



U.S. Department of Justice  
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

March 7, 2008

The Honorable John Conyers, Jr.  
Chairman  
Committee on the Judiciary  
United States House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi before the Committee on July 12, 2007, at a hearing entitled "The Drug Enforcement Administration's Regulation of Medicine".

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski  
Principal Deputy Assistant Attorney General

Cc: The Honorable Lamar S. Smith  
Ranking Member

**"The Drug Enforcement Administration's Regulation of Medicine"**

July 12, 2007

Questions for the Hearing Record  
for  
Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration

1. The Drug Enforcement Administration and the Food and Drug Administration are both involved in the approval of cannabis research (and researchers) prior to the issuance by DEA of a Schedule I registration. There seemed to be some confusion as to what this process is. Please describe in detail the process a would-be researcher must go through before DEA issues the registration and explain at each step what would prohibit the process from continuing.

**RESPONSE:**

The Controlled Substances Act (CSA) allows for bona fide research to be conducted on any schedule I controlled substance provided the researcher has obtained a registration from DEA authorizing such activity. The statutory criteria for obtaining a registration, including the role of the Secretary of Health and Human Services (HHS), are set forth in 21 U.S.C. § 823 (f). Among other things, the statute requires the researcher to submit a research protocol. The required contents of the research protocol are specified in the DEA regulations (21 C.F.R. § 1301.18). A detailed description of the process by which DEA acts on applications for registration with schedule I controlled substances is also set forth in the DEA regulations (21 C.F.R. § 1301.32). In sum, the Secretary of HHS is responsible for evaluating the qualifications and competency of the researcher and the merits of the research protocol, and DEA is responsible for ensuring that the researcher will provide adequate controls against diversion and otherwise comply with the CSA and DEA regulations. An application may be denied if: the applicant fails to meet any of the foregoing requirements; the Secretary for HHS finds the qualifications and competency of the researcher, or the merits of the research protocol, to be lacking; or DEA determines that the researcher has failed to demonstrate that he/she will maintain effective control against diversion. If DEA seeks to deny the application for any reason, it must serve the applicant with an Order to Show Cause, affording the applicant the opportunity for a hearing in accordance with the Administrative Procedure Act, 21 U.S.C. § 824(c).

2. During the hearing, testimony was offered that indicated investigations of pain management doctors and other doctors by DEA have caused concern that physicians who practice in this area of medicine are being targeted despite the service they provide to a number of pain sufferers. Does DEA believe this characterization is correct, and what is the process DEA uses to identify and

Beginning in the 1930s and through to the present, states have adopted uniform controlled substance laws that were designed to promote standards that are consistent from state to state and in harmony with federal law. One such standard that has always been a fundamental part of these uniform state laws is the requirement that controlled substances be dispensed only for legitimate medical purpose by a practitioner acting in the usual course of professional practice -- a requirement first articulated in the Harrison Narcotic Act. Accordingly, it has been the case for more than 70 years that a practitioner, who dispenses controlled substances for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both state and federal law.

4. On May 15, DEA Administrative Law Judge Mary Ellen Bittner formally transmitted her recommendation to DEA Deputy Administrator Michele Leonhart in which she found that it is "in the public interest" to end the federal monopoly on the supply of marijuana that can be used in FDA-approved research, held by the National Institute on Drug Abuse (NIDA). Following nine days of hearings, testimony, and evidence from both sides, including from researchers who reported that the government denied their requests for marijuana for use in FDA-approved research protocols, Judge Bittner concluded that, "NIDA's system for evaluating requests for marijuana has resulted in some researchers who hold DEA registrations and requisite approval from [HHS and FDA] being unable to conduct their research because NIDA has refused to provide them with marijuana. I, therefore, find that the existing supply is not adequate." She added, "Respondent's registration to cultivate marijuana would be in the public interest."

Despite this endorsement by the one neutral arbiter assigned to examine the case and despite the fact that it has been more than six years since the University of Massachusetts initially filed its application, the DEA has yet to grant the license in accordance with the recommendation. With these facts in mind, I would like to know how long it usually takes the DEA to act on a recommendation from an administrative law judge. Could you please provide me with a list of all recommendations made by administrative law judges in the DEA since January 20, 2001, along with the dates on which they were transmitted to final decision-makers at the DEA and the dates on which the recommendations were officially either followed or rejected through a final decision on the matter?

Also, when can we anticipate a decision in this case? If the decision can be anticipated to require more time than the average time required in the reply to the first question, please state the reason. In addition, can you give us a commitment that the decision will be made during this Administration?

**RESPONSE:**

Please see attached chart.

5. In his written testimony of Joseph T. Rannazzisi, DEA Deputy Assistant Administrator, Office of Diversion Control, stated, "Nineteen researchers are currently approved to conduct research with smoked marijuana on human subjects." Could you please provide the name and affiliation of each of these researchers, along with a short description of the research they are currently conducting?

**RESPONSE:**

Please note that the information requested in this question includes personally identifiable records maintained by DEA, which are protected by the Privacy Act. DEA is releasing this information to the subcommittee in response to this question under the exception for disclosures to Congress set forth in 5 U.S.C. § 552a (b)(9).

