SCOTT KENNEDY
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-1837
(202) 514-8742 (fax)
scott.p.kennedy@usdoj.gov

Counsel for Defendants Listed on Signature Page

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-DB

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS

District Judge: Kimberly J. Mueller

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INTRODUCTION

The United States Food and Drug Administration (FDA) regulates radiation-emitting electronic products through the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 360hh *et seq.*). FDA has issued comprehensive regulations establishing an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. 21 C.F.R. Subchapter J. Plaintiff now brings this suit against FDA because the agency has not promulgated performance standards for various light-emitting diode (LED) products. Compl. ¶¶ 1, 45.

However, the Court should dismiss this case under Federal Rule of Civil Procedure 12(b)(6) because Plaintiff fails to state a claim under the Administrative Procedure Act (APA) and U.S. Constitution. Compl. ¶¶ 70-78. Count One fails to state a claim because Plaintiff has not identified any final agency action, nor does he identify any statutory provision compelling the agency to promulgate performance standards for LED lights. And to the extent Count One was also intended as a challenge to FDA's inaction on Plaintiff's citizen petitions, *see* Compl. ¶¶ 46-51, FDA's subsequent denial of those petitions moots that challenge, *see* Ex. 1 (FDA response to Plaintiff's citizen petitions).[1] Moreover, Counts Two and Three fail to state a claim because they do not satisfy the elements of an equal protection violation. Because none of the counts in Plaintiff's Complaint state a claim, it should be dismissed in its entirety.

BACKGROUND

FDA is responsible for regulating radiation-emitting electronic products through the Electronic Product Radiation Control provisions of the FDCA, which were originally enacted as the Radiation

[1] The Court may take judicial notice of FDA's response to Plaintiff's citizen petitions "without converting [the] motion to dismiss into a motion for summary judgment" because FDA's response is a "matter[] of public record," *Khoja v. Orexigen Therapeutics, Inc*, 899 F.3d 988, 999 (9th Cir. 2018), and it is also publicly available at https://www.regulations.gov/document/FDA-2022-P-1151-0215, *see Applied Underwriters, Inc. v. Lara*, 530 F. Supp. 3d 914, 923-24 (E.D. Cal. 2021) ("Courts routinely take judicial notice of … information on government websites." (citation omitted)).

Control for Health and Safety Act of 1968, Pub. L. 90-602, 82 Stat. 1173 (Oct. 18, 1968). These Radiation Control provisions apply to any "electronic product," defined as:

> (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
>
> (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

21 U.S.C. § 360hh(2).

Pursuant to the Radiation Control provisions, FDA has established an electronic product radiation control program. Ex. 1 at 3-4; *see also* 21 C.F.R. Subchapter J. As part of that program, FDA conducts certain operational activities related to electronic products to "minimize the emissions of and the exposure of people to, unnecessary electronic product radiation." 21 U.S.C. § 360ii(a). These activities include "plan[ning], conduct[ing], coordinat[ing], and support[ing] research, development, training, and [other] operational activities." § 360ii(a)(2).

In addition, Section 360kk of the Radiation Control provisions requires FDA to develop and administer performance standards for electronic products if the agency "determines that such standards are necessary for the protection of the public health and safety." § 360kk(a)(1). Pursuant to section 360kk(a)(1), FDA has promulgated performance standards for a variety of electronic products, including, for example, diagnostic x-ray systems, microwave ovens, and sunlamp products. 21 C.F.R. §§ 1020.30, 1030.10, 1040.20.

While LED product manufacturers are responsible for compliance with all applicable regulations regarding radiological health, FDA has not established performance standards for LED products. Due to a long history of safety with respect to LED products and the visible wavelengths they emit, FDA has not found performance standards to control the radiation from LED products to be necessary for the protection of the public health and safety. Ex. 1 at 7. Moreover, FDA generally does not consider it necessary to issue specific performance standards for every type of electronic product because most such products do not pose a risk to public health, and because of the effectiveness of existing mitigations and

alternative approaches to protect public health including "manufacturers' voluntary compliance with consensus standards" and "applicability of other types of controls." *Id.* at 6-7.

