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**UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA**

DONALD R. EARL,

Petitioner,

v.

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Case No. C07-05413-BHS

RESPONDENT’S REPLY IN
SUPPORT OF ITS MOTION TO
DISMISS

NOTED ON MOTION CALENDAR:
November 9, 2007

I. INTRODUCTION

In this action, Petitioner seeks a writ of mandamus to compel the United States Food and Drug Administration (“FDA”) to conduct an investigation into alleged acetaminophen contamination of pet food. On September 27, 2007, before FDA had responded to the Petition for Writ of Mandamus (“the Petition”), Petitioner moved for summary judgment (R. 6). On October 12, 2007, FDA filed a Motion to Dismiss the Petition and Opposition to Petitioner’s

1 Motion for Summary Judgment (“FDA MTD”), and Petitioner responded on October 19 (“Pet.
2 Resp.”).¹ FDA now files this reply in support of its motion to dismiss.

3 As shown below, Petitioner has wholly failed to address this Court’s lack of jurisdiction
4 over his claims. Moreover, Petitioner is not entitled to the extraordinary relief of mandamus
5 because he has not shown a duty owed to him by FDA, and has failed to demonstrate the absence
6 of alternative relief. This Court should therefore dismiss the Petition and deny as moot
7 Petitioner’s motion for summary judgment.

8 II. ARGUMENT

9 A. This Court Lacks Jurisdiction Over Petitioner’s Claims

10 Petitioner contends that the Mandamus Act alone, 28 U.S.C. § 1361, gives this Court
11 jurisdiction over the Petition. See Pet. Resp. at 2-3 ¶ 6. While that statutory provision
12 undisputably vests this Court with original jurisdiction, it does not speak to the Court’s subject
13 matter jurisdiction.² As discussed in FDA’s previous brief, this Court does not have subject
14 matter jurisdiction over the Petition because the claims are not ripe, there has been no final
15 agency action, and Petitioner has not exhausted his administrative remedies. See FDA MTD at
16 10-14.

17 Petitioner asserts that his claims are ripe, see Pet. Resp. at 8 ¶ 29, 9 ¶ 33, but rather than
18 demonstrating that the issues he raises in the Petition are in fact sufficiently developed to be fit

19
20 ¹ The brief FDA filed on October 12 was both a motion to dismiss (filed as R. 12) and an
21 opposition to Petitioner’s motion for summary judgment (R. 13). While Petitioner’s Response
22 (R. 14) is captioned and was docketed only as a response to FDA’s motion to dismiss, the
23 government will assume Petitioner intended the Response to serve as well as his reply in support
24 of his motion for summary judgment. The government’s assumption is supported by the
25 Petitioner’s reliance on evidence outside the pleadings, see Pet. Resp. at 4-5, Exs. A-C, which is
26 not permitted in a motion to dismiss but is appropriate with a motion for summary judgment.

27 ² Original jurisdiction is “[a] court’s power to hear and decide a matter before any other
28 court can review the matter,” while subject matter jurisdiction is “[j]urisdiction over the nature of
the case and the type of relief sought.” Black’s Law Dictionary 869, 870 (8th ed. 2004).
Original jurisdiction is neither necessary nor sufficient to establish the ripeness, finality, and
exhaustion of administrative remedies required for subject matter jurisdiction.

