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THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA
SACRAMENTO DIVISION

MARK BAKER,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

No.2:24-cv-278-KJM-SCR

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS

Hearing Date: September 19, 2024
Time: 10:00 a.m.
Location: 501 I Street Sacramento, CA 95814
Courtroom 27, 8th Fl., Hon. Sean C. Riordan

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INTRODUCTION

After Plaintiff asked FDA to take action on LED products, the agency carefully considered his request, reviewed the evidence he submitted, and even engaged an independent organization to search the literature before denying his citizen petitions in a 19-page, science-based decision. *See generally* Ex. 1 to Defs.' Mot. to Dismiss (ECF No. 13-2) ("Petition Response"). Plaintiff may disagree with that determination, but his effort to compel a different result lacks statutory support. He therefore offers no sound reason why his opinions, however strongly held, should override FDA's expert scientific judgment, particularly given the high level of deference due to such judgment.

Even construing Plaintiff's arguments liberally, his Opposition to Defendant's Motion to Dismiss (ECF No. 15) ("Opposition") confirms that the Complaint should be dismissed. First, while Plaintiff's Opposition asserts a new claim challenging FDA's Petition Response, he cannot amend his Complaint through briefing, and regardless, amendment would be futile. Second, Plaintiff's central legal theory—which posits that Congress implicitly required FDA to take several actions concerning LED products—is based on a fundamental misreading of the Radiation Control for Health and Safety Act ("the Act"). No provision of that statute directs the agency to take discrete, mandatory action on LED products. To the contrary, Congress granted FDA the discretion to take product-specific action only where the agency finds it necessary. And third, Plaintiff's Opposition, like his Complaint, fails to satisfy the elements of a claim under the Equal Protection Clause. Defendants' motion to dismiss should therefore be granted.

ARGUMENT

I. Plaintiff's Opposition Raises New Claims that are Not Properly Before the Court.

Because a motion to dismiss under Rule 12(b)(6) is focused on the pleadings—which may only be amended in accordance with Federal Rule of Civil Procedure 15—"[s]tatements in an opposition brief do not amend the complaint." *Sears v. City of Oroville*, No. 2:22-cv-1624-KJM-KJN, 2023 WL 2958004, at *2 (E.D. Cal. April 14, 2023) (Mueller, J.) (citation omitted); *accord. Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss."). Plaintiff's Complaint must therefore be

evaluated on its own merits, without regard to any new legal theories raised in his Opposition.

For example, Plaintiff's Opposition includes a new claim that FDA's Petition Response was "not based on reasoned decionmaking" under the APA. Opp. 3. But neither that claim, nor any of Plaintiff's arguments about the Petition Response, appear in the Complaint. *Compare, e.g.*, Opp. 8, 14-17, 18, 20, 22, 28 (challenging FDA's Petition Response) *with* Compl. (ECF No. 1) at ¶¶ 70-78 (making no mention of it). Nor was this omission unintentional: as Defendants noted, the Petition Response issued *after* Plaintiff filed his Complaint, and when counsel for Defendants asked whether Plaintiff wished to amend, he declined. Mem. in Supp. of Mot. to Dismiss (ECF No. 13-1) ("Mot.") at 7 n.5. While Defendants subsequently endeavored to construe the Complaint liberally in their motion to dismiss, *see id.* at 5-7 and n.2, n.3, n.4 (addressing multiple possible interpretations of Plaintiff's claims), they also necessarily took the Complaint at face value, observing that Count One did not reference FDA's Petition Response or any other final agency action, *see id.* at 5, 7 n.5; *see also Litmon v. Harris*, 768 F.3d 1237, 1241 (9th Cir. 2014) (noting that, while courts interpret *pro se* complaints liberally, they will not supply the "essential elements" of a claim not pleaded). Plaintiff cannot now "cure [the] complaint's shortcomings" with "[n]ew averments in a brief." *Financial Indemnity Co. v. Messick*, 606 F. Supp. 3d 996, 1002 (E.D. Cal. 2022) (Mueller, J.). And for the reasons discussed below, *infra* pp. 6-8, permitting amendment to pursue this claim now would be futile.

