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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS,

Plaintiff,

No. C 07-01049 WHA

v.

The U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES, and the U.S.  
FOOD AND DRUG ADMINISTRATION,

**ORDER GRANTING  
MOTION TO DISMISS**

Defendants.

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**INTRODUCTION**

In this Administrative Procedure Act action, plaintiff Americans for Safe Access seeks to compel the United States Department of Health and Human Services to provide a “substantive” response to its petition to correct statements regarding the accepted medical use and efficacy of marijuana. Plaintiff filed its first amended complaint on August 17, 2007.

On motion to dismiss pursuant to Rule 12(b)(6), this order addresses the following two questions: (1) What constitutes an “agency action” under 5 U.S.C. 706(1), the provision of the APA which allows a court to “compel agency action unlawfully withheld or unreasonably delayed,” and (2) Is adherence to guidelines promulgated under the requirements of the Information Quality Act legally required? This order finds that it is not necessary to reach a conclusion as to the first question because plaintiff has not shown that the action it seeks to compel is legally required. This order therefore **GRANTS** defendants’ motion to dismiss.

1 **STATEMENT**

2 The Information Quality Act of 2000 directed the Office of Management and Budget to  
3 issue guidelines “that provide policy and procedural guidance to Federal agencies for ensuring  
4 and maximizing the quality, objectivity, utility, and integrity of information disseminated by  
5 Federal agencies . . . .” Pub. L. No. 105-554 § 1(1)(3) [Title V. § 515] (Dec. 21, 2000)  
6 (published at 44 U.S.C. 3516 note 4(a)). The IQA directed OMB to include the following  
7 provisions in its guidelines: (1) that federal agencies issue their own guidelines not more than  
8 one year after OMB issues its guidelines; (2) that agencies “establish administrative  
9 mechanisms allowing affected person to seek and obtain correction of information maintained  
10 and disseminated by the agency that does not comply with [the OMB guidelines];” and (3) that  
11 agencies periodically report to the director of OMB the nature and number of complaints and  
12 how they were handled. *See* 44 U.S.C. 3516 note 4(b)(2).

13 The OMB guidelines, finalized on February 22, 2002, stated the following as to  
14 information-correction procedures:

15 To facilitate public review, agencies shall establish administrative  
16 mechanisms allowing affected persons to seek and obtain, where  
17 appropriate, timely correction of information maintained and  
18 disseminated by the agency that does not comply with OMB or  
19 agency guidelines. These administrative mechanisms shall be  
flexible, appropriate to the nature and timeliness of the  
20 disseminated information, and incorporated into agency  
information resources management and administrative practices.

21 i. Agencies shall specify appropriate time periods for agency  
22 decisions on whether and how to correct the information, and  
agencies shall notify the affected persons of the corrections made.

23 ii. If the person who requested the correction does not agree with  
24 the agency’s decision (including the corrective action, if any), the  
25 person may file for reconsideration within the agency. The  
26 agency shall establish an administrative appeal process to review  
27 the agency’s initial decision, and specify appropriate time limits  
28 in which to resolve such requests for reconsideration.

67 Fed. Reg. at 8459.

1 On October 1, 2002, pursuant to the IQA and the OMB guidelines, the United States  
2 Department of Health and Human Services implemented its own guidelines. The HHS  
3 guidelines established an information-correction procedure as follows:

4 Based on a review of the information provided, the agency will  
5 determine whether a correction is warranted and if so, what action  
6 to take. The agency will respond to the requestor by letter or  
7 e-mail. The agency's response will explain the findings of the  
8 review and the actions that the agency will take, if any.  
9 The response will consider the nature and timeliness of the  
10 information involved and such factors as the significance of the  
11 correction on the use of the information, the magnitude of the  
12 correction and the resource requirements for the correction.  
13 The response will describe how the complainant may request  
14 reconsideration. The agency will respond to all requests for  
15 correction within 60 calendar days of receipt. If the request  
16 requires more than 60 calendar days to resolve, the agency will  
17 inform the complainant that more time is required and indicate the  
18 reason why and an estimated decision date.

