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10

11 UNITED STATES DISTRICT COURT  
12 NORTHERN DISTRICT OF CALIFORNIA  
13 SAN FRANCISCO

14 AMERICANS FOR SAFE ACCESS, )  
15 Plaintiff, )  
16 v. )  
17 The U.S. DEPARTMENT OF HEALTH )  
AND HUMAN SERVICES and the U.S. )  
18 FOOD AND DRUG ADMINISTRATION, )  
19 Defendants. )  
20 )

No. C 3:07-01049-WHA

Date: November 15, 2007

Time: 8:00 a.m.

**DEFENDANTS' NOTICE OF MOTION  
AND MOTION TO DISMISS  
PLAINTIFF'S AMENDED COMPLAINT**

21 Notice of Motion and Motion to Dismiss Plaintiff's Complaint, set for hearing on  
22 November 15, 2007 at 8:00 a.m. or as soon thereafter as counsel may be heard.

23 Defendants hereby move the Court to dismiss plaintiff's Complaint in its entirety for lack  
24 of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) or, in the  
25 alternative, for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), for  
26 the reasons more fully set forth in defendants' accompanying memorandum of points and  
27 authorities.

28 *Americans for Safe Access v. U.S. Dep't Health & Human Services, et al.*  
*Defendants' Notice of Motion and*  
*Motion to Dismiss Plaintiff's Amended Complaint*

1 Dated October 11, 2007

Respectfully Submitted,

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**MEMORANDUM IN SUPPORT OF  
DEFENDANTS' MOTION TO DISMISS  
PLAINTIFF'S AMENDED COMPLAINT**

21  
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1 **INTRODUCTION**

2 Plaintiff Americans for Safe Access, a California advocacy organization, asks this Court  
3 to rewrite the U.S. Department of Health and Human Services’ (“HHS”) statement made six  
4 years ago that “marijuana ha[d] no currently accepted medical use in treatment in the United  
5 States.” The Court, holding that plaintiff failed to state a claim upon which relief may be  
6 granted, has already dismissed plaintiff’s claim once with leave to amend. Plaintiff’s Amended  
7 Complaint failed to cure the defects of its original claims under the Administrative Procedure Act  
8 (“APA”), and its one new claim a request for mandamus under the APA similarly fails to  
9 establish jurisdiction or state a claim that would entitle plaintiff to relief in this Court.

10 First, plaintiff lacks Article III standing to bring its claim because it has not alleged an  
11 invasion of a legally cognizable right since the substantive statute on which it relies, the  
12 Information Quality Act (“IQA”), 44 U.S.C. § 3516 note, vests plaintiff with no such rights  
13 enforceable in this Court.

14 Even if the plaintiff had standing to raise its APA claim, it makes no assertion that the  
15 HHS statement in question has or had any binding legal effect. And, as the Court recognized in  
16 its opinion dismissing plaintiff’s first Complaint, agency acts (such as agency speech) lacking the  
17 force and effect of law are not subject to judicial review. Because the APA cannot be used to  
18 compel action that the APA doesn’t otherwise cover, plaintiff’s request for mandamus should,  
19 therefore, be denied. Plaintiff’s attempt to invoke the APA also fails because an APA cause of  
20 action depends on violation of a substantive statute and, again, the IQA does not provide plaintiff  
21 with a cognizable right upon which it may rest an APA claim. The APA further bars plaintiff’s  
22 claim because plaintiff has an adequate remedy to bring that claim under another statute, the  
23 exclusive review provisions of the Controlled Substances Act; and the APA further bars  
24 plaintiff’s claim because the determination as to whether the information in HHS’s statement  
25 regarding marijuana is appropriate for correction is within the agency’s discretion and expertise  
26 to resolve.

27 At bottom, plaintiff’s claims whether couched as review of final agency action or a  
28 request for mandamus to compel final agency action do not concern the type of agency action

1 that is reviewable under the APA. Because the IQA also does not provide for judicial review of  
2 plaintiff's claims, this Court should dismiss them.

### 3 **BACKGROUND**

#### 4 **I. Statutory and Regulatory Background**

##### 5 **A. The Information Quality Act**

6 The IQA resides in section 515 of the Treasury and General Government Appropriations  
7 Act for Fiscal Year 2001 and directs OMB to issue "guidelines" that provide "policy and  
8 procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity,  
9 utility, and integrity of information (including statistical information) disseminated by Federal  
10 agencies . . . ." Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515] (Dec. 21, 2000) (published at 44  
11 U.S.C. § 3516 note). The IQA also directs OMB to include three specific requirements in its  
12 guidelines: (1) that federal agencies develop their own information quality guidelines within one  
13 year of the issuance of OMB's guidelines; (2) that federal agencies establish administrative  
14 mechanisms for affected persons to seek correction of information that does not comply with  
15 OMB's guidelines; and (3) that federal agencies report periodically to OMB on the number and  
16 nature of complaints that they receive regarding the accuracy of the information they disseminate.  
17 See id. at § 515(b)(2). Neither the IQA itself nor its legislative history provides a mechanism for  
18 judicial review of an administrative decision concerning a request for correction of information  
19 or of the quality of information.<sup>1</sup> Indeed, the IQA provides no avenue for judicial relief at all.

##### 20 **1. OMB Guidelines**

21 OMB issued proposed guidelines implementing the IQA on June 28, 2001, 66 Fed. Reg.  
22 34489 (June 28, 2001), then, after a period for public comment, published revised guidelines on  
23 September 28, 2001, 66 Fed. Reg. 49718 (Sept. 28, 2001). Following another period for  
24

---

25 <sup>1</sup> The legislative history regarding the IQA includes the following sentence in the  
26 Conference Report and Committee Report accompanying the omnibus appropriations bill: "The  
27 conferees include a new provision requiring OMB to develop guidelines for ensuring and  
28 maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal  
agencies as proposed by the House." H.R. CONF. REP. NO. 106-1033, at 396 (2000); see also  
H.R. REP. NO. 106-756, at 83 (2000) (committee report containing nearly identical language).

