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Pro Se

THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

MARK BAKER,

Plaintiff,

vs.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants

Case No.: 2:24-CV02558-DJC JDP (PS)

PLAINTIFF RESPONSE TO DEFENDANT'S MOTION TO DISMISS

I. INTRODUCTION

1. On September 23, 2024, Plaintiff Mark Baker ("Plaintiff"), filed suit against the United States Food and Drug Administration ("FDA") and National Highway Traffic Safety Administration ("NHTSA"), for failing to comply with 21 U.S.C. 360ii(a)(6)(A) by not maintaining a liaison to test and evaluate LED headlamps, and for the FDA unlawfully dissolving the Technical Electronic Product Radiation Safety Standards Committee ("TEPRSSC" (tep-ur-sek)), in violation of 21 U.S.C. 360kk(f)(1)(A).

2. On December 3, 2024, Defendants, via the US Department of Justice ("DOJ"), responded by filing a Motion to Dismiss. Defendant's arguments for dismissal are: 1) Plaintiff has not

established standing; 2) No statute requires agency action; 3) No statute requires that TEPRSSC hold meetings.

3. Plaintiff rebuts Defendant's arguments with the following summaries:

4. 1) Standing – Plaintiff has been injured numerous times over the past 10 years from exposure to LED headlamps resulting in involuntary hospitalization, loss of employment, and psychological trauma and these injuries were caused by the FDA and NHTSA's failure to comply with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A). Thus, Plaintiff has standing to sue.

5. 2) Agency Action – The Defendant's response is that the FDA and NHTSA may act arbitrarily and capriciously and without reasoned decision making and are free to ignore even non-discretionary statutes and the will of Congress. However, Defendant's position that the FDA and NHTSA are not required to act in compliance with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A) is unsupported because federal agencies are prohibited from acting arbitrarily and capriciously, and because federal agencies must employ reasoned decision making. (*Department of Commerce v. New York* 588 U.S. (2019) quoting *Baltimore Gas & Elec. Co.* v. *Natural Resources Defense Council*, *Inc.*, 462 U.S. 87, 105 (1983).)

6. 3) TEPRSSC Meetings – TEPRSSC has met just once in the past 21 years, has only 4 out of 15 positions filled, and there is no chairperson. Defendant claims that even though the existence of TEPRSSC is mandatory, TEPRSSC is not required to meet. However, Defendant offers no reasoned decision making for why TEPRSSC has met only once in the past 21 years. Defendant FDA has no policy in place for how often TEPRSSC should meet and no policy for how to ensure that all 15 positions are filled. In addition, the FDA has

outsourced TEPRSSC duties to a secret, unnamed organization, which indicates possible conflict-of-interest or outright corruption. The FDA's decision not to hold TEPRSSC meetings is not based on reasoned decision making and is thus a violation of the Administrative Procedure Act. ("APA").

II. STANDING

7. According to the Defendant, "To establish standing, Plaintiff must demonstrate that he has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant[s], and (3) that it is likely to be redressed by a favorable decision. Spokeo v. Robbins, 578 U.S. 330, 338 (2016)." (MTD p.7, line 26). As shown below, Plaintiff meets all three criteria for standing.

8. **1) Injury in Fac**t - Plaintiff was first injured by LED vehicle headlamps around 2015. Plaintiff's most vivid recollection is of the incredible hot-white intensity of Cadillac LED Daytime Running Lights ("DRLs") and headlamps. Plaintiff's psychological reaction to LED headlamps and DRLs was a feeling of evil, an emotion that Plaintiff had never felt before. Even though the LED headlamps felt white-hot, Plaintiff was unable to avert his gaze from the LED lights, which captured Plaintiff's attention.

9. Over time, Plaintiff became more and more distraught each time Plaintiff was subjected to LED headlamps and DRLs. Plaintiff has since learned that these blue-rich LED lights are a photobiological, neurological, psychological, and hormonal health hazard and thus Plaintiff is likely reacting with fight or flight impulses due to the risk of significant harm from exposure to LED headlamps.