Plaintiff, through the non-party Softlights Foundation, advocates for LED regulation. Compl. ¶¶ 46-53 & nn.13-19. In 2022 and 2023, Plaintiff filed four citizen petitions with FDA requesting that the agency promulgate regulations to control, among other things, electromagnetic radiation from LED lights. *Id.* On May 24, 2024, FDA denied those citizen petitions because the agency found that LED performance standards are not necessary to protect the public health. Ex. 1 at 8, 17-18. In reaching that determination, FDA comprehensively reviewed the evidence Plaintiff submitted, and the agency even "engaged an independent, third-party organization to conduct a comprehensive literature search and systematic review to identify the current state of knowledge with regard to adverse health effects of LED light on humans." Ex. 1 at 18. That review concluded that the "overall quality of evidence in the literature for any health effects [from LED products] was low," and that any suggestions of adverse health impacts were "inconclusive/inconsistent." *Id.* at 18-19. FDA also observed that Plaintiff's claims about the hazards of LED products are inconsistent with "internationally accepted consensus standards," and that the evidence Plaintiff cited was insufficient to support his contentions. *Id.* at 17. The agency therefore concluded that insufficient evidence exists to "show[] that the regulations [Plaintiff] request[s] to control the emission of electronic product radiation from the LED products described is necessary for the protection of the public health and safety." *Id.* at 8.

On January 22, 2024, before FDA responded to the citizen petitions, Plaintiff filed this action challenging FDA's "failure to publish performance standards for LED products," which he alleges "has caused Plaintiff irreparable harm." *Id.* ¶ 1. Specifically, Plaintiff alleges that the absence of performance standards cause adverse physical health effects to him and the public. *Id.* ¶¶ 54-69. Plaintiff asserts three claims: first, he alleges that FDA violated the Radiation Control for Health and Safety Act by failing to "protect the public from the harms of" LED products, publish performance standards for such products, and submit reports to Congress. *Id.* ¶¶ 70-73. Plaintiff also brings claims under both the APA and U.S. Constitution, alleging that FDA's failure to publish performance standards for LED products violated the

equal protection clause. *Id.* ¶¶ 74-78. Plaintiff asks this Court to compel FDA to issue performance standards for LED products and report to Congress on the same. *Id.* ¶¶ 79-86.

Defendants now move to dismiss Plaintiff's claims under Rule 12(b)(6).

LEGAL STANDARD

Under Rule 12(b)(6), the court must dismiss a complaint if it fails to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Dismissal pursuant to Rule 12(b)(6) "can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1990). Dismissal should be granted where the "complaint is vague, conclusory, and general and does not set forth any material facts in support of the allegations." *North Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 583 (9th Cir. 1983). Although well-pleaded allegations of material fact are accepted as true and reasonable inferences are to be drawn in favor of the plaintiff, *Wyler Summit P'ship v. Turner Broad. Sys.*, 135 F.3d 658, 661 (9th Cir. 1998), the court need not "assume the truth of legal conclusions merely because they are cast in the form of factual allegations," *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (citation omitted). The Ninth Circuit has made clear that "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." *Epstein v. Wash. Energy Co.*, 83 F.3d 1136, 1140 (9th Cir. 1996); *see also Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011) ("[A]llegations … may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively.").

ARGUMENT

I. Count One Fails to State a Claim that Defendants Violated the Radiation Control for Health and Safety Act.

In Count One, Plaintiff brings a claim under the APA alleging that FDA violated (1) 21 U.S.C. §§ 360hh - 360ss by "fail[ing] to protect the public from" LED products; (2) § 360ii(a)(1)-(6) by failing

to publish performance standards; and (3) § 360jj by failing to submit reports to Congress. Compl. ¶¶ 70-73.[2] Regardless of how this claim is construed, it fails.