1 additional comment, OMB published final guidelines on February 22, 2002. See 67 Fed. Reg.  
2 8452 (Feb. 22, 2002). In its final guidelines, OMB provides guidance to federal agencies for  
3 ensuring and maximizing the quality of the information they disseminate to the public.  
4 Generally, the guidelines require federal agencies to undertake four principal responsibilities:  
5 (1) to “adopt specific standards of quality that are appropriate for the various categories of  
6 information they disseminate”; (2) to “develop a process for reviewing the quality . . . of  
7 information before it is disseminated”; (3) to “establish administrative mechanisms allowing  
8 affected persons to seek and obtain, where appropriate, timely correction of information  
9 maintained and disseminated by the agency that does not comply with OMB or agency  
10 guidelines”; and (4) to provide OMB with reports regarding the agencies’ information quality  
11 guidelines and any information quality complaints they receive. 67 Fed. Reg. at 8458-59.<sup>2</sup>

12 The consistent theme throughout the OMB guidelines is that “agencies must apply these  
13 standards flexibly,” “in a common-sense and workable manner,” and that the “guidelines . . . [do]  
14 not impose unnecessary administrative burdens that would inhibit agencies from continuing to  
15 take advantage of the Internet and other technologies to disseminate information that can be of  
16 great benefit and value to the public.” Id. at 8453. For example, the OMB guidelines provide  
17 that federal agencies are to “adopt a basic standard of quality . . . as a performance goal,” and  
18 “[q]uality is to be ensured and established at levels appropriate to the nature and timeliness of the  
19 information to be disseminated.” Id. Recognizing that the guidelines “cannot be implemented by  
20 each agency in the same way,” OMB directs agencies to “incorporate [quality standards] into  
21 their *existing agency information resources management and administrative practices* rather than  
22 create new and potentially duplicative or contradictory processes.” Id. (emphasis added).  
23 Agencies thus maintain substantial discretion in determining how best to ensure the quality of the  
24 information they disseminate.

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25  
26 <sup>2</sup> The OMB guidelines explain that an agency’s “pre-dissemination review” of information  
27 applies only “to information that the agency first disseminates on or after October 1, 2002,”  
28 while the “agency’s administrative mechanisms . . . apply to information that the agency  
disseminates on or after October 1, 2002, regardless of when the agency first disseminated the  
information.” Id. at 8458.

1 With respect to the administrative correction mechanisms, the OMB guidelines require  
2 agencies to “specify appropriate time periods for agency decisions on whether and how to correct  
3 the information” and to “establish an administrative appeal process to review the agency’s initial  
4 decision.” Id. at 8459. OMB makes clear, however, that agencies should correct information  
5 only “where appropriate,” and that “[t]hese administrative mechanisms shall be flexible” and  
6 “appropriate to the nature and timeliness of the disseminated information.” Id. As explained in  
7 the preamble to the OMB guidelines:

8 Agencies, in making their determination of whether or not to correct information,  
9 may reject claims made in bad faith or without justification, and **are required to**  
10 **undertake only the degree of correction that they conclude is appropriate for**  
11 **the nature and timeliness of the information involved**, and explain such  
12 practices in their annual fiscal year reports to OMB.

11 Id. at 8458 (emphasis added).

## 12 2. HHS Guidelines

13 On October 1, 2002, pursuant to the IQA and the OMB guidelines, the Department of  
14 Health and Human Services implemented its own “Guidelines for Ensuring the Quality of  
15 Information Disseminated to the Public.” See [www.hhs.gov/infoquality](http://www.hhs.gov/infoquality).<sup>3</sup> The HHS guidelines  
16 include department-wide umbrella guidelines and agency-specific guidelines, including the  
17 guidelines of the FDA.<sup>4</sup>

18 In its guidelines, HHS declares its commitment “to integrating the principle of  
19 information quality into every phase of information development, including creation, collection,  
20 maintenance, and dissemination.” Id. at § A. HHS recognizes that it has flexibility in  
21 implementing its guidelines given that OMB understood that OMB’s guidelines could not be  
22 implemented in the same way by all agencies and wanted agencies, instead, to apply their  
23 guidelines “in a common sense, workable manner.” Id. at § B. HHS views its guidelines as “an  
24 evolving document and process.” Id. at § D.1.

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25  
26 <sup>3</sup> HHS initially posted draft guidelines on May 1, 2002 and solicited public comments for a  
27 sixty day period. See 67 Fed. Reg. 61343, 61344 (Sept. 30, 2002).

28 <sup>4</sup> The FDA information quality guidelines implement and reiterate the OMB and HHS  
guidelines. See <http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml>.

1 \_\_\_\_\_ The HHS guidelines also establish a process for information correction requests and  
2 appeals. Id. at § E. Nothing in the HHS guidelines abrogates the OMB guideline statement that  
3 the agency must undertake only the degree of correction it deems appropriate. See generally id.  
4 HHS reminds complainants that they bear the burden of proof to establish the need for and the  
5 type of correction sought. Id. A correction request must include specific reasons for asserting  
6 that the information at issue violates OMB, HHS, or agency-specific guidelines and “specific  
7 recommendations for correcting the information.” Id. The agency aims to respond to correction  
8 requests within 60 days of receipt, and a party may appeal the agency’s decision within 30 days  
9 after that. Id. Such an appeal involves “reconsideration within the agency.” Id. The agency  
10 strives to decide any appeals within 60 days. Id. “If the request requires more than 60 calendar  
11 days to resolve, the agency will inform the complainant” and provide an “estimated decision  
12 date.” Id.

13 The HHS guidelines specifically state that “[e]xisting . . . procedures for rule-makings  
14 and other formal agency actions already provide well established procedural safeguards that  
15 allow affected persons to raise information quality issues on a timely basis. Accordingly,  
16 agencies will use these existing procedures to respond to information quality complaints that  
17 arise in this process.” Id.

#### 18 **B. The Controlled Substances Act**

19 The Controlled Substances Act, 21 U.S.C. § 801, et seq. (“CSA”), makes it unlawful to  
20 “manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or  
21 dispense” any controlled substance, “[e]xcept as authorized by [21 U.S.C. 801-904].” 21 U.S.C.  
22 § 841(a)(1); see United States v. Moore, 423 U.S. 122, 131, 135 (1975). The CSA imposes  
23 criminal and civil penalties for violations. See 21 U.S.C. §§ 841-863.

24 The CSA classifies controlled substances according to their inclusion in one of five  
25 schedules. The listing of a drug or other substance in one of the five schedules depends on  
26 whether (and to what extent) it has a currently accepted medical use,<sup>5</sup> its relative potential for

---

27 \_\_\_\_\_  
28 <sup>5</sup> The DEA Administrator has applied a “five-part test for determining whether a drug is in  
(continued...)

