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U.S. COURT OF APPEALS

**NOT FOR PUBLICATION**

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

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| DANIEL KRIPKE, on behalf of himself and the general public,<br><br>Plaintiff-Appellant,<br><br>v.<br><br>U.S. FOOD & DRUG ADMINISTRATION; et al.,<br><br>Defendants-Appellees. | No. 17-55146<br><br>D.C. No. 3:16-cv-01214-H-BLM<br><br>MEMORANDUM[*] |

Appeal from the United States District Court
for the Southern District of California
Marilyn L. Huff, District Judge, Presiding

Argued and Submitted June 7, 2018
Pasadena, California

Before: D.W. NELSON and CHRISTEN, Circuit Judges, and SHEA,[**] District Judge.

Daniel Kripke filed this action against the U.S. Food and Drug Administration (FDA) alleging the FDA unreasonably delayed deciding his citizen

[*] This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

[**] The Honorable Edward F. Shea, United States District Judge for the Eastern District of Washington, sitting by designation.

petition. The district court dismissed Kripke's complaint with prejudice for failure to state a claim. We have jurisdiction under 28 U.S.C. 1291, and we affirm.

1. The district court erred by dismissing Kripke's claims on the merits without first deciding whether Kripke had standing to sue. *See Righthaven LLC v. Hoehn*, 716 F.3d 1166, 1172 (9th Cir. 2013). As such, we address standing in the first instance and independently dismiss Kripke's complaint on the merits.

2. Kripke has Article III standing. Kripke properly alleged: (1) the FDA has violated procedural rules—specifically, 5 U.S.C. § 706(1), 21 U.S.C. §§ 351, 352, 355; and 21 C.F.R. § 10.30(e)—by unlawfully withholding or unreasonably delaying its response to Kripke's citizen petition; (2) the FDA's failure to adhere to these rules affects both his concrete interest as a treating physician and as a researcher who funds studies on the harmful side effects of hypnotic drugs; and (3) the FDA's failure to act on Kripke's citizen petition threatens those interests. *See Friends of Santa Clara River v. United States Army Corps of Engineers*, 887 F.3d 906, 918 (9th Cir. 2018). Kripke also properly alleged that the FDA's adherence to these rules may influence the FDA's stance on the safety and efficacy of hypnotic drugs. *See id*.

3. Kripke has standing to pursue his procedural claim under the Administrative Procedure Act (APA). *See Havasupai Tribe v. Provencio*, 876 F.3d

1242, 1253 (9th Cir. 2017). Kripke's clinical practice comprises of patients with sleeping disorders who take, or express an interest in being treated with, hypnotic drugs. He is also a researcher who has devoted many years to studying the side effects of hypnotic drugs, and he seeks to raise safety and efficacy concerns associated with the widespread use of hypnotic drugs that have been previously approved by the FDA. Given these allegations, Kripke's stake puts him squarely within the zone of interest of the FDA regulations. *See* 21 C.F.R. §§ 10.25(a), 10.30.

4. Kripke's claims fail on the merits. The FDA complied with 21 C.F.R. § 10.30(e) when it responded to Kripke's citizen petition within 180 days. The FDA's response does not constitute an abuse of discretion. As expressly permitted by 21 C.F.R. § 10.30(e)(2)(iv), the FDA provided Kripke with an interim response stating that it was unable to reach a decision. The FDA's failure to resolve Kripke's complex citizen petition within seven months of its filing was not unreasonable—Kripke's petition included over 100 references and eight requests concerning at least ten previously approved drugs.

5. The district court did not err by denying Kripke leave to amend his complaint because any amendment would have been futile. *See Newton v. Parker Drilling Mgmt. Servs., Ltd.*, 881 F.3d 1078, 1083 (9th Cir. 2018).

**AFFIRMED.**