requests that the Court enter a limited TRO to extend the comment period in the Federal Register Notice from August 9, 2021 to August 30, 2021 or other date determined by the Court.

FACTS

A. AKA

AKA is a Virginia nonstock corporation located in Haymarket, Virginia. Complaint ¶ 4. AKA was formed to protect the right of all Americans to use the natural botanical Kratom for improved health and well-being. Kratom (Mitragyna speciosa) is a botanical that has been used for hundreds of years as a food, and to safely alleviate pain, combat fatigue and help with the effects of anxiety and depression.[3] Unfortunately, the spread of

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[2] The factual allegations in AKA's Complaint have been verified by C. McKlain Haddow. Dkt. No. 1-8.

[3] Additional information about kratom (Mitragyna speciosa) is found in ¶ 12 of the Complaint. It is a tree in the coffee family, found in Thailand and other tropical countries. It is indigenous to Thailand, Indonesia, Malaysia, Myanmar, and Papua New Guinea, where it has been used in herbal medicine since at least the nineteenth century. Traditionally, in Southeast Asia, people have chewed its leaves or made them into a tea that is used to fight fatigue and improve work productivity. Kratom is particularly popular in Thailand where it is sometimes mixed with iced-down caffeinated soda. Kratom leaves

misinformation, both scientific and anecdotal, about Kratom has created a challenging regulatory environment. AKA organizes and represents a community of responsible consumers, provide the general public with clarification surrounding matters of health and wellness where kratom could play an important role, educate lawmakers and regulators and support scientific research efforts. AKA maintains a website at https://www.americankratom.org. *Id.* ¶ 13.

AKA is dedicated to protecting the rights of all Americans to legally consume safe kratom to better manage their overall health and well-being. Advocating for the estimated 12–15 million Americans who regularly use kratom, the AKA seeks to provide accurate and science-based information on kratom's safe use to legislators, policymakers, and

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can be chewed, and dry kratom can be swallowed, brewed or consumed in cooked meals. The leaves are dark green and glossy and can grow to over 14–20 cm (5.5–7.9 in) long and 7–12 cm (2.8–4.7 in) wide when fully open, are ovate-acuminate in shape, and opposite in growth pattern, with 12–17 pairs of veins. The flowers, which are deep yellow, grow in clusters of three at the ends of the branches. Kratom was first formally described by the Dutch colonial botanist Pieter Korthals in 1839, who named it Stephegyne speciosa; it was renamed and reclassified several times before George Darby Haviland provided the final name and classification in 1859. The species, Mitragyna speciose, has two active chemical compounds: miragyna and 7-hydroxymitragynine. The physiological effects of these compounds are similar to sedatives when consumed in high doses and to stimulants when consumed in low doses. In Western countries, it is most often found in powders, capsules, extracts, or even drinks. In the United States, kratom is widely available as powder from dried leaves, capsules, tablets, extract, tea or whole leaves. Kratom comes in many strains that are sorted by the strain, originating country (Thailand, Indonesia, etc.), and the color – green, red, and white. While each color, country, and strain is recognized for its differing effects, the color changes little, meaning even a red or white strain kratom will still look green. The taste of kratom has been described as bitter and horrible, prompting many kratom users to consume it via capsule instead of powders. When consumed in powder form, users tend to mix it in water and drink it very quickly or brew it as a tea. When consumed in water, the horrible taste remains, hence the reason to consume it quickly. Whereas, when consumed in a tea, users can mix in other tea herbs to mask the awful taste. And, of course, if consumed in capsule form, there is no taste at all. The smell of kratom in powder form is quite mild but distinctively leaf-like. It can be compared to fresh lawn clippings or grass.

consumers. *Id*. ¶ 14. AKA's mission and intent to provide science-based comments provides it with standing to seek the requested relief.

Kratom has many beneficial purposes and is an all-natural product. The AKA advocates for responsible legislation and regulations to protect consumers from contaminated, adulterated, and mislabeled kratom products. The AKA maintains a GMP good manufacturing practices ("GMP") program to encourage vendors to commit to high GMP standards in producing safe kratom products and verify compliance with an annual independent third-party audit. The AKA also regularly surveys the kratom marketplace under its Truth in Labeling program to identify kratom sellers who make illegal therapeutic claims on kratom products, and violators are reported to the FDA. It is committed to safe product manufacturing and marketing to protect consumers. AKA supports a global initiative to demonstrate responsible use and practical knowledge the United States and other countries that they may rely upon when considering kratom regulatory policies. Kratom trees are a natural resource, and the AKA supports and advocates for sustainable harvesting techniques and reforestation efforts. *Id*. ¶. 15.