1 abuse, and the degree of psychological or physical dependence to which its use may lead. 21  
2 U.S.C. § 812(b). The CSA imposes restrictions on the manufacture, distribution, and dispensing  
3 of the substance according to the schedule in which it has been placed. See 21 U.S.C. §§ 821-  
4 829. Marijuana is included in schedule I, the most restrictive schedule, because it has “a high  
5 potential for abuse,” “no currently accepted medical use in treatment in the United States,” and  
6 “a lack of accepted safety for use . . . under medical supervision.” 21 U.S.C. § 812(b)(1)(A)-(C);  
7 U.S. v. Oakland Cannabis Buyers’ Co-op., 532 U.S. 483, 492 (2001).

8 The CSA establishes an exclusive set of statutory procedures under which controlled  
9 substances that have been placed in schedule I (or any other schedule) may be transferred to  
10 another schedule or be entirely removed from the schedules. 21 U.S.C. § 811(a). See 21 U.S.C.  
11 § 811(a); Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1137 (D.C. Cir. 1994)  
12 (“ACT”) (upholding Administrator’s decision declining to transfer marijuana from schedule I to  
13 schedule II). The responsibility for determining whether a drug should be rescheduled “is  
14 assigned to the Attorney General in consultation with the Secretary of Health and Human  
15 Services (“HHS”). The Attorney General has delegated his functions to the Administrator of the  
16 DEA.” Gettman v. DEA, 290 F.3d 430, 432 (D.C. Cir. 2002) (citing 21 U.S.C. § 811(b) and 28  
17 C.F.R. § 0.100(b)).

## 18 **II. Factual and Procedural Background**

### 19 **A. Jon Gettman’s Unsuccessful Petition to the Drug Enforcement** 20 **Administration Seeking Rescheduling of Marijuana and HHS’s Statements** 21 **to DEA**

22 On July 10, 1995, Jon Gettman petitioned the DEA under the rescheduling provisions of  
23 the CSA to reschedule certain controlled substances, including marijuana. See Department of  
24 Justice, Drug Enforcement Administration, “Notice of Denial of Petition,” 66 Fed. Reg. 20038

25 \_\_\_\_\_  
26 5(...continued)

27 ‘currently accepted medical use’: ‘(1) The drug’s chemistry must be known and reproducible; (2)  
28 there must be adequate safety studies; (3) there must be adequate and well-controlled studies  
proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific  
evidence must be widely available.’” Alliance for Cannabis Therapeutics v. DEA (“ACT”), 15  
F.3d 1131, 1135 (D.C. Cir. 1994) (quoting 57 Fed. Reg. 10499, 10506 (March 26, 1992)).

1 (April 18, 2001). Pursuant to the CSA, the Administrator of the DEA consulted with HHS. Id.  
2 at 20038, 20039. In response, an HHS official, the Assistant Secretary for Health, sent a letter  
3 and attached analysis to the DEA Administrator. Id. at 20039. DEA chose to publish the  
4 Assistant Secretary’s letter and accompanying analysis in the Federal Register. Id. The Assistant  
5 Secretary’s letter includes the statement that plaintiff now seeks to challenge that marijuana has  
6 no currently accepted medical use in treatment in the United States. See id. at 20039; Compl. ¶ 9  
7 (citing 66 Fed. Reg. 20039) see also 66 Fed. Reg. 20038, 20051 (repeating statement in a  
8 heading). “Based on the HHS evaluation and all other relevant data, DEA . . . concluded that  
9 there is no substantial evidence that marijuana should be removed from schedule I” under the  
10 CSA. 66 Fed. Reg. at 20038. Accordingly, DEA denied Mr. Gettman’s petition. Id.; see also  
11 generally Gettman, 290 F.3d 430.

#### 12 **B. Plaintiff’s IQA Request for Correction**

13 On October 6, 2004, HHS received a request from plaintiff for correction of certain  
14 statements pursuant to the IQA and the OMB and HHS IQA guidelines. See Request for  
15 Correction, available at <http://aspe.hhs.gov/infoquality/requests.shtml> (request no. 20). Plaintiff  
16 requested correction of four statements<sup>6</sup> contained in the Assistant Secretary’s letter to the DEA  
17

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18 <sup>6</sup> Those four statements were:

- 19 • “[T]here have been no studies that have scientifically assessed the efficacy of  
20 marijuana for any medical condition” Request for Correction 1-2, quoting 66 Fed.  
21 Reg. 20051 (plaintiff’s Request mis-cited this statement as appearing on page  
22 20052);
- 23 • “A material conflict of opinion among experts precludes a finding that marijuana  
24 has been accepted by qualified experts. *At this time*, it is clear that there is not a  
25 consensus of medical opinion concerning medical applications of marijuana.” See  
26 Request for Correction at 2, quoting 66 Fed. Reg. 20051-52 (emphasis added;  
27 italicized portion not quoted by plaintiff) (plaintiff’s Request mis-cited this  
28 statement as appearing in full on page 20052);
- “[A] complete scientific analysis of all the chemical components found in  
marijuana has not been conducted.” See Request for correction at 2, quoting 66  
Fed. Reg. 20051; and
- Marijuana “has no currently accepted medical use in treatment in the United  
States[.]” See Request for Correction at 2, quoting 66 Fed. Reg. 20039 (January  
(continued...))

1 Administrator and the accompanying HHS analysis that DEA published in the Federal Register.  
2 Id. 1-2, citing 66 Fed. Reg. 20038, 20039, 20051, 20052. Following three interim responses,  
3 HHS resolved plaintiff's Request for Correction on April 20, 2005, noting in pertinent part:

4 Both the Office of Management and Budget (OMB) and the HHS Information Quality  
5 Guidelines provide that federal government agencies may use existing processes that are  
6 in place to address correction requests from the public. In the case of marijuana HHS  
7 currently is in the process of conducting a review in response to the petition for change  
8 [in scheduling under the CSA] that was submitted to DEA in October 2002 by the  
Coalition for Rescheduling Cannabis (CRC), an association of public-interest groups and  
medical cannabis patients that includes the ASA. In the course of the review, HHS will  
evaluate all the publicly available peer reviewed literature on the efficacy of marijuana.

9 April 20, 2005 Response, available at <http://aspe.hhs.gov/infoquality/requests.shtml> (request no.  
10 20) (footnote omitted). HHS received plaintiff's Request for Reconsideration on May 20, 2005.

11 See Request for Reconsideration, available at <http://aspe.hhs.gov/infoquality/requests.shtml>  
12 (request no. 20). In its Request for Reconsideration, plaintiff complained that the government's  
13 response to the rescheduling petition may take a long time. Id. Following six interim responses,  
14 HHS responded to plaintiff's Request for Reconsideration on June 12, 2006. See Response to  
15 Request for Reconsideration, available at <http://aspe.hhs.gov/infoquality/requests.shtml> (request  
16 no. 20). The agency acknowledged that plaintiff was arguing that "the CSA process should not  
17 be utilized because of the length of time it involves," but stated that "a comprehensive review is  
18 essential to ensure that our recommendation [to DEA] is accurate." Id.