1 for judicial review, Petitioner merely states that FDA is taking too long to initiate an
2 investigation. Id. at 8-9 ¶¶ 29-33. Complaining about the length of time an agency is taking to
3 make a decision does not demonstrate that a matter is ripe for judicial review. Additionally, the
4 Response is silent regarding the lack of a final agency action, and in fact concedes that “no
5 investigation into the matter has officially been commenced, nor has an official decision been
6 ordered.” Id. at 9 ¶ 35. Finally, Petitioner appears to concede that he made no attempt to exhaust
7 his administrative remedies before seeking judicial review by filing this lawsuit, but defends his
8 failure to exhaust only on grounds that pursuing administrative remedies would essentially delay
9 resolution of this matter indefinitely. Pet. Resp. at 9-10 ¶¶ 36, 37. To the contrary, however,
10 submitting a request for administrative relief through the citizen petition process, 21 C.F.R..
11 § 10.30, would permit FDA to reach a considered, final decision, which could then serve as the
12 basis for a lawsuit, should Petitioner disagree with FDA’s final decision, 21 C.F.R. § 10.45(b).
13 “If a plaintiff is required to exhaust administrative remedies but fails to do so, the federal courts
14 do not have jurisdiction to hear the plaintiff’s claim.” Blanchard v. Morton Sch. Dist., 420 F.3d
15 918, 920-21 (9th Cir. 2005).

16 Moreover, FDA’s decisions whether or not to initiate an investigation are discretionary
17 and not subject to judicial review, pursuant to Heckler v. Chaney, 470 U.S. 821, 838 (1985). See
18 also FDA MTD at 14-16. Petitioner makes no attempt to show why Heckler does not apply to
19 his claims, but instead lists “four conditions that may exist in the exercise of discretion” –
20 without providing a source for those “conditions” – and then concludes that “[a]buse of
21 discretion has already taken place.” Pet. Resp. at 7 ¶ 26, at 9 ¶ 35.³ Petitioner appears to argue
22 that FDA has discretion in its handling of “routine, day to day matters,” id. at 8 ¶ 27, but that
23 regarding “an unprecedented poisoning event of epic proportions” such as the one Petitioner
24

25 ³ The government notes that although Petitioner emphatically denies that the
26 Administrative Procedure Act (“APA”) applies to this case, he nonetheless invokes an APA
27 standard of review, abuse of discretion, see 5 U.S.C. § 706(2)(A), in his response brief. See Pet.
28 Resp. at 9 ¶¶ 35, 36.

1 alleges has occurred with acetaminophen in pet food, Congress intended to somehow limit that
2 discretion, id. at 8 ¶ 28. Petitioner has not provided any support for this contention, and cannot
3 do so, particularly due to the holding of Heckler and its progeny that judicial review simply is not
4 available for a federal agency’s exercise of enforcement discretion.⁴

5 In sum, this case is not ripe for judicial review; there is no final agency action; petitioner
6 has failed to exhaust administrative relief; and Heckler bars judicial review of discretionary
7 enforcement decisions. This Court has no jurisdiction to consider the merits of Petitioner’s
8 request for mandamus relief, and must dismiss the petition under Fed. R. Civ. P. 12(b)(1) for lack
9 of jurisdiction.

10 B. Mandamus Relief is Not Warranted Here

11 FDA’s previous brief explained why it appeared the Petition should be interpreted as
12 seeking relief under the Administrative Procedure Act (“APA”), even though Petitioner said (in
13 both the Petition and the summary judgment motion) that he was seeking relief under the
14 Mandamus Act, 28 U.S.C. § 1361. See FDA MTD at 5-9 (quoting Air Line Pilots Ass’n, Int’l v.
15 Transamerica Airlines, Inc., 817 F.2d 510, 516 (9th Cir. 1987) (“[a] complaint is not to be
16 dismissed because the plaintiff’s lawyer has misconceived the proper legal theory of its claim”)
17 (internal quotation marks and citation omitted)). In his Response, Petitioner now expressly
18 disclaims any reliance upon the APA or any other cause of action. Pet. Resp. at 2 ¶ 3 (“The
19 Petitioner explicitly brings this action under the provisions of 28 U.S.C. § 1361 and no other.
20 Those portions of the Respondent’s Motion not substantially relevant to 28 U.S.C. § 1361 should
21

22 ⁴ Though not material here, the Response is simply mistaken when it asserts that the
23 Mandamus Act, 28 U.S.C. § 1361, and the Federal Food, Drug, and Cosmetic Act (“FDCA”)
24 both explicitly waive the government’s sovereign immunity. See Pet. Resp. at 6 ¶ 22. Neither
25 the Mandamus Act nor the FDCA actually contain such waivers. Instead, when mandamus is
26 sought against an administrative agency, the necessary waiver of sovereign immunity is supplied
27 by the APA, 5 U.S.C. § 702; this is true even when, as Petitioner has emphatically stated, the
28 Mandamus Act is the sole vehicle used to seek mandamus. See United States v. Mitchell, 463
U.S. 206, 227 & n.32 (1983); Pit River Home & Agric. Coop. Ass’n v. United States, 30 F.3d
1088, 1098 n.5 (9th Cir. 1994).