Plaintiff's Opposition also asserts a new argument that FDA violated 21 U.S.C. § 360kk(f)(1)(A) by failing to consult the Technical Electronic Product Radiation Safety Standards Committee ("Standards Committee") before denying his request. Opp. 4. But while Plaintiff's Complaint alleged that the Standards Committee has vacancies and has not met recently, Compl. ¶ 25, it did not place Defendants on notice of his new contention that the Committee's status is unlawful, nor did it indicate that he sought relief on that basis, *compare* Opp. 3-6 *with* Compl. ¶ 25.[1]

For related reasons, the Court should also disregard Plaintiff's arguments that Defendants

[1] Similarly, if Plaintiff now seeks to pursue a legal theory under the Americans with Disabilities Act, *see* Opp. 34, he cannot because he pleaded no such claim, *see* Compl. ¶¶ 70-78.

provided "no evidence" in support of their motion to dismiss. Opp. 8, 16, 19, 21, 24, 36. "The purpose of [Rule] 12(b)(6) is to enable defendants to challenge the legal sufficiency of complaints," *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987), so the "focus" of such a motion is necessarily "the complaint," *Schneider v. California Dep't of Corrections*, 151 F.3d 1194, 1197 n.1 (9th Cir.1998). Consequently, a defendant does not bear the burden of adducing evidence in support of a motion under Rule 12(b)(6); instead, the question is whether the Complaint contains "well-pleaded facts, not legal conclusions . . . that plausibly give rise to an entitlement to relief" as a matter of law. *Whitaker v. Tesla Motors, Inc.*, 985 F.3d 1173, 1176 (9th Cir. 2021) (citation omitted)."[2]

II. Regardless, Plaintiff's Arguments in Opposition are Meritless.

A. Count One fails to identify a violation of the Act.

Count One alleges that FDA violated the Act, Compl. ¶¶ 70-73, but Plaintiff's Opposition makes clear that this claim is based upon a fundamental misreading of its text. Plaintiff argues that, because 21 U.S.C. § 360ii(a) requires FDA to "carry out a radiation control program designed to protect the public" from electronic product radiation generally, it also requires FDA to establish such a program for every specific type of product that emits electronic product radiation, including LED products. Opp. 7, ¶ 15. Plaintiff extends the same reasoning to each subpart of § 360ii(a). Opp. 7-12; *see also* Opp. 31 (applying similar reasoning to § 360jj). This reading is both unsupported by, and irreconcilable with, the Act.

Plaintiff appears to present his reading of the Act as part of a claim under 5 U.S.C. § 706(1) to "compel agency action unlawfully withheld," *see, e.g.*, Opp. 7 (arguing the Act imposes a "non-discretionary requirement" for LED products). But "even giving a liberal construction to [this] *pro se* [claim] does not" render it plausible. *See Halcomb v. Office of the Senate Sergeant-at-Arms*, 209 F. Supp.

[2] Plaintiff also styled his Opposition as a "Request for Summary Judgment," Opp. 1, but that request is both improper and premature. Because counts One and Two arise under the APA, *see* Compl. ¶¶ 70-75, they likely implicate Local Rule 261, which calls for cross-motions for summary judgment only after the pleadings are closed and an administrative record is filed. Moreover, because Plaintiff's Complaint is subject to dismissal under Rule 12(b)(6), for reasons of judicial economy the Court should address Defendants' motion to dismiss before entertaining any motion for summary judgment. Plaintiff's brief was properly docketed as an Opposition, *see* ECF No. 15, but should the Court construe it as a motion for summary judgment, Defendants reserve the right to move to strike that motion or otherwise respond.

2d 175, 179 (D.D.C. 2002). That is because a claim under § 706(1) can only proceed if the agency "failed to take a *discrete* agency action that it is *required to take*." *Norton v. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). And under the Rule 12(b)(6) standard, the Court is not required to accept Plaintiff's "legal conclusions" about a statute, *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011).