10. Plaintiff eventually suffered a catastrophic mental breakdown due to continued exposure to LED headlamps and other LED lighting sources and was involuntarily hospitalized and

subsequently lost his job as a math teacher in 2019. Plaintiff has not been employed since. Plaintiff's medical records document these events. Thus, Plaintiff has met the criteria for Injury in Fact.

11. **2) Injury Traceable to FDA and NHTSA Actions** – No automaker has complied with the Administrative Procedure Act and submitted a petition to NHTSA for authorization to manufacture and sell vehicles using LED headlamp technology. In 2014, the US Department of Energy described LEDs as "radically new technology" with "directional" light and "unique characteristics."[1] Because no automaker submitted a petition to NHTSA for permission to use LED headlamp technology, NHTSA never engaged in the rulemaking process for LED vehicle headlamps and never updated its headlamp standard, FMVSS-108, to address the directional light and unique characteristics (e.g. blue wavelength light) of this radically new technology.

12. As LED vehicle headlamp technology started appearing on vehicles, the FDA and NHTSA did not consult each other and did not establish a liaison to test and evaluate LED vehicle headlamp technology, despite the DOE's warnings that LEDs are a directional light source with unique characteristics. The FDA and NHTSA failed to establish that LED vehicle headlamp technology, with its intense beam and use of blue-rich light, is biologically safe for humans. Nor did the FDA and NHTSA take any collaborative action to ensure that LED vehicle headlamps are safe for individuals with autism, epilepsy, migraines, or photophobia. Neither the FDA nor NHTSA established any performance standards, such as limits on intensity or limits on blue wavelength light, to ensure the protection of Plaintiff

[1] https://www1.eere.energy.gov/buildings/publications/pdfs/ssl/ssl_lessons-learned_2014.pdf

or the public in general. It is this failure of the FDA and NHTSA to comply with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A) that directly led to Plaintiff's injuries. Thus, Plaintiff has met the criteria for Traceability to Defendant's Conduct.

13. **3) Redressability by Favorable Decision** - The Soft Lights Foundation, with Plaintiff as President, has submitted several regulatory petitions to NHTSA and the FDA to solve the issue of debilitating and dangerous LED vehicle headlamp glare. A petition submitted on March 1, 2024, requests that NHTSA set an overall limit on intensity. (APPENDIX A). A petition submitted on May 15, 2024, requests that NHTSA set a limit on blue wavelength light. (APPENDIX B). NHTSA is required to either approve or deny each petition within 120 days yet failed to do so. On October 22, 2024, the Soft Lights Foundation submitted a letter to NHTSA requesting justification for NHTSA's failure to approve or deny the petitions.[2] NHTSA did not respond.

14. Thus, even when presented with solutions for how to solve the hazardous and dangerous glare from LED vehicle headlamps that would help alleviate Plaintiff's injuries, NHTSA and the FDA have still chosen not to consult with each other, not to maintain a liaison to evaluate the Soft Lights Foundation petitions, and not to have TEPRSSC provide technical assistance in this matter. Since a ruling by this court directing the FDA and NHTSA to comply with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A) would likely result in performance standards for LED vehicle headlamps to limit the intensity and blue wavelength light that is causing Plaintiff's injuries, Plaintiff has met the criteria for Redressability by Favorable Decision.

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[2] https://www.softlights.org/wp-content/uploads/2024/10/Headlight-Intensity-Failure-to-Decide.pdf

15. In this section, Plaintiff has shown that Plaintiff has met all three criteria for standing to sue.

III. AGENCY ACTION

16. Defendant claims that 21 U.S.C. 360ii(a)(6)(A) does not require the FDA and NHTSA to liaise to test and evaluate LED headlamps. This is a false claim.

17. 21 U.S.C. 360ii(a)(6)(A) states, "[The FDA] shall consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on techniques, equipment, and programs for testing and evaluating electronic product radiation,".

18. As can be seen in the statute, the FDA shall (meaning "must") both consult and maintain liaison with federal agencies, which includes NHTSA, to test and evaluate electronic product radiation, which includes LED vehicle headlamps.