19 Plaintiff filed its Complaint in this action on February 21, 2007. On July 24, 2007, this  
20 Court dismissed plaintiff's Complaint but provided plaintiff leave to amend to add a claim under  
21 5 U.S.C. § 706(1). See *Americans for Safe Access v. Dep't of Health and Human Services*, Civ.  
22 No. 07-1049-WHA, 2007 WL 2141289 (N.D. Cal. July 24, 2007), Docket Entry No. 41  
23 ("Opinion"). The Court held that plaintiff's claims failed because "the IQA does not subject

24  
25 6(...continued)

26 17, 2001 letter from the Surgeon General to the DEA Administrator).

27 As noted in the text, in its Complaint plaintiff purports to challenge HHS's alleged denial of  
28 plaintiff's request for correction of only the fourth statement listed above. See Compl. ¶¶ 7, 16,  
Request for Relief. Cf. supra note 5 (discussing five-part test used by the DEA Administrator to  
evaluate whether a drug has a currently accepted medical use in treatment in the U.S.).



1 agency IQA decisions to judicial review. Nor is there any final agency action on the present  
2 record” that would permit review under the APA. Id. at 4.

### 3 ARGUMENT

#### 4 **III. Plaintiff Has Failed to State a Case or Controversy Subject to Judicial Resolution.**

5 Plaintiff has failed its burden to establish this Court’s subject matter jurisdiction over its  
6 claims because those claims do not meet the “bedrock” constitutional requirement that they  
7 present a justiciable “case or controversy” for this Court’s decision. See Valley Forge Christian  
8 Coll. v. Am. United for Separation of Church & State, 454 U.S. 464, 471 (1982).

9 “To invoke the jurisdiction of an Article III court, the plaintiff[] ‘must have suffered an  
10 injury in fact.’ The injury ‘required by Art. III may exist solely by virtue of statutes creating legal  
11 rights, the invasion of which creates standing.’” Salt Institute v. Leavitt, 440 F.3d 156, 158 (4<sup>th</sup>  
12 Cir. 2006), quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 578 (1992) (internal  
13 citations, quotation marks omitted). The injury alleged by plaintiff is “the asserted incorrectness  
14 in [HHS’s] public statements.” Id.; see Am. Compl. ¶ 7. That asserted injury is not a legally  
15 cognizable one, however, because plaintiff has no enforceable, legal right to the correctness of  
16 agency information. See id. at 159; Americans for Safe Access v. Dep’t of Health and Human  
17 Services, Civ. No. 07-1049-WHA, 2007 WL 2141289 (N.D. Cal. July 24, 2007), Docket Entry  
18 No. 41 (“Opinion”) at 5-6. Accordingly, plaintiff “has not alleged an invasion of a legal right  
19 and, thus, ha[s] failed to establish an injury in fact sufficient to satisfy Article III.” Salt Institute  
20 v. Leavitt, 440 F.3d at 159 (noting “appellants confuse two distinct standing inquiries: the  
21 concreteness of the alleged injury and the status of the claimed right”).

22 “The IQA provided only an administrative remedy.” Opinion at 5; see also Salt Institute  
23 v. Thompson, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004) (“The language of the IQA reflects  
24 Congress’s intent that any challenges to the quality of information disseminated by federal  
25 agencies should take place in administrative proceedings before federal agencies and not in the  
26 courts.”), aff’d, 440 F.3d 156, supra. Indeed, the IQA expressly sets out the non-judicial  
27 mechanism by which the agency’s handling of correction requests such as plaintiff’s should be  
28 reviewed. The IQA provides that agencies should be required to “[r]eport periodically to the

1 director [of OMB] - (i) the number and nature of complaints received by the agency regarding the  
2 accuracy of information disseminated by the agency; and (ii) how such complaints were handled  
3 by the agency.” 44 U.S.C. § 3516 note. Thus, “by its terms, this statute creates no legal rights in  
4 any third parties. Instead, it orders the Office of Management and Budget to draft guidelines  
5 concerning information quality and specifies what those guidelines should contain.” Salt  
6 Institute v. Leavitt, 440 F.3d at 159.

7         Accordingly, “even assuming that concrete interests of the [plaintiff is] affected, there is  
8 nothing that can be done by way of judicial review to redress the adverse consequences . . . that  
9 they say they are suffering. This is because only [the Executive] can do that” under the IQA.<sup>7</sup>  
10 See Guerrero v. Clinton, 157 F.3d 1190, 1194 (9<sup>th</sup> Cir. 1998) (holding agency statements in  
11 statutorily required report to Congress unreviewable because they have no direct legal effect). In  
12 such a context, as this Court has recognized before, recognition at law of plaintiff’s claim would  
13 frustrate the intent of Congress since a “court order dictating compliance along plaintiffs’ and the  
14 court’s [wishes] would be inconsistent with Congress’ apparent desire to allow agencies to  
15 improve on their own.” Center For Biological Diversity v. Abraham, 218 F. Supp. 2d 1143,  
16 1160 (N.D. Cal. 2002) (Alsup, J.), citing Guerrero, 157 F.3d at 1193-94.

17         Plaintiff has not alleged the invasion of a legally cognizable right and, accordingly, lacks  
18 Article III standing. For that reason alone, the Court should dismiss plaintiff’s Complaint for  
19 lack of subject matter jurisdiction.

#### 20 **IV. HHS’s Response to Plaintiff’s IQA Petition Is Not Reviewable Under the** 21 **Administrative Procedure Act.**

22         This Court has already dismissed plaintiff’s claims under the APA, 5 U.S.C. § 706(2)(A)  
23 & (C), “alleging that defendants’ response to their petition constituted final agency action in  
24 violation of the IQA.” Opinion at 7. The Court granted plaintiff leave to amend its Complaint to  
25 state a claim it raised at oral argument that the Court should “compel agency action unlawfully  
26 withheld or unreasonably delayed” under the APA, 5 U.S.C. § 706(1). Plaintiff has done so, but

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27         <sup>7</sup> Similarly, as defendants have explained, plaintiff’s interests as an advocacy organization  
28 are well outside the zone of interests of the IQA and so plaintiff lacks prudential standing as well.  
Def. Mem. 17-18.

1 its new claim suffers from the same flaws.