Contrary to Plaintiff's reading, 21 U.S.C. § 360ii(a) and its six subparts do not contain a discrete, mandatory directive to take any action with respect to LED products. Instead, § 360ii(a) contains a broad, generalized requirement to "establish and carry out an electronic product radiation control program." The required components of that program—which are similarly broad—include "plan[ning] . . . operational activities" to minimize "unnecessary" exposures; "liais[ing]" and "consult[ing]" with other federal agencies; and "study[ing]" electronic product radiation, among other things. *Id.* § 360ii(a)(2)-(6); *see also* Pet. Resp. 6. The only program component in § 360ii(a) involving action on specific "electronic products" is § 360ii(a)(1), but that provision only directs the agency to "develop . . . performance standards" under 21 U.S.C. § 360kk without specifying any products in particular.[3] The breadth of these provisions is significant, because "if Congress wanted to mandate that" FDA take product-specific action on LED products, "Congress knew how to write such a law," but it "did not do so in this statute." *Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc.*, 596 U.S. 880, 887 (2022); *see also City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 296 (2013) ("Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion.").

Nor can the Court "assume that Congress has omitted from its adopted text [a] requirement" to take action on LED products "that [Congress] nonetheless intends to apply." *Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 341 (2005). This is particularly true because "Congress has shown

[3] This also explains why Defendants' motion (Mot. 1)—like FDA's Petition Response (Pet. Resp. 3)—focused on performance standards under § 360kk. This was not to "distract the Court" from § 360ii(a), Opp. 17. Instead, it was because § 360kk confers the best authority for FDA to do what Plaintiff appears to want: product-specific action to "protect [the] public" from LEDs. Compl. ¶ 1. Even so, Defendants' motion did not "ignore[]" Plaintiff's arguments about the subparts of § 360ii(a). Opp. 2. Rather, it addressed those succinctly, commensurate with the conclusive nature of the Complaint's allegations about them. *See* Mot. at 5 n.2, 6 n.4, 6-*7; see also* Compl. ¶¶ 28-34.

elsewhere in the same statute that it knows how to make such a [product-specific] requirement manifest." *Id.* For example, in 21 U.S.C. § 360jj(a)(1)(C), Congress directed FDA to specifically study "the need for controlling the sale of . . . antiquated X-ray equipment . . . ." Why would Congress have failed to similarly specify in § 360ii(a)—either in the original statute, or in the years since LED products entered the mainstream—that it was requiring FDA to take action on LED products specifically? The most "straightforward" interpretation—and therefore, the "best" one—is that Congress never intended such a requirement. *Jones v. Hendrix,* 599 U.S. 465, 480 (2023).[4]

Plaintiff's argument is even more implausible when considered within the "context" of the "overall statutory scheme," as it must be. *Turkiye Halk Bankasi A.S. v. United States,* 598 U.S. 264, 275 (2023). The logic behind Plaintiff's reading of § 360ii(a)—which posits that FDA must take action on LED products because they emit electronic product radiation, *see* Opp. 7 ¶ 5—would also require FDA to establish a new program, develop performance standards, and conduct operational activities to minimize emissions for each of the innumerable everyday electronic products that emit such radiation. *See* 21 U.S.C. § 360hh(1)-(2) (defining "electronic product radiation" and "electronic product"). It would therefore leave the agency no discretion to determine which electronic products require action and which do not. This is irreconcilable with § 360kk(a), which gave the agency discretion to promulgate performance standards for electronic products *only* "if [it] determines" them to be necessary. It is also irreconcilable with § 360ii(a)(2), which requires the agency to use its judgment by "plan[ning] . . . operational activities" to minimize "*unnecessary* electronic product radiation" (not *all* such radiation). Plaintiff's construction of the Act therefore fails, because "[b]asic principles of statutory interpretation require that" § 360kk, the subparts of § 360ii(a), and every other provision Plaintiff cites be construed "in harmony with one another, not set [] at cross-purposes." *Jones v. Hendrix*, 599 U.S. 465, 478 (2023).[5]

[4] Plaintiff's arguments about other provisions in the Act all fail for the same reason: namely, he unpersuasively seeks to convert a broad, generalized directive about electromagnetic product radiation into a mandatory, discrete requirement involving LED products. For example, while Plaintiff suggests (Opp. 31) that 21 U.S.C. § 360jj requires FDA to study and submit reports about LED products specifically, that section contains no such requirement, *see id.*

[5] Moreover, to the extent Plaintiff suggests that LED products are wholly unregulated, he is (cont'd.)

