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CLERK, U.S. DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA
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4 THE UNITED STATES DISTRICT COURT
5 FOR THE EASTERN DISTRICT OF CALIFORNIA
6 SACRAMENTO DIVISION

8 MARK BAKER,

9 Plaintiff,

10 vs.

11 U.S. DEPARTMENT OF HEALTH AND

12 HUMAN SERVICES, ET AL.,

13 Defendants

Case No.: 2:24-CV0278-KJM DB PS

PLAINTIFF'S MEMORANDUM OF POINTS
AND AUTHORITIES IN SUPPORT OF
MOTION TO DISMISS

Hearing Date: November 7, 2024

Time: 10:00am

Location: 501 I Street, Sacramento, CA 95814

Courtroom 27, 8th Floor, Hon. Sean C.
Riordan

Case Filed: January 22, 2024

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PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO
DISMISS HEARING DATE: NOVEMBER 7, 2024 TIME: 10:00AM LOCATION: 501 I STREET,
SACRAMENTO, CA 95814 COURTROOM 27, 8TH FLOOR, HON. SEAN C. RIORDAN CASE FILED:
JANUARY 22, 2024 - 1

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8 **I. INTRODUCTION**

9 Plaintiff respectfully moves to voluntarily dismiss this action without prejudice or
10 conditions, pursuant to Federal Rule of Civil Procedure 41(a)(2). This relief is proper for
11 several reasons.

12 A. Defendant Jeffrey Shuren had previously been the Director of the Food and Drug
13 Administration (“FDA”) Center for Devices and Radiological Health (“CDRH”) for
14 the past approximately 14 years. Defendant Shuren retired in July, 2024. Defendant
15 Shuren was directly responsible for the FDA’s decision to dissolve the Technical
16 Electronic Product Radiation Safety Standards Committee (“TEPRSSC”) and to not
17 carry out an electronic product control program for Light Emitting Diode (“LED”)
18 products, as required by 21 U.S.C. Part C. The FDA CDRH is now overseen by
19 Acting Director Michelle Tarver and Dr. Tarver may have an entirely different view
20 on whether to comply with 21 U.S.C. Part C for LED products.

21 B. Plaintiff’s claim is for Defendants’ failure to comply with six sections of the
22 electronic radiation control program: 21 U.S.C. 360ii(a)(1), 21 U.S.C. 360ii(a)(2), 21
23 U.S.C. 360ii(a)(3), 21 U.S.C. 360ii(a)(4), 21 U.S.C. 360ii(a)(5), and 21 U.S.C.

1 360ii(a)(6), some of which are non-discretionary and some of which are
2 discretionary. Defendants' Motion to Dismiss focused solely on the discretionary
3 statutes.

4 C. On September 23, 2024, Plaintiff filed a claim against the FDA and National
5 Highway Traffic Safety Administration ("NHTSA") for failure to comply with 21
6 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A), case number 2:24 CV02558
7 DJC JDP (PS).

8 D. Plaintiff's new claim against the FDA and NHTSA is based only on two issues: 1)
9 whether TEPRSSC is functioning properly, and 2) the requirement for the FDA to
10 "maintain liaison" with NHTSA for LED vehicle headlights. Plaintiff's new claim is
11 far more narrowly focused, involving only the question of whether TEPRSSC is
12 properly functioning, and the question of whether the FDA and NHTSA are
13 maintaining a liaison for LED vehicle headlights. Plaintiff believes that all parties
14 (Plaintiff, Defendant, and Court) will benefit if the question of whether the FDA must
15 reconstitute TEPRSSC and the question of whether the FDA and NHTSA must
16 maintain a liaison, is addressed by this Court first in Plaintiff's new claim, and then
17 the questions for this claim, such as whether performance standards should be
18 promulgated or whether the lack of an electronic product radiation control program
19 for LED products violates Plaintiff's 5th Amendment right to equal protection, can be
20 more easily answered after a ruling on Plaintiff's new FDA/NHTSA claim.

1 **II. PROCEDURAL BACKGROUND**

2 Plaintiff filed this claim on January 22, 2024. Defendant filed a Motion to Dismiss
3 on July 29, 2024. Plaintiff filed a Response to Defendant’s Motion to Dismiss on August
4 5, 2024. Defendant filed a Reply in Support of Motion to Dismiss on August 15, 2024. A
5 hearing on the Motion to Dismiss was held by this Court on September 19, 2024. The
6 Motion to Dismiss is now being considered by this Court.

7 Plaintiff filed the new claim against the FDA and NHTSA on September 23, 2024.
8

9 **III. DISMISSAL IS APPROPRIATE UNDER RULE 41(a)(2)**

10 According to Federal Rule of Civil Procedure 41(a)(2), after an opposing party has
11 served a Motion to Dismiss, “an action may be dismissed at the plaintiff’s request only by
12 court order, on terms that the court considers proper.”

13 Plaintiff believes that this Court would appreciate the opportunity to address the
14 issues of FDA compliance with 21 U.S.C. Part C for LED products in a more orderly
15 fashion. A ruling on this claim, which involves multiple discretionary and non-
16 discretionary statutes, and a question involving the 5th Amendment Equal Protection
17 Clause, is more complex than a ruling on a claim which involves only non-discretionary
18 statutes.

19 In addition, Plaintiff believes that a proper functioning TEPRSSC is fundamental to
20 this claim because any proposed performance standards must be guided by consultation
21 with TEPRSSC, as per 21 U.S.C. 360kk(f)(1)(A). Since this claim did not request a ruling
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23

1 on whether TEPRSSC is properly functioning, a ruling involving TEPRSSC in the new
2 FDA/NHTSA claim would benefit the Court's decision making for this claim.

3 Finally, because the FDA CDRH has new leadership after 14 years under the previous
4 Director, Defendants FDA and NHTSA may choose not to litigate Plaintiff's new
5 FDA/NHTSA claim due to this change in leadership and may choose instead to implement
6 a radiation control program for LED vehicle headlights as required by law.

7 Plaintiff believes that dismissal of this claim will not prejudice either Plaintiff or
8 Defendant and will simply serve to provide more clarity on issues concerning the electronic
9 product radiation control program for LED products via Plaintiff's new lawsuit against the
10 FDA and NHTSA.

11 12 IV. CONCLUSION

13 Based on foregoing, the Court should grant Plaintiff's motion to dismiss this case
14 without prejudice.

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16 Dated: September 25, 2024

17 Respectfully Submitted,

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