12 If the individual submitting the complaint does not agree with the  
13 agency's decision (including the corrective action), the  
14 complainant may send a written hard copy or electronic request  
15 for reconsideration within 30 days of receipt of the agency's  
16 decision. The appeal shall state the reasons why the agency  
17 response is insufficient or inadequate. Complainants shall attach  
18 a copy of their original request and the agency response to it,  
19 clearly mark the appeal with the words, "Information Quality  
20 Appeal," and send the appeal to the specific agency appeals  
21 address.

18 The agency official who handles the original complaint will not  
19 have responsibility for resolving the appeal. The agency will  
20 respond to all requests for appeals within 60 calendar days of  
21 receipt. If the request requires more than 60 calendar days to  
22 resolve, the agency will inform the complainant that more time is  
23 required and indicate the reason why and an estimated decision  
24 date.

21 <http://aspe.hhs.gov/infoquality/Guidelines/index.shtml>.

22 Plaintiff filed an information-correction request with HHS on October 4, 2004, asking  
23 HHS to correct information it was disseminating about the medical use of marijuana (Compl.  
24 ¶ 15). Specifically, plaintiff disagrees with defendants' statements that marijuana "has no  
25 currently accepted medical use in treatment in the United States" (Compl. ¶ 1). HHS responded  
26 on December 1, 2004, stating that it needed to consult with the Drug Enforcement  
27 Administration, which was contemporaneously reviewing a petition to reschedule marijuana, in  
28 order to provide a response. Plaintiff protested this response as inexcusable delay, but HHS

1 nevertheless continued to state that it needed more time to coordinate agency review (Compl.  
2 ¶¶ 18–19). On April 20, 2005, HHS denied plaintiff’s information-correct petition, and plaintiff  
3 appealed on May 19, 2005. Subsequently, HHS made a series of interim responses noting that  
4 the process was still ongoing, and on July 12, 2006, noted that it anticipated providing a response  
5 by September 2006 in connection with a marijuana rescheduling petition pending before the  
6 DEA. According to plaintiff, this marked the conclusion of the administrative IQA petition  
7 process, as plaintiff was left without additional avenues of recourse (Compl. ¶¶ 19–22)).

8 Plaintiff filed suit on February 21, 2007, seeking declaratory and injunctive relief under  
9 the Administrative Procedure Act. On July 24, 2007, this Court granted defendants’ motion to  
10 dismiss the original complaint for failure to state a claim under Rule 12(b)(6), but granted  
11 plaintiff leave to amend to proceed on a theory that defendants unlawfully withheld or delayed  
12 agency action by not providing a *substantive* response to plaintiff’s information-correction  
13 petition. Plaintiff did so amend its complaint, and filed its amended complaint on August 17,  
14 2007. Defendants then filed a second motion to dismiss under Rule 12(b)(6) on October 11,  
15 2007.

## 16 ANALYSIS

### 17 1. “FINAL” AGENCY ACTION UNDER SECTION 706(1).

18 The APA allows judicial review of federal agency action that is either “made reviewable  
19 by statute [or] final agency action for which there is no other adequate remedy in a court.”  
20 5 U.S.C. 704. It also directs the reviewing court to “compel agency action unlawfully withheld  
21 or unreasonably delayed.” 5 U.S.C. 706(1). A claim under Section 706(1) “can proceed only  
22 where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is required  
23 to take.” *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004).

24 Plaintiff argues that an action under Section 706(1) only needs to be a “discrete” action,  
25 not a “final agency action,” stating that “courts have routinely entertained suits under the APA  
26 for denials of administrative petitions” (Opp. 11). Plaintiff cites numerous cases on this point,  
27 all of which are similarly unhelpful inasmuch as they all address final agency actions.  
28

1 Defendants, however, note several decisions, including two district court decisions within  
2 the Ninth Circuit that have squarely addressed this question and have held that Section 706(1)  
3 requires that the action sought to be compelled must be final agency action. *See Elhaouat v.*  
4 *Miller*, 2007 WL 2332488 at \*3 (E.D. Penn., Aug. 9, 2007); *High Sierra Hikers Ass'n v. United*  
5 *States Forest Serv.*, 436 F. Supp. 2d 1117, 1140 (E.D. Cal., June 8, 2006); *Friends of Yosemite*  
6 *Valley v. Scarlett*, 439 F. Supp. 2d 1074, 1086 (E.D. Cal., July 19, 2006). Ultimately it is not  
7 necessary for this order to rule on the question because plaintiff fails to meet the second  
8 requirement under Section 706(1); that the action to be compelled is legally required.