Finally, even assuming § 360ii(a) and its subparts amount to discrete requirements under *Norton*, FDA has satisfied them. For example, § 360ii(a) directed FDA to develop a control program, which FDA has done. *See generally* 21 C.F.R. Subchapter J. And § 360ii(a)(1) directed FDA to develop performance standards for electronic products, which FDA has also done. *See, e.g.*, 21 C.F.R. §§ 1020.30, 1030.10, 1040.20. FDA has also "support[ed]" "training" and "operational activities" to "minimize . . . unnecessary electronic product radiation" by—to list just one of many illustrative examples—promoting patient safety through its Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging.[6] Extensive illustrative examples similarly exist for each subpart of § 360ii(a).[7]

For all of these reasons, Plaintiff has not stated—and cannot state—a viable claim that the Act *required* FDA to take any *discrete* action concerning LED products. Count One therefore fails to plausibly allege a violation of the statute.

B. Permitting Amendment to Entertain Plaintiff's New Claims Would be Futile.

A court need not permit a *pro se* plaintiff to amend before dismissal where "the complaint's deficiencies could not be cured by amendment." *Consiglio v. Woodford*, No. 2:5-CV-1701-GEB-GGH,

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mistaken. For example, LED manufacturers must comply with all applicable regulations regarding radiological health and safety. *See, e.g.*, 21 C.F.R. § 1002.20 ("accidental radiation occurrence reports"); 21 C.F.R. Part 1003 ("notification of defects"); 21 CFR Part 1004 ("repurchase, repairs, or replacement of electronic products"). And FDA's Petition Response was based in part on the existence of several "internationally accepted consensus standards," which "provide guidelines for lamps with spatially uniform and spatially non-uniform optical outputs, and recommend measurement at different points for spatially non-uniform light." Pet. Resp. at 9 (citing multiple standards).

[6] https://www.fda.gov/radiation-emitting-products/radiation-safety/initiative-reduce-unnecessary-radiation-exposure-medical-imaging. For the reasons previously noted (Mot. 1 n.1), the Court may take judicial notice of this source and those below without conversion to a motion for summary judgment.

[7] For example, as to § 360ii(a)(3), FDA has participated in a federal-state partnership to characterize the X-ray radiation doses patients receive. https://www.fda.gov/radiation-emitting-products/radiation-safety/nationwide-evaluation-x-ray-trends-next. Regarding § 360ii(a)(4), FDA conducts research to help ensure patient access to devices that are electromagnetically and electrically safe and effective. https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/electromagnetic-and-electrical-safety-program-research-electromagnetic-and-electrical-safety-medical. Regarding § 360ii(a)(5), FDA's Winchester Engineering and Analytical Center studies the safety of radiation-emitting electronic products. https://www.fda.gov/media/165615/download. And regarding § 360ii(6), FDA engages with other federal agencies on multiple committees and activities. *See, e.g.*, https://www.fda.gov/media/135022/download.

2007 WL 1655496 (E.D. Cal. June 5, 2007), *report and recommendation adopted*, 2007 WL 2326082 (E.D. Cal. Aug. 13, 2007); *Smallwood v. NCsoft Corp.*, 730 F. Supp. 2d 1213, 1222 (D. Haw. 2010) (even with a *pro se* litigant, "the court may deny leave to amend where amendment would be futile").

While Plaintiff's Opposition introduced a new claim challenging FDA's Petition Response, *supra*, p. 2, dismissal remains proper because amendment of the Complaint to include this claim would be futile. FDA's Petition Response denied Plaintiff's request to initiate rulemaking. Pet. Resp. 1 ("denying" requests to "establish new regulations"). Such a decision is subject to "extremely limited and highly deferential" review above and beyond the deference ordinarily due under the arbitrary-and-capricious standard. *Compassion Over Killing v. FDA*, 849 F.3d 849, 854 (9th Cir. 2017) (citing *Massachusetts v. EPA*, 549 U.S. 497, 527-28 (2007)). Accordingly, courts will reverse such a decision "only for compelling cause, such as plain error of law or a fundamental change in the factual premises previously considered by the agency." *McAfee v. FDA*, 36 F.4th 272, 274 (D.C. Cir. 2022) (citation omitted).