2 Plaintiff's complaint is, at bottom, a quarrel with agency speech. The agency speech in  
3 question has no direct legal effect and was made in the course of proceedings under the  
4 Controlled Substances Act, 21 U.S.C. § 801, et seq., ("CSA"), which has its own exclusive  
5 provision for judicial review. "Under these circumstances, the presumption of reviewability of  
6 agency action is woefully inapposite." Guerrero, 157 F.3d at 1196 (quoting Natural Resources  
7 Defense Council, Inc. v. Hodel, 865 F.2d 288, 319 (D.C. Cir. 1988)).<sup>8</sup>

8 As this Court has held, plaintiff cannot establish subject matter jurisdiction under the  
9 APA for its claim because the action of which it complains is not made reviewable by statute and  
10 because it does not qualify as final agency action under the APA. Opinion at 4. In addition,  
11 plaintiff has another adequate remedy under the CSA and the agency's response to plaintiff's  
12 IQA Request for Correction of the agency's statement is committed to agency discretion by law.  
13 See 5 U.S.C. §§ 701(a)(2), 704. The agency did not, therefore, violate any clear statutory duty  
14 when it determined how to respond to plaintiff's IQA request.

15 **A. Plaintiff Fails To Plead A Claim Under 5 U.S.C. § 706(1) That Would Entitle**  
16 **Plaintiff To The Mandamus Order It Seeks .**

17 This Court's review of plaintiff's claim under 5 U.S.C. § 706(1) is similar to review of a  
18 claim for mandamus relief. See Independence Mining Co. v. Babbitt, 105 F.3d 502, 506-507 (9<sup>th</sup>  
19 Cir. 1997).<sup>9</sup> Under the Mandamus Act or the APA, mandamus relief may be granted only when  
20 (1) the plaintiff's claim is clear and certain; (2) the duty is "ministerial and so plainly prescribed  
21 as to be free from doubt;" and (3) no other adequate remedy is available. See Oregon Natural

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22 <sup>8</sup> While the Supreme Court has "read the APA as embodying a 'basic presumption of  
23 judicial review,'" Lincoln v. Vigil, 508 U.S. 182, 190 (1993) (quoting Abbott Laboratories v.  
24 Gardner, 387 U.S. 136, 140 (1967)), the Court has also recognized that "[t]his is 'just' a  
25 presumption." Id. (quoting Block v. Community Nutrition Institute, 467 U.S. 340, 349 (1984)).  
26 Moreover, the APA waiver of sovereign immunity must be read strictly in favor of the United  
27 States. Department of the Army v. Blue Fox, Inc., 525 U.S. 255, 261 (1999); Gallo Cattle Co. v.  
28 Department of Agriculture, 159 F.3d 1194, 1198 (9<sup>th</sup> Cir. 1998).

<sup>9</sup> See also Japan Whaling Ass'n v. American Cetacean Soc., 478 U.S. 221, 230 n.4 (1986)  
(a claim for mandamus under 28 U.S.C. § 1361 is "in essence" a claim for relief under 5 U.S.C.  
§ 706).

1 Resources Council v. Harrell, 52 F.3d 1499, 1508 (9<sup>th</sup> Cir. 1995). Thus, as the Supreme Court  
2 has held, “a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed  
3 to take a *discrete* agency action that it is *required* to take.” Norton v. Southern Utah Wilderness  
4 Alliance (“SUWA”), 542 U.S. 55, 64 (2004) (emphasis in original). “These limitations rule out  
5 several kinds of challenges,” *id.*, including plaintiff’s.

6 **1. Plaintiff Has Failed To State A Claim To Compel Agency Action**  
7 **Under The APA Because The “Action” In Question Is Not Cognizable**  
8 **Under The APA.**

9 First, plaintiff’s new claim fails because the APA does not waive sovereign immunity for  
10 a claim that seeks only to compel non-binding agency speech. The “action” plaintiff seeks to  
11 compel would not be “final agency action,” or “agency action” at all, under the terms of the APA.  
12 As the Supreme Court noted, where, as here, “no other statute provides a private right of action,”  
13 the agency action a plaintiff challenges “must be *final* agency action.” SUWA, 542 U.S. at 61-  
14 62, quoting 5 U.S.C. § 704 (emphasis as in SUWA). “The APA provides relief for a failure to  
15 act in” the provision now invoked by plaintiff, “§ 706(1): ‘The reviewing court shall . . . compel  
16 agency action unlawfully withheld or unreasonably delayed.’” *Id.* at 62. Thus, to state a claim  
17 under the APA and invoke its waiver of sovereign immunity, plaintiff must identify “an ‘agency  
18 action,’ either as the action complained of (in §§ 702 and 704) or as the action to be compelled  
19 (in § 706(1)).” *Id.*

20 Moreover, the “agency action” sought to be compelled must qualify as “final agency  
21 action.” Section 706(1) has been described as a “limited exception to the finality doctrine” that  
22 permits jurisdiction “only when there has been a genuine failure to act.” Ecology Center v.  
23 United States Forest Service, 192 F.3d 922, 926 (9<sup>th</sup> Cir. 1999). That is because the inaction  
24 itself may be seen as depriving the underlying action of sufficient finality. *See id.* Put another  
25 way, “[i]n certain circumstances, agency inaction may be sufficiently final to make judicial  
26 review appropriate.” Sierra Club v. Peterson, 228 F.3d 559, 568 (5<sup>th</sup> Cir. 2000), cert. denied, 532  
27 U.S. 1051 (2001). Under 5 U.S.C. § 704, however, the action sought to be compelled by an APA  
28 claim must itself qualify as “final agency action,” *i.e.*, action that is conclusive and that carries  
legal consequences, *see Bennett*, 520 U.S. at 177-178, and that, if taken by the agency rather than

1 withheld, would be reviewable under Section 706(2). Section 704 provides that finality is a  
2 condition of “judicial review” under the APA, without distinguishing between review under  
3 Section 706(1) of an agency’s failures to act (a form of “agency action” under Section 551(13))  
4 and review under Section 706(2) of an agency’s affirmative acts. See also Aladjem v. Cuomo,  
5 Civ. No. 96-6576, 1997 WL 700511, at \*3 n.2 (E.D. Pa. Oct. 30, 1997) (Pollak, J.) (noting that 5  
6 U.S.C. § 704 defines the types of agency actions subject to judicial review while § 706 defines  
7 the scope of review over reviewable actions). Accordingly, the Ninth Circuit “has refused to  
8 allow plaintiffs to evade the finality requirement with complaints about the sufficiency of an  
9 agency action ‘dressed up as an agency’s failure to act.’” Ecology Ctr., 192 F.3d at 926 (quoting  
10 Nevada v. Watkins, 939 F.2d 710, 714 n. 1 (9<sup>th</sup> Cir. 1991)).