9 **2. ACTION LEGALLY REQUIRED.**

10 “[T]he only action that can be compelled under the APA is action legally *required*.”  
11 *Norton*, 542 U.S. at 63. In this case, plaintiff argues that defendants have unreasonably delayed  
12 in making a substantive response, but a delay “cannot be unreasonable with respect to action that  
13 is not required.” *Id.* at 63 n.1. Plaintiff argues that the language in the IQA, which directs the  
14 OMB to issue guidelines that would “require” agencies to issue their own guidelines that would  
15 allow “affected persons to seek and obtain correction of information” creates a legal requirement  
16 (Opp. 12) (quoting 67 Fed. Reg. 8452, 8459 (Feb. 22, 2003)). Furthermore, plaintiff notes that  
17 the OMB guidelines state that agencies “shall specify appropriate time periods for agency  
18 decisions.” *Ibid.* As stated above, the HHS guidelines direct the agency to respond to requests  
19 for correction and appeals within sixty days.

20 Defendants rely on *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006), in  
21 which the Fourth Circuit held that the IQA “creates no legal rights in any third parties.”  
22 Defendants further argue that the HHS guidelines do not impose a strict deadline because  
23 they only state that “[t]he agency will respond to all requests for correction within 60 calendar  
24 days of receipt,” and if the requests requires more than 60 days, the agency “will inform the  
25 complainant that more time is required and indicate the reason why.”  
26 <http://aspe.hhs.gov/infoquality/Guidelines/index.shtml>. Plaintiff does not dispute that defendants  
27 *did* respond but, instead, argues that defendants’ response amounted to a “nonsubstantive final  
28 denial” (Compl. ¶ 22).

1 Defendants also contend that the OMB guidelines do not *mandate* a substantive response,  
2 but instead “underscore the ‘flexibility’ that the guidelines give the agencies” (Reply 16).  
3 Guidelines are by nature advisory, but the Ninth Circuit has recognized that “[a]n agency’s  
4 regulations *may* create judicially enforceable duties.” *Lowry v. Barnhart*, 329 F.3d 1019, 1022  
5 (9th Cir. 2003) (emphasis added). In *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 602 (E.D.  
6 Va., Nov. 15, 2004), however, Judge Gerald Lee considered whether an agency’s actions under  
7 the IQA and the OMB guidelines were judicially reviewable and stated that “[a]gency  
8 dissemination of advisory information that has no legal impact has consistently been found  
9 inadequate to constitute final agency action and thus is unreviewable by federal courts under the  
10 APA.” That decision held that “neither the IQA nor the OMB Guidelines provide judicially  
11 manageable standards that would allow meaningful judicial review to determine whether an  
12 agency properly exercised its discretion in deciding a request to correct a prior communication.”  
13 *Ibid*. The OMB guidelines give discretion to agencies by stating that “agencies, in making their  
14 determination of whether or not to correct information, may reject claims made in bad faith or  
15 without justification, and are required to undertake only the degree of correction that they  
16 conclude is appropriate for the nature and timeliness of the information involved.” 67 Fed. Reg.  
17 at 8458.

18 In addition to the holding in *Salt Institute*, other courts have held similar language to  
19 allow discretion on the part of agencies, and render action not legally required. *See Steenholdt v.*  
20 *FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (regulations allowing rescission of a designation for  
21 any reason the administration considers appropriate not judicially reviewable).

22 This order agrees that the IQA and OMB guidelines do not create a duty to perform  
23 legally required actions that are judicially reviewable. Since plaintiff has not shown that the  
24 action it seeks to compel is legally required, defendants’ motion to dismiss for failure to state a  
25 claim must be **GRANTED**.

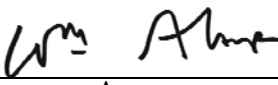
## 26 CONCLUSION

27 Plaintiff has failed to show that defendants have unreasonably delayed the performance  
28 of a legally required duty. For the above reasons, defendants’ motion to dismiss for failure to

1 state a claim pursuant to Rule 12(b)(6) is hereby **GRANTED**. Further leave to amend is  
2 unwarranted. The Clerk shall close the file.

3  
4 **IT IS SO ORDERED.**

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6 Dated: November 20, 2007.

  
7 WILLIAM ALSUP  
8 UNITED STATES DISTRICT JUDGE

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