B. FDA'S HOSTILITY TO KRATOM

The regulatory history of kratom provides some important context for AKA's motion. For some time, the FDA has been hostile to the use by consumers of kratom. It has attempted to remove kratom from the market. For example, the FDA issued warning letters to certain companies selling kratom. However, apparently fearing defeat, it has never filed an action against any those companies to stop sales of kratom. *Id*. ¶ 16.

Since at least 2016, the FDA has sought to enlist the Drug Enforcement Administration ("DEA") to list kratom as a Schedule I drug under the Controlled

Substances Act ("CSA"). *See* 21 U.S.C. § 811. In a letter to DEA, dated May 18, 2016, the then Assistant Secretary of HHS advised that, based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for mitragynine and 7-hydroxymitragynine. The Assistant Secretary also stated that the HHS had no objection to the temporary placement of mitragynine and 7-hydroxymitragynine into schedule I of the CSA. In response, the DEA, on August 31, 2016, published in the Federal Register a Notice of Intent ("NOI") to temporarily reclassify two constituents of kratom (mitragynine and 7-hydroxymitragynine) as Schedule I narcotics under the CSA. Citing public outcry, insufficiency of evidence to support the scheduling under the CSA, and a need to obtain more research, DEA withdrew its NOI on October 13, 2016. The FDA submitted a second recommendation to the Acting Administrator of DEA on October 17, 2017, to once again recommend that the same two constituents of kratom be scheduled as Schedule I narcotics under the CSA. Finally, on August 8, 2018, the HHS Assistant Secretary for Health wrote to the Acting Administrator of the DEA, and, based on "concerns for unintended public health consequences" and "in light of the underdeveloped state of the science," rescinded the prior recommendation dated October 17, 2017. Complaint ¶ 17.

FDA's hostility to kratom has been criticized by respected scientists. In September 2016, for example, 11 scientists from well-respected research institutions wrote to Congress expressing grave concern about the potential to schedule kratom under the CSA. The letter stated that there are a significant number of individuals using kratom as a treatment for numerous medical conditions, including chronic pain, depression, and weaning addictions to other, more dangerous opioids. Although instances of self-

medication are concerning to us in the medical community, the majority of such patients so far report that they achieve therapeutic benefits with few side effects, while occurrences of serious abuse or dependence remain infrequent. The scientists also expressed concern that scheduling kratom under the CSA would inhibit research into the benefits of kratom to the public. Complaint ¶ 18; Ex. 2 (Dkt. No. 1-2); *see also* Exs. 3-4 (Dkt. Nos. 3-4).

In June 2018, nine scientists from well-established universities and institutions wrote a letter to Congressional leadership warning against the FDA's attempt to schedule kratom under the CSA and that such an action was not supported by the science. Complaint ¶ 19; Ex. 5 (Dkt. No. 1-5); *see also* Ex. 7 (Dkt. No. 1-7).

On August 16, 2018, the HHS Assistant Secretary for Health wrote to the Acting Administrator of the DEA to urge that kratom not be scheduled under the CSA, either temporarily or permanently, without further scientific research. Complaint ¶ 20; Ex. 6 (Dkt. No. 1-6). Inexplicably, this decision by HHS was kept from the public until 2021. The FDA continued to allow the public, policy makers at the federal, state, and local levels, the media, and the scientific community to believe its recommendation to schedule kratom was actively being considered by DEA, which was no longer the case. Complaint ¶ 21.

D. FEDERAL REGISTER NOTICE

On July 23, 2021, FDA as part of HHS filed a Federal Register Notice requesting comments on international drug scheduling for a series of products, one of which was kratom. 86 Fed. Reg. 39038. Complaint ¶ 22; Ex. 1 (Dkt. No. 1-1).

