

U.S. Department of Justice Civil Division

Consumer Protection Branch

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Sent via e-mail and U.S. mail

Re: Baker v. U.S. Food and Drug Admin., et al., No. 2:24-cv-02558-DC-SCR (E.D. Cal.)

Mr. Baker:

On December 11, 2024, you issued "Interrogatories to Defendant FDA Set 1" and "Interrogatories to Defendant NHTSA Set 1" in reference to the above litigation. However, for the reasons set forth in Defendants' December 23, 2024 brief in Opposition to Plaintiff's Petition for Writ of Mandate (ECF No. 12) ("Defs. Pet. Opp."), and for the reasons discussed in the parties' December 12, 2024 meet and confer, Defendants maintain that discovery in this case is improper, particularly at this time.

As discussed in greater detail in Defendants' Opposition to Plaintiff's Petition for Writ of Mandate, Plaintiff's claims arise under the Administrative Procedure Act ("APA"), and the "focal point" for review of an APA claim is "the administrative record already in existence, not some new record made initially in the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam)). And because APA review is focused on the administrative record, the "standard discovery tools of civil litigation" generally "do not apply" in such cases. *Comprehensive Cmty. Dev. Corp. v. Sebelius*, 890 F. Supp. 2d 305, 312 (S.D.N.Y. 2012); see also Blue Mountains Biodiversity Project v. Jeffries, 99 F.4th 438, 452 (9th Cir. 2024) ("In APA agency review cases, private parties may not introduce new facts, and discovery is ordinarily not available."); Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd., 663 F.3d 476, 487 (D.C. Cir. 2011) ("Discovery typically is not available in APA cases."); Pub. Power Council v. Johnson, 674 F.2d 791, 794 (9th Cir. 1982) ("[A]gency actions are to be judged on the agency record alone, without discovery.").

Both the Federal Rules of Civil Procedure and this Court's Local Rules further demonstrate that discovery is generally improper and unauthorized in a case such as this one. *See*

Fed. R. Civ. P. 26(f)(1), 26(a)(1)(B) (exempting actions "for review on an administrative record" from the Rule 26(f) meet and confer requirement and the initial disclosures requirement); *see also* E.D. Cal. L.R. 261(a) (setting forth a default schedule for most cases involving review of an administrative record that lacks any directives or deadlines related to discovery).

To seek discovery in this case, Plaintiff must demonstrate to the Court's satisfaction that any extra-record documents sought "are necessary to adequately review the [agency]'s decision." *Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010). Plaintiff must also satisfy one of the "narrow exceptions to th[e] general rule" that "courts reviewing an agency decision are limited to the administrative record." *Lands Council v. Powell*, 395 F.3d 1019, 1029–30 (9th Cir. 2005). Therefore, absent a Court order finding that Plaintiff has satisfied one or more of the "limited exceptions" permitting discovery in an APA case, *id.*, discovery in this case is improper.

Defendants reserve the right to assert appropriate objections to Plaintiff's discovery requests and/or otherwise respond if the Court orders that such discovery is warranted. This reservation is appropriate under the circumstances because, in addition to the issues discussed above, Defendants are not yet obligated to produce the administrative record in this case. See Defs. Pet. Opp. At 3-5 (explaining this issue). And unless and until production of the administrative record is ordered by the Court—if any of Plaintiff's claims survive Defendants' pending Motion to Dismiss, ECF No. 9—Defendants are not in a position to fully evaluate the extent to which Plaintiff's requests are overly broad, unduly burdensome, disproportionate to the needs of the case, duplicative, or otherwise inappropriate. See Defs. Pet. Resp. at 3-5 (explaining why Plaintiff's effort to seek discovery at this stage of the litigation is premature in addition to being improper). Indeed, the administrative record, once produced, would likely provide all of the information required for the Court's resolution of the merits of Plaintiffs' claims. Moreover, Defendants are not in a position to fully evaluate Plaintiff's requests until the Court issues a decision on Defendants' motion to dismiss. See Defs. Pet. Resp. at 3-5. For the reasons set forth in that motion, the Court may at least refine or narrow the issues in this case even if it does not dismiss Plaintiff's Complaint, which would in turn bear on whether and to what extent Plaintiff's requests are disproportionate to the needs of the case or otherwise improper.

Sincerely,

/s/ Scott P. Kennedy
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