1 not be taken into consideration.”). Petitioner is authorized to disavow reliance upon the APA if
2 he wishes; “the party who brings a suit is master to decide what law he will rely upon.” The Fair
3 v. Kohler Die & Specialty Co., 228 U.S. 22, 25 (1913) (Holmes, J.). Thus, if the Court finds that
4 it has subject-matter jurisdiction, the only analysis necessary under Rule 12(b)(6) would be
5 determining whether the Petition fails to state a Mandamus Act claim, because Petitioner has
6 disclaimed all other causes of action.

7 As explained in the government’s previous filing, in order to show that mandamus is
8 warranted here, Petitioner must demonstrate (1) that his claim is clear and certain, (2) that FDA’s
9 duty is ministerial and “so plainly prescribed as to be free from doubt,” and (3) that no alternative
10 relief is available. See FDA MTD at 16.⁵ While Petitioner acknowledges this standard, see Pet.
11 Resp. at 7 ¶ 24, the Response is devoid of any mention of the first prong, and Petitioner fails to
12 demonstrate that either the second or the third prongs have been met. Thus, even if the Court
13 were to find that it does have jurisdiction to consider the Petition, it would be obliged to dismiss
14 it under Rule 12(b)(6) for failure to state a claim upon which relief could be granted.

15 1. Petitioner has not shown a duty owed to him by FDA

16 Petitioner’s continued reliance on FDA’s mission statement to create a duty owed to him
17 sufficient to give rise to mandamus relief is misplaced. FDA’s mission statement, 21 U.S.C.
18 § 393(b), is simply a general statement of FDA’s function as a public health agency. In support
19 of his claim, Petitioner quotes section 393(b)(1), see Pet. Resp. at 4 ¶ 12, which provides that
20 FDA shall “promote the public health by promptly and efficiently reviewing clinical research and
21 taking appropriate action on the marketing of regulated products in a timely manner.” The
22 quoted language is of no help whatsoever to Petitioner, however, because Petitioner has not
23

24 ⁵ Petitioner makes several factual allegations and asserts that they demonstrate
25 “exceptional circumstances” warranting mandamus relief. Pet. Resp. at 6-7 ¶ 23. But the
26 standard for determining whether mandamus is appropriate is the three-prong test described
27 above, not some subjective inquiry into the existence of “exceptional circumstances,” which
28 Petitioner makes no attempt to define. And, as discussed above, Petitioner has failed to meet the
standard for mandamus.

1 submitted clinical research data to FDA for review and section 393(b)(1) is therefore irrelevant,
2 even if it did create an enforceable, ministerial duty on FDA.

3 A case on which Petitioner relies, Paunescu v. INS, 76 F. Supp. 2d 896 (N.D. Ill. 1999),
4 is inapposite. Pl. Response at 3 ¶ 11.⁶ Plaintiffs in that case were seeking an order of mandamus
5 to compel the Immigration and Naturalization Service (“INS”) to reach a decision on their
6 applications for visas. See id. at 898. The court found that a statutory provision, 8 U.S.C.
7 § 1255, imposed a duty on the INS to adjudicate such applications within a reasonable time. See
8 id. at 900-01. Here, however, as discussed in FDA’s previous brief, see FDA MTD at 18,
9 Petitioner has not pointed to any statutory provision that imposes a duty on FDA to initiate
10 investigations, much less investigations into allegedly acetaminophen-contaminated pet food.
11 Petitioner’s reliance on Paunescu, therefore, is misplaced.