The Federal Register Notice wrote that the United States is a party to the 1971 Convention on Psychotropic Substances ("Psychotropic Convention"). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has

information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations and provide the U.N. Secretary-General with information in support of its opinion. The Notice then goes on to say that:

> Paragraph (d)(2)(A) of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the Federal Register and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

86 Fed. Reg. at 39039; *see also* Complaint ¶ 24.

The WHO notice at issue was sent to Secretary Becerra on or about **June 10**, 2021. The Federal Register Notice quoted from some of the WHO communication (with "nonrelevant text removed"). 86 Fed. Reg. at 39039.

> The WHO communication specifically called out kratom for review:
>
> *Pre-reviews:* The substances listed below have been proposed for a pre-review. The purpose of a pre-review is to determine whether current information justifies an Expert Committee critical review. A pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed.
>
> Herbal drugs: 6. Kratom, mitragynine, 7- hydroxymitragynine

Id. In discussing the substances under review, the FDA once again displays its hostility to kratom. The Notice concludes:

> Mitragynine and 7- hydroxymitragynine are the main active constituents of the plant *Mitragyna speciosa,* commonly known as kratom, an indigenous plant of Southeast Asia. Kratom is abused for its ability to produce opioid-like effects. Kratom is available in several different forms to include

> dried/crushed leaves, powder, capsules, tablets, liquids, and gum/ resin. Kratom is an increasingly popular drug of abuse and readily available on the recreational drug market in the United States. Evidence suggests that kratom is abused individually and with other psychoactive substances. Kratom does not have an approved medical use in the United States and has not been studied as a treatment agent in the United States. Kratom has a history of being used as an opium substitute in Southeast Asia. In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms. Consumption of kratom can lead to a number of health impacts, including, among others, respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom has been reported to have both narcotic and stimulant-like effects, and withdrawal symptoms may include hostility, aggression, excessive tearing, aching of muscles and bones, and jerky limb movements. Kratom is not a controlled substance under the CSA.

Id. at 39040.

The Notice also states that "HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/ export) of these drug substances and could impose certain recordkeeping requirements on them." *Id*.

The FDA's description of kratom is overwhelmingly negative. There is nothing in the Federal Register Notice that indicates that the FDA has consider the benefits from kratom set forth in HHS' August 16, 2018 letter to DEA. Ex. 6. Nor did it consider the statements by doctors, scientists, and legislators. Exs. 2-5, 7. It did not include any recent study finding that kratom is unsafe when used appropriately. Complaint ¶ 28.

E. INADEQUATE NOTICE AND COMMENT PERIOD

While Defendants received the WHO communication on or about June 10, 2021, the FDA waited until **July 23** to publish a Federal Register notice seeking comment by **August 9**. There was no excuse for such delay. Nor does it appear that WHO has a deadline for materials regarding the substances at issue. *Id*. ¶ 29.

Notice and the opportunity to comment regarding the substances listed in the WHO communication, including kratom, is required by the CSA:

> Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

21 U.S.C. § 811(d)(2)(A). Providing the public with only 17 calendar days (11 business days) with notice and the opportunity to prepare and submit comments on kratom is unreasonable, contrary to the CSA and the procedural safeguards of the APA. Complaint ¶ 31. Agencies must give interested persons an opportunity to submit written data, views or arguments too agencies. 5 U.S.C. § 553(c). Typically, the required time period is 30 days. *Id.* § 553(d). The Federal Register Notice's August 9 deadline is inadequate and unlawful.

AKA asked FDA to extend the deadline for comments from August 9 to August 30. A copy was emailed to the person in FDA's Office of Policy who issued the notice. No response has been received, necessitating the filing of AKA's Complaint and this TRO motion.[4]

[4] According to the information available on the government's website regulations.gov, as of August 5, 2021, the FDA received more than 6,400 comments. *Id.* ¶ 33.