11 Here, as defendants have previously noted and plaintiff has not refuted, the action sought  
12 to be compelled agency speech that lacks any direct legal effect would not qualify as  
13 reviewable final agency action. It therefore cannot be compelled under Section 706(1). “Agency  
14 dissemination of advisory information that has no legal impact has consistently been found  
15 inadequate to constitute final agency action and thus is unreviewable by federal courts under the  
16 APA.” Salt Institute v. Thompson, 345 F. Supp. 2d at 602. That is because courts have long  
17 held that agency speech without direct legal consequences does not qualify as an “exercise” of  
18 agency “power” cognizable under the APA. Cf. Whitman v. American Trucking Associations,  
19 531 U.S. 457, 478 (2001) (construing term “agency action”). Such speech differs from “the  
20 prototypical exercise of agency power” in which the agency is “exercising legislative functions  
21 . . . or adjudicatory functions that have been specifically ordained by Congress.” Hodel, 865 F.2d  
22 at 318 (ruling report to Congress not reviewable). An agency statement, such as that at issue  
23 here, that is an “educational undertaking” and does not “impose an obligation, determine a right  
24 or liability or fix a legal relationship” is not reviewable agency action, even though plaintiff  
25 alleges the statement will cost it money. American Trucking Assoc., Inc. v. United States, 755  
26 F.2d 1292, 1296-97 (7<sup>th</sup> Cir. 1985). See also Dalton v. Specter, 511 U.S. 462, 470 (1994) (base  
27 closure recommendations by Secretary of Defense and Defense Base Closure and Realignment  
28 Commission to President do not constitute “final agency action”); Franklin v. Massachusetts, 505

1 U.S. 788, 798-99 (1992) (census report from Secretary of Commerce to President is not “final  
2 agency action”); LaFlamme v. FERC, 945 F.2d 1124 (9<sup>th</sup> Cir. 1991) (Forest Service letter to  
3 FERC retracting adverse comments about a FERC order did not constitute final agency action  
4 because the letter did not impose any obligation, deny any right, or fix any legal relationship);  
5 Kukatush Mining Corp. v. SEC, 309 F.2d 647, 650 (D.C. Cir. 1962) (Bazelon, C.J., dissenting on  
6 other grounds) (SEC cautionary list that does not determine legal rights is unreviewable); cf.  
7 International Telephone & Telegraph Corp. v. Local 134, 419 U.S. 428, 442-48 (1975) (agency  
8 process without binding effect, even if it leads to significant “practical consequences,” is not  
9 reviewable under 5 U.S.C. § 551); Center For Biological Diversity, 218 F. Supp. 2d at 1162 n.8  
10 (discussing “the principle that reporting-to-Congress obligations are not judicially reviewable”)  
11 (citing Guerrero, 157 F.3d at 1194-96, and Hodel, 865 F.2d at 316-19).

12 The fact that the IQA affords plaintiff with an opportunity to seek *administrative*  
13 correction of HHS’s statement does not convert the statement into agency action and permit  
14 plaintiff to seek judicial review under any portion of the APA. The lack of a “substantive  
15 response” to plaintiff’s request for correction, like a response, does “not augment the  
16 [statement’s] legal force or practical effect.” FTC v. Standard Oil Co. of California, 449 U.S.  
17 232, 243 (1980). See id. (plaintiffs’ exhaustion of administrative remedies did not transform the  
18 FTC’s issuance of a complaint into final agency action, and explaining that the plaintiff had  
19 “mistaken exhaustion for finality”); Ma v. Reno, 114 F.3d 128, 130 (9<sup>th</sup> Cir. 1997) (“the doctrine  
20 of exhaustion of administrative remedies . . . is conceptually distinct from the doctrine of  
21 finality”); see also Regional Management Corp. v. Legal Services Corp., 186 F.3d 457, 462 n.6  
22 (4<sup>th</sup> Cir. 1999) (“the existence of a right of action and of an exhaustion requirement are separate  
23 issues”). Accord Aerosource v. Slater, 142 F.3d 572, 579 (3<sup>rd</sup> Cir. 1998) (“if a court treated the  
24 denial of an application to reconsider an action which is not in itself a final order as a final order,  
25 then a petitioner simply by asking for reconsideration could convert a nonfinal action into a final  
26 order. Of course, this conversion should not be permitted.”) (citing Standard Oil).

27 “[P]laintiff has failed to plead that the IQA grants any legal right to the correction of  
28 information.” Opinion at 7. Indeed, “[t]he IQA . . . does not create any legal right to

1 information or its correctness” enforceable in this Court. Id. at 8, quoting Salt Inst. v. Leavitt,  
2 440 F.3d at 159; see also Salt Institute v. Thompson, 345 F. Supp. 2d at 602; In re Operation of  
3 the Missouri River System Litigation, 363 F. Supp. 2d 1145, 1174-75 (D. Minn. 2004).

4 Similarly, plaintiff “has failed to plead that defendants’ response to their administrative appeal  
5 constituted final agency action,” Opinion at 7, or that the “substantive response” plaintiff seeks  
6 *would* constitute such an action. Since the definitive response plaintiff seeks would be agency  
7 speech without the force and effect of law, it would not be “final agency action” (or even “agency  
8 action”) reviewable under the APA. And because the APA does not permit the compulsion of  
9 that which could not be reviewed, plaintiff’s Section 706(1) claim fails.