12 2. Alternative relief is available to Petitioner

13 Petitioner asserts, again without support, that “[t]he APA does not provide [Petitioner
14 with] adequate alternative relief.” Pet. Resp. at 3 ¶ 10. Petitioner, however, fails to elaborate on
15 this conclusory statement, offering no explanation for how and why the variety of relief
16 potentially available to him under the APA is inadequate, such as its providing a cause of action
17 to any “person suffering legal wrong because of agency action, or adversely affected or aggrieved
18 by agency action within the meaning of a relevant statute.” 5 U.S.C. § 702. Furthermore, as
19 explained previously, Petitioner has also failed to seek relief through administrative means, in the
20 form of a citizen petition to FDA. See FDA MTD at 13-14, 19. To be sure, as noted above, see
21 page 3, supra, Petitioner appears to contend that seeking administrative relief might lead to
22 indefinite delay. In the event that Petitioner thought the administrative process was taking too
23 long, he could attempt to show that agency action was “unreasonably delayed” under the APA,
24 5 U.S.C. § 706(1). To date, however, Petitioner has made no effort to avail himself of available

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26 ⁶ The quotation Petitioner attributes to Paunescu (“[a] contrary position would permit the
27 INS to delay indefinitely”) does not appear anywhere in the text or even headnotes of the
28 opinion.

1 avenues of administrative relief, and Petitioner’s mere contentions alone are insufficient to
2 demonstrate the unavailability of alternative relief.⁷ His request for an order of mandamus
3 should thus be denied.

4 III. CONCLUSION

5 For the foregoing reasons, as well as those in the government’s previous filing, the
6 government’s Motion to Dismiss should be granted, and Petitioner’s Motion for Summary
7 Judgment should be denied as moot.

8 Dated: November 8, 2007

Respectfully submitted,

9 JEFFREY C. SULLIVAN
10 United States Attorney

11 THOMAS M. WOODS
12 Assistant United States Attorney
13 700 Stewart Street, Suite 5220
14 Seattle, WA 98101
15 206-553-4312

13 OF COUNSEL:

14 DANIEL MERON
15 General Counsel

PETER D. KEISLER
Assistant Attorney General

16 GERALD F. MASOUDI
17 Associate General Counsel
18 Food and Drug Division

C. FREDERICK BECKNER III
Deputy Assistant Attorney General

17 ERIC M. BLUMBERG
18 Deputy Chief Counsel, Litigation

EUGENE M. THIROLF
Director

19 SHOSHANA HUTCHINSON
20 Associate Chief Counsel, Litigation
21 U.S. Dept. of Health & Human Services
22 Office of the General Counsel
23 5600 Fishers Lane, GCF-1
24 Rockville, MD 20857
25 301-827-8579

/s/ Daniel K. Crane-Hirsch
DANIEL K. CRANE-HIRSCH
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
202-616-8242

26 _____
27 ⁷ Petitioner asserts that “[t]he courts recognize administration petitions as inadequate
28 alternatives under these circumstances,” Pet. Resp. at 10 ¶ 37, but cites no authority.

1 **CERTIFICATE OF SERVICE**

2
3 I HEREBY CERTIFY that the foregoing is being filed on the 8th day of November, 2007,
4 using the Court's CM/ECF system.

5 I further certify that I will send a copy of the foregoing to Petitioner via first class U.S.
6 mail, postage pre-paid, and via e-mail, at the following addresses:

7 Mr. Donald R. Earl, *pro se*
8 3090 Discovery Road
9 Port Townsend, WA 98368-9633
10 Phone: (360) 379-6604
11 don-earl@waypoint.com

12 Dated: November 8, 2007

13 /s/ Daniel K. Crane-Hirsch
14 DANIEL K. CRANE-HIRSCH
15 Trial Attorney
16 Office of Consumer Litigation
17 U.S. Department of Justice
18 P.O. Box 386
19 Washington, D.C. 20044
20 202-616-8242