ARGUMENT

In deciding whether to grant a TRO, the Court must consider four factors: (1) the likelihood of success on the merits; (2) the irreparable harm to the plaintiff if the TRO is not granted; (3) whether the equities, on balance, favor a TRO; and (4) the public interest. *See, e.g., Winter v. Natural Resources Defense Council,* 129 S. Ct. 365, 374 (2008); *Chaplaincy of Full Gospel Churches v. England,* 454 F.3d 290, 297 (D.C. Cir. 2006). Although the moving party bears the burden on all four factors, it is not necessary for the moving party to make an equally strong showing on each. Rather, "district courts may employ a sliding scale under which a particularly strong showing in one area can compensate for weakness in another." *Brady Campaign to Prevent Gun Violence v. Salazar,* 612 F. Supp. 2d 1, 11-12 (D.D.C. 2009); *see also England*, 454 F.3d at 297. Thus, "[i]f the showing in one area is particularly strong, an injunction may issue even if the showings in the other areas is rather weak." *England*, 454 F.3d at 297. Irrespective of the sliding scale, each of the four factors weighs in favor of AKA's motion to extend the comment period. TRO and preliminary injunction enjoining implementation of the Interim Final Rules until a full notice and comment period is allowed.

I. AKA WILL LIKELY SUCCEED ON THE MERITS.

AKA is likely to prevail on the merits of its claim that Defendants failed to provide a sufficient opportunity for AKA and other stakeholders to provide meaningful comment and input on the abuse liability and diversion of certain substances, kratom, that FDA would consider in responding to a June 10, 2021, notice from the WHO. The Notice seeks comments from interested persons "concerning abuse potential, actual abuse, medical

usefulness, trafficking, and impact of scheduling changes on availability for medical use of seven drug substances", one of which is kratom. 89 Fed. Reg. 39038. The Federal Register Notice admits that "WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances." 89 Fed. Reg. 39038-39. The WHO has set up a process by which kratom becomes an illegal drug in the United States and other countries.

The importance of the notice and comment requirement is well established. Providing notice and opportunity for comment before taking regulatory action improves the quality of administrative rulemaking and enhances the quality of judicial review of agency actions. See, e.g., *Int'l Union, United Mine Workers of Am. v. MSHA*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) ("Notice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."). Notice and comment requirements exist to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (citing 5 U.S.C. § 553(b)-(c)). "The notice and comment procedure also is designed to encourage public participation in the administrative process." *N.C. Growers' Assn., Inc. v. United Farm Workers*, 702 F.3d 755, (4th Cir. 2012). Significantly, "[t]he opportunity for comment must be a **meaningful opportunity**." *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009) (emphasis added); *see also N.C. Growers' Assn., Inc.*, 702 F.3d at 763; *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d

Cir. 2011). An agency's "failure to provide a meaningful opportunity to comment is underscored by the brevity of the comment period." *California, by and through Xavier Becerra v. U.S. Dep't of the Interior*, 381 F. Supp. 3d 1153, 1176 (N.D. Cal. 2019).

And we should not forget that agencies themselves benefit from public comments. *See, e,g., Public Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993). Comments provide a public platform discuss the real world effects of proposed agency action on those most affected by it and to minimize unintended consequences.

AKA and other stakeholders have a right to provide comments. The FDA admits that "[t]his notice requesting comments is required by the Controlled Substances Act (CSA)." 86 Fed. Reg. 39038. The CSA provides that, upon receipt of a notification from pursuant to article 2 of the Convention on Psychotropic Substances the Secretary of Health and Human Services shall "publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance." 21 U.S.C. § 811(d)(2)(A). Such comments are to be used in preparing the HHS Secretary's response to the international agency. *Id.* Here, the government has received such a notice from the WHO under article 2 of the Convention on Psychotropic Substances regarding the scheduling of a substance, kratom. The HHS Secretary "shall" "provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance." *Id.* The Federal Register Notice was published on July 23. 2021 and mandated that comments be submitted by **August 9** – 17 calendar days and 11 business days from publication. The Notice

expressly states that comments received after that date "will not be considered." 89 Fed. Reg. 39038.

Such a truncated comment period is contrary to the CSA and the Administrative Procedures Act. Courts must "hold unlawful and set aside agency action that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Defendants have not provided the required adequate opportunity for AKA and the public, including the AKA, to provide substantive and meaningful comments on whether kratom should be restricted as a controlled substance.