10 **2. Plaintiff’s Claim Also Fails Because The Agency Speech It Seeks To**  
11 **Compel Is Not Legally Required.**

12 As noted above, the Supreme Court has held that “a claim under § 706(1) can proceed  
13 only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is  
14 *required* to take.” SUWA, 542 U.S. at 64. Defendants have explained above that the action  
15 plaintiff seeks to compel does not qualify because it is not “agency action” cognizable under the  
16 APA. Plaintiff’s claim also fails because the action is not required by law, and “[t]he limitation  
17 to required agency action rules out judicial direction of even discrete agency action that is not  
18 demanded by law.” Id., 542 U.S. at 63.<sup>10</sup>

19 Plaintiff has not identified a source of law that required HHS to provide a “substantive”  
20 response (Am. Compl. ¶ 22) to plaintiff’s IQA request for correction within a time certain. The  
21 statute itself provides no such deadlines for agency responses. Indeed, it “creates no legal rights  
22 in any third parties.” Salt Institute v. Leavitt, 440 F.3d at 159. Rather, the IQA “orders the  
23 Office of Management and Budget to draft guidelines concerning information quality and

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24 <sup>10</sup> See also Center for Biological Diversity v. Veneman, 335 F.3d 849, 854 (9<sup>th</sup> Cir. 2003)  
25 (under § 706(1), plaintiffs “must identify a statutory provision mandating agency action”); San  
26 Francisco BayKeeper v. Whitman, 287 F.3d 764, 770 (9<sup>th</sup> Cir. 2002) (“for a claim of  
27 unreasonable delay to survive, the agency must have a statutory duty in the first place”); accord,  
28 ONRC Action v. Bureau of Land Mgmt., 150 F.3d 1132, 1137 (9<sup>th</sup> Cir. 1998) (judicial  
intervention under § 706(1) is warranted “[w]hen agency recalcitrance is in the face of clear  
statutory duty or is of such a magnitude that it amounts to an abdication of statutory  
responsibility” (citations omitted)).

1 specifies what those guidelines should contain.” Id. Specifically, the statute requires OMB to  
2 issue “guidelines . . . that provide policy and procedural guidance to Federal agencies for  
3 ensuring and maximizing the quality, objectivity, utility and integrity” of information  
4 disseminated by those agencies. Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515(a)], 114 Stat.  
5 2763, 2763A-153 (Dec. 21, 2000).<sup>11</sup>

6 Nor do the OMB guidelines mandate the substantive response that plaintiff seeks to  
7 compel. The OMB guidelines eschew “detailed, prescriptive, ‘one-size-fits-all’ government-  
8 wide guidelines that would artificially require different types of dissemination activities to be  
9 treated in the same manner,” and underscore the “flexibility” that the guidelines give the  
10 agencies. 67 Fed. Reg. at 8452. In particular, OMB stressed that agencies, “in making their  
11 determination whether or not to correct information, may reject claims made in bad faith or  
12 without justification, and are required to undertake only the degree of correction that they  
13 conclude is appropriate for the nature and timeliness of the information involved, and explain  
14 such practices in their annual fiscal year reports to OMB.” Id. at 8458 (emphasis added); see also  
15 OMB Guidelines § III(3) (agencies shall establish administrative mechanisms allowing affected  
16 persons to seek and obtain, “where appropriate,” correction of agency information).

17 The HHS guidelines likewise counsel flexibility and afford the agency considerable  
18 deference, indicating that the discretionary determination whether to “correct” prior agency  
19 speech will depend upon the agency’s evaluation of, among other things, “the significance of the  
20 correction on the use of the information, the magnitude of the correction and the resource  
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27 <sup>11</sup> Congress’s decision not to specify when information should be corrected by agencies  
28 indicates that Congress did not intend that federal courts would take control over the flow  
information among federal agencies. See Salt Inst. v. Thompson, 345 F. Supp. 2d at 602-03; In  
re Operation of the Missouri River Sys., 363 F. Supp. 2d at 1175.



1 requirements<sup>[12]</sup> for the correction.” [www.hhs.gov/infoquality](http://www.hhs.gov/infoquality) § E.<sup>13</sup> Put another way,  
2 defendants have not violated any clear and unmistakable duty since the determination of how to  
3 respond to plaintiff’s Request for Correction was “committed to agency discretion by law.” See,  
4 e.g., Heckler v. Chaney, 470 U.S. 821, 830 (1984); Legal Services of Northern California, Inc. v.  
5 Arnett, 114 F. 3d 135, 140 (9<sup>th</sup> Cir. 1997); Rank v. Nimmo, 677 F.2d 692, 699-700 (9<sup>th</sup> Cir.  
6 1982).

7 Nor do any of the guidelines impose a strict deadline. The HHS guidelines state that  
8 “[t]he agency will respond to all requests for correction within 60 calendar days of receipt. If the  
9 request requires more than 60 calendar days to resolve, the agency will inform the complainant  
10 that more time is required and indicate the reason why and an estimated decision date.” Id.

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11  
12 12 The reference to “resource requirements” should make courts particularly cautious, as the  
13 Supreme Court has found agency resource allocation determinations (and determinations that rest  
14 on discretionary resource allocations) committed to agency discretion by law. See, e.g., Lincoln  
v. Vigil, 508 U.S. 182 (1993).

15 13 The HHS guidelines also state that “[e]xisting public comment procedures for  
16 rulemakings and other formal agency actions already provide well established procedural  
17 safeguards that allow affected persons to raise information quality issues on a timely basis.  
18 Accordingly, agencies will use these existing procedures to respond to information quality  
19 complaints that arise in this process.” See [www.hhs.gov/infoquality](http://www.hhs.gov/infoquality) § E. As noted above, HHS  
channeled plaintiff’s concerns to an existing and ongoing process: consideration of a related  
petition to reschedule marijuana under the CSA.

20 The HHS guidelines further provide that “[i]n cases where the agency disseminates a  
21 study, analysis, or other information prior to the final agency action or information product,  
22 requests for correction will be considered in those cases where *in the agency’s judgment*” two  
23 conditions have been met. Id. (emphasis added; quoted in Am. Compl. ¶ 14). Those conditions  
24 are that “issuing an earlier response would not unduly delay issuance of the agency action or  
25 information product *and* the complainant has shown a reasonable likelihood of suffering actual  
26 harm from the agency’s dissemination” if the agency does not resolve the IQA petition  
27 separately. Id. (emphasis added). As defendants have noted, plaintiff’s IQA petition did not  
28 challenge any statement that was “disseminated” by HHS or FDA within the meaning of the IQA.  
See Brief in Support of Defendants’ Motion to Dismiss (Docket No. 31) at 31-32; Reply Brief  
(Docket No. 39) at 17-18. Moreover, plaintiff did not show a reasonable likelihood of suffering  
actual, cognizable harm from any HHS or FDA dissemination. Cf. generally Brief in Support of  
Defendants’ Motion to Dismiss at 13-17 (explaining plaintiffs have not established any injury in  
fact); Reply Brief at 3-6 (same). Finally, this language from the HHS guidelines provides neither  
the kind of firm deadline nor the sort of clear and unmistakable duty on the agency that would be  
amenable to judicial enforcement on a petition for mandamus.