19. A liaison in this case is cooperation between two federal agencies, FDA and NHTSA. Nowhere in Defendant's Motion to Dismiss is there any indication that such a liaison between the FDA and NHTSA exists. Defendant provides no copies of email communications between the FDA and NHTSA, no phone records, no program names, no listing of individuals from each organization who are cooperating, and no meeting dates. In other words, the Defendant concedes that the liaison between the FDA and NHTSA does not exist, even though the liaison is mandated by 21 U.S.C. 360ii(a)(6)(A).

20. In a December 2, 2022, letter to the Soft Lights Foundation, NHTSA wrote, "NHTSA, as an agency focused on automotive safety, also recognizes the expertise of its sister agencies

that are health-focused, such as the FDA."[3] In other words, NHTSA is stating that NHTSA makes no effort to ensure that LED vehicle headlamps are biologically safe for humans, and is stating that NHTSA completely defers to the FDA for ensuring that LED vehicle headlamps are biologically safe. Defendant, in fact, concedes this deference, stating "Each agency has also recognized, and deferred to, the other's distinct area of expertise and authority." (MTD p.12, line 9). This deference of NHTSA to the FDA for health-related matters concerning LED vehicle headlamps is directly contrary to 21 U.S.C. 360ii(a)(6)(A) and the will of Congress which mandates that the FDA and NHTSA maintain a liaison and collaborate together to ensure that LED headlamps are safe for public exposure.

21. Defendant claims that 21 U.S.C. 360ii(a)(6)(A) does not require a discreet agency action and refers to Norton v. S. Utah Wilderness All., 542 U.S. 55, 64 (2004) (MTD p.14, line 10). Yet 21 U.S.C. 360ii(a)(6)(A) is a non-discretionary statute which directs the FDA to maintain a liaison with federal agencies on matters involving electromagnetic radiation. As described above, the FDA and NHTSA have no such liaison. The FDA has not contacted NHTSA to establish the liaison, nor has NHTSA contacted the FDA to establish the liaison.

22. If the FDA is to claim that a liaison between the FDA and NHTSA is not necessary, then the FDA must make this decision using reasoned decision making and cannot act arbitrarily or capriciously. However, the FDA has not used any type of reasoned decision making regarding why the FDA-NHTSA liaison does not exist, nor has NHTSA any used type of reasoned decision making as to why NHTSA defers to the FDA for ensuring that LED vehicle headlamps are biologically safe. Neither the FDA nor NHTSA have any policies in

[3] https://www.softlights.org/wp-content/uploads/2022/12/NHTSA-220815-006_ND.pdf

place that would guide those agencies as to what criteria is used when deciding that a liaison between the two agencies should not exist. For example, there is no Memorandum of Understanding between NHTSA and the FDA that might detail the contact persons, how often meetings should take place, and/or what topics should be addressed.

23. Over 64,000 individuals have signed a petition to ban blinding headlights.[4] This petition was started in 2016 when LED headlamps first started appearing on vehicles. In addition to the 64,000+ signatures, there are thousands of comments from the public, describing the harmful and debilitating impacts of LED vehicle headlamps. (APPENDIX C). There can be no doubt that LED vehicle headlamps are hazardous and dangerous and need to be regulated.

24. Due to the failure of NHTSA and the FDA to collaborate and establish performance standards for LED vehicle headlamps, Plaintiff, as President of the Soft Lights Foundation, was contacted in September 2024 by a staff member of a state legislator requesting assistance writing a law called the Safe Headlights Act. Plaintiff wrote a bill to limit intensity and blue wavelength light at the state level and this bill is now being introduced into the state assembly. Passage of this state-level bill may result in significant upheaval in the auto industry, as automakers will now be forced to ensure that their vehicles comply with both state and federal vehicle headlamp standards. NHTSA and the FDA could have, and possibly still can, prevent this situation by complying with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A).