Further, an adequate comment period is necessary because the Federal Register Notice makes clear that FDA is hostile to the use of kratom.[5] This has been true since at least 2016 when the FDA failed to have kratom become a controlled substance under the CSA. *See, e.g.*, Complaint ¶ 17. There is nothing in the Notice that sets forth the beneficial uses of kratom. In June 2018, nine scientists from well-established universities and institutions wrote a letter to Congressional leadership warning against the FDA's attempt to schedule kratom under the CSA as being contrary to science. Complaint ¶ 19; Ex. 5 (Dkt.

[5] 89 Fed. Reg. at 39040 ("Kratom is abused for its ability to produce opioid-like effects. Kratom is available in several different forms to include dried/crushed leaves, powder, capsules, tablets, liquids, and gum/ resin. Kratom is an increasingly popular drug of abuse and readily available on the recreational drug market in the United States. Evidence suggests that kratom is abused individually and with other psychoactive substances. Kratom does not have an approved medical use in the United States and has not been studied as a treatment agent in the United States. Kratom has a history of being used as an opium substitute in Southeast Asia. In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms. Consumption of kratom can lead to a number of health impacts, including, among others, respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom has been reported to have both narcotic and stimulant-like effects, and withdrawal symptoms may include hostility, aggression, excessive tearing, aching of muscles and bones, and jerky limb movements. Kratom is not a controlled substance under the CSA.").

No. 1-5). On August 16, 2018, the HHS Assistant Secretary for Health wrote to the Acting Administrator of the DEA to urge that kratom not be scheduled under the CSA, either temporarily or permanently, without further scientific research. Ex. 6 (Dkt. No. 1-6); see also Ex. 7 (Dkt. No. 1-7). There is no indication in the Notice that the FDA has any new research to support scheduling.

Given the FDA's apparent prejudgment of the issue (and contrary to the August 2018 letter from HHS' then Acting Assistant Secretary for Health and Senior Advisor for Opioid Policy (Ex. 6, Dkt. No. 1-6), AKA and the public should be given an adequate amount of time to prepare and make submissions. The August 9 deadline does not allow for that. *See United Steelworkers of Am. v. Marshall,* 647 F.2d 1189, 1225 (D.C. Cir. 1980) (noting importance of comment procedures for airing "criticisms which the Agency might find convincing").

II. AKA WOULD BE IRREPARABLY HARMED IF THE TRO IS DENIED.

The Notice's August 9 deadline is arbitrary. AKA, its members, consumers and others who rely upon the scientifically proven benefits of kratom will be irreparably harmed by the limited amount of time currently given to prepare and file comments with the FDA. This result would harm those denied the right to fully comment on the important issues raised by the WHO and FDA's Notice. *See Sugar Cane Growers Cooperative of Fla. v. Veneman,* 289 F.3d 89, 94-95 (D.C. Cir. 2002). The harm to AKA and others cannot be remedied by money damages.

III. THE BALANCE OF THE EQUITIES FAVOR GRANTING A TRO.

In the case, the equities tip toward AKA, which (along with interested parties) has a statutory right to submit comments under the CSA. Defendants admit they received the

WHO notice for comments on June 10, 2021. 89 Fed. Reg. at 39039. They waited **six weeks** to publish the Notice in the Federal Register, doing so on July 23. *Id*. They gave the public, however, only 17 days to file comments pursuant to the CSA. There is no explanation in the Federal Register Notice for the delay in publishing the Notice and the truncated comment period. Indeed, in other international drug scheduling notices, Defendants provided at least 30 days for comments. *See, e.g.*, 86 Fed. Reg. 10097 (Feb. 18, 2021); 84 Fed. Reg. 72370 (Dec. 31, 2019). Defendants will not be harmed or unfairly prejudiced if the comment period for kratom is extended from August 9 to August 30.

IV. THE REQUESTED TRO IS IN THE PUBLIC INTEREST.

The notice and comment procedure serves the public interest and is a "primary method of assuring that an agency's decisions will be informed and responsive." *New Jersey v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). And as set forth above, § 811(d)(2)(a) of the CSA provides the public with the right to comment on decisions that could lead to the national and international scheduling a controlled substance. The brief extension of the comment deadline would be in the public interest.

CONCLUSION

For the foregoing reasons, AKA respectfully request that the Court issue a temporary restraining order to briefly extend the comment period in the Federal Register Notice from August 9, 2021 to August 30, 2021 or other date determined by the Court.

Dated: August 9, 2021

Respectfully submitted,

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