1 Similar language addresses HHS’s response to and resolution of an appeal on the agency’s  
2 decision. By their terms, the guidelines do not require that a request be *resolved* within 60 days  
3 or any time certain; they require only that there be a response in 60 days, and say nothing about  
4 the relative “substance” of such a response. It is undisputed that plaintiff’s IQA petition received  
5 a response, as did plaintiff’s appeal. Am. Compl. ¶¶ 17, 22. Indeed, plaintiff alleges not that it  
6 was denied a resolution but that it received a “nonsubstantive final denial” that “mark[ed] the  
7 conclusion of the administrative IQA petition process.” *Id.* ¶ 22.

8 Judicial intervention under § 706(1) is warranted only “[w]hen agency recalcitrance is in  
9 the face of clear statutory duty or is of such a magnitude that it amounts to an abdication of  
10 statutory responsibility.” *ONRC*, 150 F.3d at 1137 (citations omitted). Plaintiff has identified  
11 no such clear and unmistakable duty. For that reason, as well, the Court should dismiss its claim.  
12 *Cf.* 5 U.S.C. § 701(a)(2) (no APA review of actions “committed to agency discretion by law”); *In*  
13 *re Operation of the Missouri River System Litigation*, 363 F. Supp. 2d at 1174-75 (finding  
14 response to IQA petitions committed to agency discretion by law).

15 **B. Plaintiff’s APA Claim Is Precluded Because it Has An Adequate Remedy in a**  
16 **Court Under the CSA.**

17 For its claim to be reviewable under the APA, plaintiff must establish that it otherwise  
18 has no “adequate” remedy in a court. 5 U.S.C. § 704. This preclusion of suits challenging  
19 agency action for which there exists another adequate remedy in court reflects Congress’s intent  
20 that the APA not create an additional remedy for particular agency action for which Congress has  
21 established a specific review process. *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988).

22 Here, plaintiff seeks to challenge a statement made by HHS to DEA in the CSA  
23 rescheduling process. The CSA provides plaintiff with an adequate indeed, an exclusive  
24 remedy for a plaintiff who is aggrieved by such a conclusion. The CSA, 21 U.S.C. § 877,  
25 provides:

26 All final determinations, findings, and conclusions of the [DEA] under this  
27 subchapter shall be final and conclusive decisions of the matters involved, except  
28 that any person aggrieved by a final decision of the [DEA] may obtain review of  
the decision in the United States Court of Appeals for the District of Columbia or  
for the circuit in which his principal place of business is located upon petition  
filed with the court and delivered to the Attorney General within thirty days after

1 notice of the decision. Findings of fact by the [DEA], if supported by substantial  
2 evidence, shall be conclusive.

3 Thus, plaintiff's challenge to HHS's recommendation to DEA, which DEA adopted and  
4 published in the Federal Register, is fully cognizable, and was required to be made, under the  
5 CSA itself. John Doe, Inc. v. DEA, 484 F.3d 561, 568 (D.C. Cir. 2007) (Title "21 U.S.C. § 877  
6 vests exclusive jurisdiction in the courts of appeals over '[a]ll final determinations, findings, and  
7 conclusions' of the DEA applying the CSA"); Oregon v. Ashcroft, 368 F.3d 1118, 1121 n.1 (9<sup>th</sup>  
8 Cir. 2004). The waiver of immunity in the APA, by its terms, does not "affect [] other  
9 limitations on judicial review. . . ." 5 U.S.C. § 702. Moreover, the APA expressly creates an  
10 exception to the provisions authorizing judicial review where other "statutes preclude judicial  
11 review. . . ." 5 U.S.C. § 701(a). Accordingly, plaintiff cannot bypass the exclusive right of  
12 review in the CSA with an APA challenge in this Court.

13 That the CSA's limitations period may prevent plaintiff from now maintaining its claim  
14 under that Act, or that the CSA review process may take some time, does not alter the conclusion  
15 that the CSA, 21 U.S.C. § 877, is an adequate remedy within the meaning of 5 U.S.C. § 704. See  
16 Sable Communications of California, Inc. v. FCC, 827 F.2d 640, 642 (9<sup>th</sup> Cir. 1987) (statutory  
17 review provision was "adequate" for APA purposes even though plaintiff's petition under that  
18 review provision was dismissed as untimely) (citing FCC v. ITT World Communications, Inc.,  
19 466 U.S. 463, 469 (1984) (rejecting argument that review in the court of appeals is inadequate  
20 and that APA action in district court could therefore proceed) and Telecommunications Research  
21 and Action Center v. FCC, 750 F.2d 70, 78 (D.C. Cir. 1984) ("Where statutory review is  
22 available in the Court of Appeals it will rarely be inadequate.")); Mitchell v. United States, 930  
23 F.2d 893, 897 (Fed. Cir. 1991) (available remedy in Claims Court was adequate even though the  
24 plaintiff's claim in that court may have been time-barred). Section 704 is triggered whenever  
25 Congress has provided an adequate remedy for a particular agency action, notwithstanding the  
26 fact that the plaintiffs before the court may not be entitled to that remedy. See Sable, 827 F.2d at  
27 642; Mitchell, 930 F.2d at 897.

28 To the extent plaintiff argues that the exclusive CSA review procedure would not apply to

1 the HHS statement of which plaintiff complains because that statement was not clearly adopted  
2 as part of the “final determinations, findings, and conclusions of the” DEA, 21 U.S.C. § 877,  
3 plaintiff’s argument only underscores another fatal flaw in plaintiff’s Complaint, discussed supra:  
4 the agency speech that plaintiff seeks to challenge had no direct legal effect, does not qualify as  
5 final agency action, and thus is not amenable to judicial review under the APA.

6 **C. Plaintiff Has Not Cured The Defects In Its Original APA Claims.**

7 This Court previously dismissed plaintiff’s claims under the APA, 5 U.S.C. § 706(2)(A),  
8 seeking review in this Court of the purportedly final agency action with regard to plaintiff’s IQA  
9 request. Plaintiff has done nothing to cure the defects in those claims, including the failure to  
10 allege a final agency action cognizable under the APA that injured plaintiff or to point to another  
11 statute authorizing judicial review. See Opinion at 4; see also Defendants’ Memorandum in  
12 Support of Defendants’ Motion to Dismiss (Docket Entry No. 31) and Defendants’ Reply  
13 Memorandum (Docket Entry No. 39) (each explaining why plaintiff’s claims fail as a matter of  
14 law; incorporated herein by reference).

15 **CONCLUSION**

16 Accordingly, for all of the foregoing reasons, this Court should grant defendants’ Motion  
17 to Dismiss Plaintiff’s Amended Complaint.

18 Dated October 11, 2007

Respectfully Submitted,

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