1. To the extent Count One can be construed as a claim under 5 U.S.C. § 706(2) of the APA, that claim fails because Plaintiff does not identify any final agency action. 5 U.S.C. § 704 (limiting APA review to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy"); *see also San Luis Unit Food Producers v. United States*, 709 F.3d 798, 801 (9th Cir. 2013) (noting that this defect is jurisdictional); *Pebble Ltd. P'ship v. EPA*, 604 Fed. App'x 623, 625 (9th Cir. 2015) (same). Final agency action has two separate requirements: "[f]irst, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citations and quotation marks omitted). Here, Plaintiff does not allege in his Complaint that FDA took any action, much less final agency action. Compl. ¶¶ 70-73. Thus, the Complaint fails to state a claim under the APA.[3]

2. Alternatively, to the extent Count One can instead be construed as an effort under 5 U.S.C. § 706(1) to compel FDA to promulgate performance standards for LED products, Plaintiff fails to establish that such standards are required by statute. "[A] claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *Norton*

[2] The latter two categories of allegations require minimal analysis. Plaintiff's conclusory assertion that FDA violated each of the subsections in § 360ii(a)(1)-(6), Compl. ¶ 72, fails because Plaintiff does not identify any present duty to act imposed by those sections that FDA is not already performing as part of its administration of the Radiation Control provisions discussed above. *Supra*, pp. 2-3. And his allegation that FDA violated of 21 U.S.C. § 360jj by failing to submit reports to Congress, Compl. ¶ 73, fails because that section only requires reports to be submitted "from time to time" as FDA "may find necessary," *id.*, and Plaintiff does not identify any specific report that FDA was obligated to submit yet did not.

[3] To the extent Plaintiff's claim can be construed as a challenge under § 706(2) to FDA's existing regulations in 21 C.F.R. Part 1040 and their omission of performance standards for LED products, Plaintiff has failed to plead accrual of an injury within the six-year statute of limitations under 28 U.S.C. § 2401(a). *Perez-Guzman v. Lynch*, 835 F.3d 1066, 1077 (9th Cir. 2016) ("Procedural challenges to agency rules under the Administrative Procedure Act are subject to the general six-year limitations period in the U.S. Code."). FDA promulgated its Part 1040 regulations on July 31, 1975. 40 Fed. Reg. 32,252.

v. S. Utah Wilderness All., 542 U.S. 55, 64 (2004) (emphasis in original). For example, in *San Luis Unit Food Producers*, the Ninth Circuit held that a § 706(1) claim failed where the agency was "not legally required to" deliver the amount of irrigation water desired by the plaintiffs because the relevant statutes instead gave the agency "discretion" to allocate that water as appropriate. 709 F.3d at 801.

Here, Plaintiff similarly fails to establish that issuance of performance standards for LED products is "legally required." *Norton*, 542 U.S. at 63. Under 21 U.S.C. § 360kk(a)(1), the Secretary is directed to "prescribe performance standards for electronic products" only "*if he determines* that such standards are necessary for the protection of the public health and safety." *Id.* (emphasis added). That essential precondition has not been met because FDA has not determined that LED-specific performance standards are necessary to protect the public health and safety. In fact, FDA has concluded the opposite, stating in response to Plaintiff's citizen petitions that "insufficient evidence exists … to demonstrate that a performance standard to control the emission of electronic product radiation by products that use LEDs is necessary at this time for the protection of the public health and safety." Ex. 1 at 19; *see also id.* at 8. Plaintiff may disagree with FDA on this issue, but Plaintiff's opinion cannot satisfy the precondition to § 360kk(a)(1). Nor can it override FDA's conclusion to the contrary, particularly given the "high level of deference" due to "scientific judgment[s]" within FDA's "area of expertise." *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009) (citation and quotation marks omitted); *see also Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *Ipsen Biopharmaceuticals, Inc. v. Becerra, et al.* __ F. 4th __, 2024 WL 3529399, *4 (D.C. Cir. July 9, 2024) (similar).[4]

Although Plaintiff briefly cites other statutory provisions, including the entirety of the FDCA's Electronic Product Radiation Control provisions, 21 U.S.C. §§ 360hh *et seq.*, and § 360ii(a), Compl. ¶¶ 71-72, he fails to explain how these provisions give rise to a present and mandatory duty under *Norton*

[4] Plaintiff further alleges that FDA failed to comply with 21 U.S.C. § 360ii(a)(2) by not "minimiz[ing] emissions of, and exposure to, LED product radiation." Compl. ¶¶ 27, 30. But that provision only requires FDA to minimize such emissions and exposures in the course of certain non-regulatory "operational activities" not at issue here. § 360ii(a)(2). It does not require FDA to issue performance standards for, or otherwise regulate, LED products for the public at large, as Plaintiff appears to contend. *See id.*

to promulgate performance standards for LED products. And to the extent Plaintiff alleges a failure to engage in *any* radiation control measures required by statute, such claims plainly fail in light of FDA's longstanding radiation control regulations discussed above. *Supra* pp. 2-3.