[4] https://change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives/

25. Defendant claims that, "both FDA and NHSTA have considered Plaintiff's assertions about LED headlamps but nonetheless have not taken steps to revise their existing regulations." (MTD p.12, line 7). This is an untrue statement. In the 19-page denial based on the review by the secret outside agency of the four Soft Lights Foundation petitions to regulate LED products, including petition FDA-2023-P-3828-0001 to regulate LED vehicle headlamps, the FDA ignored the issue of LED vehicle headlamps.[5] The FDA's denial letter does not even mention the 64,000+ signatures on the petition to ban blinding headlights, does not mention the seizures, migraines, and thoughts of suicide that have been reported as a result of exposure to LED vehicle headlamps, does not mention that intensity limits are set at infinity for LED vehicle headlamps in FMVSS-108, does not mention that NHTSA FMVSS-108 has no limits on blue wavelength light, and does not refer to any testing or evaluation that the FDA or NHTSA has performed for LED vehicle headlamps. The FDA in fact took no action to consider the photobiological, neurological, psychological, hormonal, or physical impacts of LED vehicle headlamps, and so it is no surprise that the FDA and NHTSA failed to propose any performance standards for LED vehicle headlamps.

26. Defendant claims that the FDA may arbitrarily and capriciously ignore the electromagnetic radiation from all LED products because there is no specific statute listing which electronic products the FDA should be regulating. Defendant states, "Why would Congress have failed to similarly specify in § 360ii(a)(6)(A)—either in the original statute, or in the years

[5] https://www.regulations.gov/document/FDA-2023-P-3828-0001

since LED product use entered the mainstream—that it was requiring FDA to liaise with other agencies about LED products specifically?" (MTD p.15, line 14).

27. The answer to Defendant's own rhetorical question is that Congress intelligently enacted 21 U.S.C. Part C to protect the public from the harms of all electromagnetic radiation from all electronic products by providing a framework for the FDA to work with, and then allowing the FDA to test, evaluate, research, study and use reasoned decision making in deciding which products need specific performance standards and which do not. It is inconceivable that Congress should be expected to list every single electronic product ever invented or ever will be invented in a statute. The problem here is that the FDA and NHTSA have inexplicably chosen to ignore the requirements of 21 U.S.C. 360ii(a)(6)(A), establish a liaison, collaborate, test and evaluate LED headlamps, and then determine if performance standards are necessary. Defendant's concept that 21 U.S.C. 360ii(a)(6)(A) is not a discrete requirement has no basis in fact.

28. Defendant writes, "even if Plaintiff were correct that § 360ii(a)(6)(A) requires FDA to liaise with other agencies about LED products, such as headlamps, the statute nonetheless vests FDA with discretion to determine which agencies are the "appropriate" ones with which to liaise." (MTD p.16, line 10). 21 U.S.C. 360ii(a)(6) uses the phrase, "other appropriate Federal departments and agencies." The term "appropriate" could be considered discretionary IF the FDA employed reasoned decision making to decide which federal departments and agencies would be "appropriate". Due to the ubiquity of LED technology, it seems unlikely that there could even be a single federal department or agency that isn't somehow involved with LED technology. The Department of Energy is involved with LED streetlights. The Access Board is involved with the impacts of LED

light on individuals with disabilities. OSHA is involved with the impact of LED flashing lights on first responders. The CPSC is involved with the impact of LED washing machine indicator lights. Thus, the term "appropriate" in this case is non-discretionary and inclusive of all federal departments and agencies, unless the FDA can provide a strong and convincing argument that an agency such as NHTSA is not an appropriate agency to maintain a liaison with.

29. As per 21 U.S.C. 360ii(a)(6)(A), the FDA and NHTSA must be collaborating, testing and evaluating LED vehicle headlamps for photobiological, neurological, psychological, hormonal, and physical safety. During this testing and evaluation, the TEPRSSC must be intimately involved, providing technical guidance to the FDA and NHTSA about the unique characteristics of LED vehicle headlamp technology. There must be reports written about the impacts of LED vehicle headlamps which are then used to decide whether performance standards are necessary for LED vehicle headlamps. None of this is occurring.