Plaintiff's Opposition demonstrates that his arguments about FDA's Petition Response cannot pass this high bar. For the reasons discussed above, *supra* pp. 3-6, Plaintiff has not identified a plain error of law underlying FDA's decision. Nor does he identify a fundamental change in the factual premises considered by the agency in denying his petitions: to the contrary, Plaintiff acknowledges that FDA's Petition Response "relied" on the "evidence submitted by" his own foundation, Opp. 25. Plaintiff's claim instead amounts to a "scientific debate" with an expert agency about the risks and benefits of LED products, and courts "avoid" such disputes. *Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537, 555 (3d Cir. 2023) (citation omitted) (noting that courts will not "substitute [their] judgment for the agency's" after the latter has "weigh[ed] the evidence" on a scientific matter).

Indeed, far from offering a "compelling cause" for reversal, *McAfee*, 36 F.4th at 274, the Opposition does not even identify any "relevant factors" FDA failed to consider, as would be required under ordinary arbitrary-and-capricious review. *Motor Vehicle Mfrs. Ass'n. v. State Farm*, 463 U.S. 29, 43 (1983). For example, while Plaintiff accuses FDA of "ignor[ing]" anecdotal reports of individuals who believe they were harmed by LED products, Opp. 12, the agency explained that, "[w]hen making regulatory decisions, FDA generally gives scientific data and expert opinions . . . much greater weight

than personal stories or experiences because the latter . . . generally do not provide all factors that may be contributing to any adverse health effects, the extent of the population that may be impacted, under what conditions, and the characteristics of products, if any, that pose a risk." Pet. Resp. 7.

In addition, Plaintiff's position that FDA's Petition Response offered only "conclusory" assertions (Opp. 15, 16, 18, 21, 22, 26) is belied by its text. For example, while Plaintiff faults as conclusory FDA's determination that the existing scientific evidence does not justify performance standards for LED products (Opp. 22), he fails to acknowledge the extensive rationale underlying that conclusion, which included an analysis rebutting Plaintiff's interpretation of the Act (Pet. Resp. 3-4, 6-7); a comprehensive scientific analysis of the studies, arguments, and information Plaintiff submitted about LED products (*id.* at 7-18); and the findings of an independent organization FDA engaged "to conduct a comprehensive literature search . . . to identify the current state of knowledge with regard to adverse health effects of LED light on humans," (*id.* at Resp. 18-19).[8] That review concluded "that the overall quality of evidence in the literature for any health effects [from LED products] was low" due in part to the significant "limitations" of the studies available. *Id.* These limitations included, for example, a "lack of randomization," "small sample sizes," and "no comparison of LED to other forms of lighting with the same attributes." *Id.* The review further found an absence of conclusive, consistent reports of "adverse health effects" from LED lighting in the literature. *Id.* All of this renders Plaintiff's comparison (Opp. 14-16) to *Environmental. Health Trust v. FCC*, 9 F.4th 893 (D.C. Cir. 2021) unavailing. There, unlike here, the defendant agency only cited to several "conclusory statements" on another agency's webpage in justifying its decision, and it otherwise offered "no articulation of the factual bases" for that determination, nor did it grapple with the studies the plaintiff had submitted. *Id.* at 905 (cleaned up).

Thus, while Plaintiff may disagree with FDA's rationale, the relevant legal standard forbids substituting his personal opinions for the agency's scientific analysis. *See, e.g.*, *Compassion Over Killing*,

[8] The scope of this search belies Plaintiff's suggestion that FDA's analysis "relied solely on the submission of evidence submitted by" Plaintiff's foundation, Opp. 25.

849 F.3d at 854. The Opposition's putative challenge to the Petition Response therefore fails.[9]

C. Plaintiff's Opposition Also Confirms that Counts Two and Three Do Not State a Plausible Claim Under the Equal Protection Clause.

Even "a liberal interpretation of a *pro se* civil rights complaint may not supply essential elements of the claim that were not initially pled," so "[v]ague and conclusory allegations of . . . civil rights violations are not sufficient to withstand a motion to dismiss." *Litmon v. Harris*, 768 F.3d 1237, 1241 (9th Cir. 2014). With that principle in mind, Plaintiff's Opposition confirms that his claims under the Equal Protective Clause—Counts Two and Three (Compl. ¶¶ 74-78)—are subject to dismissal.