3. Finally, to the extent Count One seeks to compel a response to Plaintiff's citizen petitions under § 706(1), Compl. ¶¶ 46-51, FDA's subsequent action denying the petitions renders that claim moot. *Friends of the Wild Swan, Inc. v. EPA*, 130 F. Supp. 2d 1184, 1192 (D. Mont. 1999) (challenge to agency inaction moot when action taken); *see also Environmental Working Grp. v. FDA*, 301 F. Supp. 3d 165, 174 n.9 (D.D.C. 2018) (noting FDA's response to plaintiff's citizen petition mooted claim of unreasonable delay).[5]

II. Counts Two and Three Fail to State a Claim Under the Equal Protection Clause.

Plaintiff brings his equal protection challenge as both an APA claim and a constitutional claim, Compl. ¶¶ 74-78, but both challenges fail because Plaintiff fails to plausibly allege a violation of the equal protection clause.

To state a claim under the equal protection clause, Plaintiff must allege that he is a member of a class that has been "treated disparately" by the government as compared to another "class that is similarly situated." *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1063 (9th Cir. 2014) (citation and quotation marks omitted); *see also Fauconier v. Clarke*, 966 F.3d. 265, 277 (4th Cir. 2020) (an equal protection claim requires plausible allegations that plaintiff "has been treated differently from others with whom he is similarly situated and that the unequal treatment was the result of intentional or purposeful discrimination.").[6] Thus, Plaintiff must identify two comparator groups, which "need not be similar in all

[5] FDA denied Plaintiffs' citizen petitions *after* this lawsuit was filed. And after FDA issued its denial, counsel for Defendants conferred with Plaintiff about whether he intended to amend his Complaint, and he stated he did not. For that reason, and because Plaintiffs' Complaint does not reference FDA's denial of Plaintiffs' citizen petitioners, Count One cannot be construed as a challenge to the merits of FDA's denial of Plaintiff's citizen petitions.

[6] Plaintiff brings his claims under the Fifth Amendment. Compl. ¶¶ 77-78. The due process analysis under that amendment is "precisely" the same as that under the Fourteenth Amendment. *United States v. Carrillo-Lopez*, 68 F.4th 1133, 1139 (9th Cir. 2023).

respects, but [] must be similar in those respects relevant" to the action at issue. *Ariz. Dream Act Coal.* 757 F.3d at 1064. In addition, Plaintiff must plausibly allege that any disparate treatment of these two groups was not justified under the appropriate level of review. *See id.* at 1064-65. Here, rational basis review applies, because Plaintiff does not allege that FDA "employs suspect classifications" or "impinges on fundamental rights." *Olson v. California*, 104 F.4th 66, 76 (9th Cir. 2024) (citing *Hodel v. Indiana*, 452 U.S. 314, 331 (1981)); *see also Country Classic Dairies, Inc. v. Milk Control Bureau*, 847 F.2d 593, 596 (9th Cir. 1988) (applying rational basis review in the absence of a fundamental right or suspect class). Consequently, the challenged governmental conduct is "presumed [to be] constitutional," and Plaintiff's Complaint must "negative every conceivable basis which might support" the disparate treatment alleged.[7] *Heller v. Doe ex rel. Doe*, 509 U.S. 312, 320 (1993) (citation omitted); *see also Olson*, 104 F.4th at 71-72 (making clear that Plaintiff bears this burden at the pleading stage).