30. The decision by the FDA and NHTSA to not collaborate on testing and evaluating LED vehicle headlamps is unjustifiable, when so many individuals have put the FDA and NHTSA on notice that LED vehicle headlamps are a hazard and danger to society and when states are now writing their own LED vehicle headlamp regulations due to the FDA and NHTSA's non-compliance with 21 U.S.C. 360ii(a)(6)(A).

31. Because the FDA and NHTSA have acted arbitrarily and capriciously and without using reasoned decision making in deciding not to maintain a liaison as required by 21 U.S.C. 360ii(a)(6)(A), the Defendant's claim that the FDA and NHTSA are not required to maintain a liaison to test and evaluate LED vehicle headlamps fails.

IV. TEPRSSC

32. The Defendant states that TEPRSSC has not been dissolved and that TEPRSSC "continues to have a role in "advis[ing] FDA regarding proposed performance standards". (MTD p.17, line 13). This is a false statement. The last time TEPRSSC met was in 2016. Before that, the last time TEPRSSC met was in 2003. Thus, between 2003 and 2024, TEPRSSC met just one time. It should be considered fraud to claim that TEPRSSC is advising the FDA regarding proposed performance standards when TEPRSSC has met just once in the past 21 years.

33. The Defendant claims that it is perfectly reasonable for TEPRSSC to have only 4 out of 15 members, no chairperson, and to have met only once in the past 21 years. A rational person should not find this situation reasonable. Why is TEPRSSC not meeting regularly? Is it because no electronic products have been invented in the past 21 years? Is it because cell towers, cell phones, WiFi routers, smart meters, LED vehicle headlamps, LED flashing lights on emergency vehicles, LED streetlights, LED general service lamps, and LED indicator lights on appliances have all been proven to be benign, with no adverse impacts on human health, and therefore there is no reason for TEPRSSC to have meetings?

34. The FDA has no policy in place that details how often TEPRSSC should meet or how to fill vacancies. Thus, the FDA is acting arbitrarily and capriciously, and without any reasoned decision making, when deciding that meeting only once every 21 years meets the intent of Congress for TEPRSSC to be an integral part of the FDA's Radiation Control Program.

35. 21 U.S.C. 360kk(f)(1)(A) states, "The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the "Committee") which he shall consult before prescribing any standard under this section.".

The Defendant states, “To the contrary, the statute requires FDA to ensure that the Committee is prepared for consultation only when the agency is contemplating “prescribing a [performance] standard under” § 360kk.” (MTD p.18, line 3). The Defendant inauthentically inserts the nonexistent concept “only when contemplating prescribing a performance standard”. The Defendant misconstrues the term “before” to mean “immediately before prescribing and after all research has been conducted.”

36. In a logical reading of 21 U.S.C. 360kk(f)(1)(A) and within the context of the Radiation Control Program and considering the intent of Congress, the term “before” means “at all times up to and including a recommendation of performance standards.” Thus, Defendant’s claim that, “the agency and Committee would only be required to consult on LED products if and when FDA were to prescribe a performance standard for such products—and FDA has already decided against doing so.” (MTD p. 12, line 16) is clearly untrue. The purpose of the 15 member TEPRSSC is to provide assistance to the FDA as part of an ongoing process for all electronic products that emit electromagnetic radiation and is not a committee that should be reconstituted every 21 years or so.

37. After the Soft Lights Foundation submitted four different petitions to the FDA to request that the FDA establish a Radiation Control Program for LED products, the FDA inexplicably outsourced the petitions to a secret organization that the FDA declines to name, rather than asking the members of TEPRSSC to review the petitions. What is the purpose of using this secret outside organization, with no known qualifications, to evaluate the Soft Lights Foundation petitions requesting compliance with 21 U.S.C 360ii for LED products? Why not just use TEPRSSC, as Congress has directed? It’s difficult not to

notice the implication that this situation involves some type of conflict-of-interest, illicit action, willful disregard for the law, or outright corruption.