To state an equal protection claim, a plaintiff must allege facts plausibly showing that the defendants acted with an intent or purpose to discriminate against him based upon membership in a protected class, *Lee v. City of L.A.*, 250 F.3d 668, 686 (9th Cir. 2011), or that similarly situated individuals were intentionally treated differently without a rational relationship to a legitimate state purpose, *Engquist v. Oregon Dep't of Agr.*, 553 U.S. 591, 601–602 (2008). Notably, even if a defendant's "facially neutral policies had a foreseeably disproportionate impact on an identifiable group," that "does not mean that they violated the Equal Protection Clause." *Lee*, 250 F.3d at 687. Rather, "[w]here the challenged governmental policy is 'facially neutral,' proof of its disproportionate impact on an identifiable group can satisfy the intent requirement only if it tends to show that some invidious or discriminatory purpose underlies the policy." *Id.* at 686 (citation omitted).

Here, the government conduct Plaintiff seeks to challenge—FDA's alleged failure to issue performance standards or otherwise take product-specific action on LED products, Opp. 32-33—is facially neutral because it does not differentiate between any two groups. Plaintiff appears to contend that FDA's inaction in this regard has had disproportionate "impacts" on individuals who, due to certain

[9] Nor should Plaintiff be permitted to amend to pursue his futile contentions about the Standards Committee. Plaintiff alleges that 21 U.S.C. § 360kk(f)(1)(A) required FDA to consult this Committee before issuing "its decision to not publish performance standards for LED products," Opp. 5, but this gets the requirement backward: the statute directs FDA to consult the Committee "before *prescribing* any" standard, not before *declining* to prescribe one. 21 U.S.C. § 360kk(f)(1)(A) (emphasis added). Indeed, FDA was also under no obligation to engage the independent organization (Pet. Resp. 18) with which it chose to consult.

medical conditions, allegedly have a greater sensitivity to LED light. *Id* at 33. But aside from several vague, conclusory allegations involving "discriminatory" barriers, Compl. ¶¶ 59, 78; Opp. 30, 33, Plaintiff does not, and cannot, plausibly identify any "invidious or discriminatory purposes underl[ying]" FDA's inaction. *Lee*, 250 F.3d at 686; *see also* Compl. ¶¶ 59-69, 74-78; Opp. 32-35.

Regardless, for Counts Two and Three to survive, Plaintiff would also need to have plausibly alleged that FDA's challenged conduct cannot survive the applicable level of scrutiny. *See, e.g.*, *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1064-65 (9th Cir. 2014). Here, even if Plaintiff had identified discriminatory conduct based on a disability, rational basis review would apply because "a governmental policy that purposefully treats the disabled differently from the non-disabled need only be rationally related to legitimate legislative goals to pass constitutional muster." *Martin v. Ca. Dep't of Veterans Affairs*, 560 F.3d 1042, 1049–50 (9th Cir. 2009) (citation omitted); *see also City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 442-43 (1985).

Applying those principles at the motion to dismiss stage, Plaintiff must "plead facts in [his] complaint establishing that there is not 'any reasonable conceivable state of facts that could provide a rational basis for the classification.'" *Estate of Vargas v. Binnewies*, No. 1:16-cv-1240-DAD-EPG, 2018 WL 1518568, at *7 (E.D. Cal. March 28, 2018) (quoting *Hettinga v. United States*, 677 F.3d 471, 479 (D.C. Cir. 2012)). Those allegations must be "sufficient to overcome the presumption of rationality that applies to government classification." *Id.* (quoting *Wroblewski v. City of Washburn*, 965 F.2d 452, 460 (7th Cir. 1992)). Plaintiff has not rebutted Defendants' argument that he failed to satisfy this element. *See* Mot. 9. Instead, in responding to it, Plaintiff reiterates his allegations that FDA "did not engage in a robust scientific review" in denying his citizen petitions and otherwise "failed to implement" the LED-specific actions Plaintiff incorrectly believes to be required by statute, Opp. 35. These contentions are refuted above, *supra* pp. 3-8, and in any event they do not establish the absence of any rational basis for FDA's challenged conduct. Counts Two and Three should therefore be dismissed.

CONCLUSION

For the foregoing reasons, the Court should grant the Defendants' Motion to Dismiss.

DATED: August 15, 2024

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via e-mail on August 15, 2024 to mbaker@softlights.org pursuant to Mr. Baker's written consent to accept service via e-mail. This document will also be sent by U.S. mail to Mr. Baker's address on file with the Court:

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