Counts Two and Three fail at the outset because they do not allege that Defendants engaged in any action at all, much less disparate treatment. Compl. ¶¶ 74-78. Plaintiff alleges generally that "LED radiation creates a discriminatory barrier for [him]," *id.* ¶ 78, but he does not allege that Defendants treated him differently from any other group, *e.g.*, Compl. ¶ 66 (alleging that Plaintiff had to quit his job as a teacher due to LED exposure). Indeed, Plaintiff's claims center on FDA's failure to promulgate regulations, *see id.* ¶ 75, but such conduct, by its very nature, is generally applicable to the public at large and therefore does not distinguish between any groups. *Tenser v. Silverman*, No. 20-56176, 2021 WL 4958986, at *1 (9th Cir. Oct. 26, 2021) (unpublished) (affirming dismissal of equal protection claim where challenged conduct applied equally to those who were "similarly situated" to plaintiff). For this reason alone, Plaintiff has failed to state a claim under the equal protection clause. *Quillar v. California Dep't of Corr.*, CIV S04-1203 FCD-KJM-P, 2007 WL 2069942, at *3 (E.D. Cal. July 13, 2007), *report and recommendation adopted*, 2007 WL 2340235 (E.D. Cal. Aug. 16, 2007) (finding that a complaint should be dismissed because plaintiff failed to allege that "defendants … treated plaintiff differently").

[7] Rational basis review also applies to the extent Plaintiff alleges "a class of one" specific to himself. *Vill. of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000).

Yet even if Plaintiff alleged that Defendants had taken some pertinent action, his equal protection claims would still fail because Plaintiff's allegations also do not identify two similarly situated groups. Plaintiff appears to maintain that there exists a class of LED-sensitive individuals who suffer greater harm from LED exposure compared to others. Compl. ¶ 55 (alleging that "many individuals" have "significant adverse health impacts" from LED products). But even if that is so, Plaintiff fails to plausibly allege that these groups are similar in all relevant respects, as he must to support his claim. *Cf. Budd v. Harrisson*, No. 2:23-CV-2313 KJN P, 2024 WL 382554, at *2 (E.D. Cal. Feb. 1, 2024), *report and recommendation adopted sub nom. Budd v. Harrison*, 2024 WL 1444004 (E.D. Cal. Apr. 3, 2024) (finding that plaintiff failed to demonstrate that he and another individual were "similarly situated" where it was likely that the other individual "suffered from a different medical condition than plaintiff").

And even assuming Plaintiff could establish that Defendants engaged in disparate treatment of two similarly situated groups, his claims would nonetheless fail because he does not negate "every [reasonably] conceivable basis which might support such disparate treatment," as he must to challenge differential treatment subject to rational basis review. *Armour v. City of Indianapolis*, 566 U.S. 673, 681, 685 (2012). Far from suggesting any unlawful motive, FDA's articulated findings in its denial of Plaintiffs' citizen petitions demonstrate that the agency engaged in a robust scientific review and made a reasoned judgment based on the available evidence. Ex. 1 at 8, 18-19. Specifically, FDA determined that Plaintiff's petitions did not show "that the regulations [he] request[s] to control the emission of electronic product radiation from the LED products [are] necessary for the protection of the public health and safety." *Id.* at 8. FDA further "determined that insufficient evidence exists in the literature to demonstrate that a performance standard to control the emission of electronic product radiation by products that use LEDs is necessary at this time for the protection of the public health and safety." *Id.* at 19. Plaintiff does not, and cannot, plausibly allege that FDA lacked a rational basis for its determination under these circumstances. Thus, even assuming this action somehow differentiated between two similarly situated groups, Plaintiff fails to allege that the agency's determination fails rational basis review.

For each of these reasons, Plaintiff fails to state an equal protection claim under the APA or the Constitution. Accordingly, Counts Two and Three should be dismissed.

CONCLUSION

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

DATED: July 29, 2024

Respectfully Submitted,

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel
U.S. Department of Health and Human Services

MARK RAZA
Chief Counsel

WENDY VICENTE
Deputy Chief Counsel, Litigation

ELIZABETH NORFORD
Associate Chief Counsel
Office of the General Counsel
U.S. Food and Drug Administration
10903 New Hampshire Avenue
White Oak 31, Rm. 4428
Silver Spring, MD 20993-0002

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director

LISA K. HSIAO
Senior Deputy Director

HILARY K. PERKINS
Assistant Director

/s/ Scott P. Kennedy
Scott Kennedy
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-1837
(202) 514-8742 (fax)
scott.p.kennedy@usdoj.gov

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via e-mail on July 29, 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 on July 29, 2024, to Mr. Baker's address on file with the Court:

9450 SW Gemini Drive, PMB 44671

Beaverton, OR 97008

July 29, 2024

/s/ *Scott P. Kennedy*
SCOTT P. KENNEDY