38. By outsourcing the review of the four Soft Lights Foundation petitions to a secret company, but not documenting why TEPRSSC wasn't used instead, the FDA has acted arbitrarily and capriciously, in violation of the APA. In addition, the public was harmed by this action because TEPRSSC meetings are required to be publicly documented and the TEPRSSC committee consists of members of the public. By using a secret outside agency, hiding the outside agency's qualifications, documentation, and decision-making processes, and by excluding the public's right to have representatives on TEPRSSC, the FDA has acted negligently and unlawfully.

V. MOTION TO DISMISS

39. For the Motion to Dismiss, the Defendant invokes Federal Rule of Civil Procedures 12(b)(1) and 12(b)(6).

40. **FRCP 12(b)(1) – Jurisdiction**. Defendant claims that Plaintiff has failed to establish standing. However, as detailed above, Plaintiff has established standing by showing that 1) Plaintiff has suffered an injuries in fact caused by exposure to LED vehicle headlamps; 2) The FDA and NHTSA's failure to comply with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A) caused the injuries; and 3) A ruling by this court to compel the FDA and NHTSA to maintain a liaison to test and evaluate LED vehicle headlamps and to compel the FDA to establish a properly functioning TEPRSSC will redress those injuries. Thus, Defendant's Motion to Dismiss fails for 12(b)(1).

41. **FRCP 12(b)(6) – Stating a Claim**. Defendant claims that Plaintiff has failed to state a discrete action that the FDA and NHTSA are required to take. However, as detailed above, Plaintiff has established that 21 U.S.C. 360ii(a)(6)(A) requires the discrete action that NHTSA and FDA establish and maintain a liaison. Defendant made no effort to even try to convince the court that the liaison between NHTSA and the FDA does exist, but instead the Defendant attempted to claim that the liaison between NHTSA and the FDA is discretionary. Plaintiff showed that, in fact, a liaison between NHTSA and the FDA is non-discretionary because NHTSA is involved with electronic products that emit electromagnetic radiation, Plaintiff and the public are being harmed by LED vehicle headlamps, states are now implementing their own regulations for LED vehicle headlamps, and NHTSA relies on the expertise of the FDA to assist NHTSA with establishing photobiological, psychological, neurological, hormonal, and physical safety requirements for LED vehicle headlamps.

42. Plaintiff further showed that TEPRSSC is an integral part of all Radiation Control Programs, that TEPRSSC must be continually operational, not just once every 21 years, and that the FDA's decision to outsource TEPRSSC involvement to a secret outside agency violates the Congressional requirement that FDA decision making be transparent and that the public be involved in FDA decision making.

43. Thus, Defendant's Motion to Dismiss fails for 12(b)(6).

VI. CONCLUSION

44. Plaintiff has shown that: 1) Plaintiff has standing to sue because Plaintiff has been injured by the FDA and NHTSA's failure to comply with 21 U.S.C 360ii(a)(6)(A) and 21 U.S.C 360kk(f)(1)(A) for LED vehicle headlamps; 2) The FDA and NHTSA have a non-

discretionary duty to consult with each other and maintain a liaison to test and evaluate LED vehicle headlamps as per 21 U.S.C 360ii(a)(6)(A); and 3) The TEPRSSC's functions have been unlawfully usurped by the FDA and outsourced to a secret outside agency, in violation of 21 U.S.C. 360kk(f)(1)(A).

45. Defendant's position is that the debilitating glare caused by the use of LED headlamps is just a fact of life and that the problem cannot be solved, while ignoring the requirements of 21 U.S.C 360ii(a)(6)(A) and 21 U.S.C 360kk(f)(1)(A) which mandate that the FDA and NHTSA maintain a liaison and consult each other and the members of TEPRSSC to solve exactly such problems.

46. Federal agencies are not free to ignore the statutes and are not free to act arbitrarily and capriciously and without reasoned decision making, as Defendant claims. The LED headlamp glare issue is a real problem to solve, but it won't be solved with the FDA and NHTSA acting as if they can ignore their duties and statutory requirements.

47. Plaintiff respectfully requests that this Court deny Defendant's Motion to Dismiss.

Dated: December 5, 2024

Respectfully Submitted,

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