- Donald Abrams, M.D. (University of California - San Francisco; CMCR\*)
- Mark Agius, M.D. (University of California-Davis; CMCR\*)
- Robert Block, Ph.D. (University of Iowa)
- Louis Cantilena, M.D., Ph.D. (Uniformed Services University of Health Services)
- Jody Corey-Bloom, M.D., Ph.D. (University of California-San Diego; CMCR\*)
- Ronald Ellis, M.D., Ph.D. (University of California-San Diego; CMCR\*)
- Richard Foltin, Ph.D. (Columbia University)
- Alan Gevins, Ph.D. (SAM Technology Inc.)
- Mark Greenwald, Ph.D. (Wayne State University)
- Kent Hutchison, Ph.D. (University of Colorado)
- Thomas Kelly, Ph.D. (University of Kentucky)
- Scott Lane, Ph.D. (University of Texas-Houston)
- Anthony Liguori, Ph.D. (Wake Forest School of Medicine)
- Scott Lukas, Ph.D. (McLean Hospital)
- Jane Metrick, Ph.D. (Brown University)
- Godfrey Pearlson, M.D. (Institute of Living)
- Donald Tashkin, M.D. (University of California Los Angeles)
- Mark Wallace, M.D. (University of California - San Diego; CMCR\*)
- Barth Wilsey, M.D. (Department of Veteran Affairs; CMCR\*)

Of the 19 researchers listed above, 13 are conducting NIDA-funded drug abuse research. An additional 6 are affiliated with the \*Center for Medicinal Cannabis Research (CMCR) from the University of California and are investigating the use of smoked marijuana in six approved studies.

The CMCR studies are evaluating the use of cannabis for the treatment of: HIV-related peripheral neuropathy; cancer pain; spasticity/tremor in MS patients; and chemotherapy-induced delayed nausea. These studies represent the breadth and scope of research using marijuana to study the potential therapeutic effectiveness of marijuana's active ingredients.

**Cases in Which Administrative Law Judge's Opinion Issued**  
**January 1, 2001 - July 26, 2007**  
*(Revised August 1, 2007)*

\* Arranged according to the date the Judge's opinion is rendered.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
01-4	Peterson	11/16/00	1/12/01	2/12/01	10/10/01	
00-12	Ford	12/9/99	2/6/01	3/16/01	2/24/03	
99-34	Shaffer	9/17/99	3/27/01	4/30/01	5/6/02	
01-1	The Church of the Living Tye	11/30/99	4/17/01	6/12/01	3/26/03	
01-17	Thomassen	3/9/01	4/23/01	5/24/01	10/10/01	
00-4	Owens	11/1/99	5/4/01	6/4/01	7/24/02	
01-18	Resnick	3/22/01	5/16/01	6/18/01	10/10/01	
00-24	Leslie	6/20/00	8/2/01	9/14/01	3/6/03	
01-6	Scolaro	11/22/00	8/3/01	9/7/01	6/11/02	
01-37	Anthony	8/6/01	10/3/01	11/20/01	5/6/02	
01-38	Weinstein	8/7/01	10/3/01	11/19/01	5/6/02	
01-36	Yemlo	8/6/01	10/3/01	11/19/01	5/6/02	
00-41	Mediplas Innovations	9/15/00	10/4/01	11/20/01	5/30/02	
01-43	Mills	8/20/01	1/8/02	2/12/02	5/6/02	
02-1	Dearwood Pharmacy	10/12/01	3/7/02	10/29/02	6/23/03	
01-22	Xtrame	5/4/01	4/3/02	5/7/02	12/2/02	
01-12	Indace <sup>1</sup>	2/8/01	4/5/02	6/5/02	12/13/02 & 11/9/04	
01-13	Malladi <sup>2</sup>	2/8/01	4/5/02	6/5/02	12/13/02 & 11/9/04	
02-17	Washburn	1/25/02	4/25/02	6/4/02	9/12/02	

<sup>1</sup> The United States Court of Appeals for the District of Columbia Circuit remanded both *Indace* and *Malladi* to the Deputy Administrator, necessitating second final orders in both cases. See 69 Fed. Reg. 67,951 (2004).

<sup>2</sup> See fn. 1.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
02-34	Arwas	3/21/02	4/29/02	5/29/02	9/18/02	
01-3	Penick Corp.	11/15/00	5/29/02	8/5/02	1/29/03	
02-38	Graves	4/29/02	6/10/02	7/10/02	11/4/02	
01-30	Jackson	7/2/01	6/13/02	7/17/02	4/21/03	
02-15	Genesis	1/22/02	6/26/02	8/8/02	3/13/03	
02-37	Hamilton	4/22/02	7/9/02	8/8/02	9/18/02	
02-25	Talley	2/26/02	7/15/02	8/21/02	11/20/02	
02-41	Cleggett-Lucas	5/17/02	7/13/02	10/29/02	4/21/03	
00-22	OTC	6/9/00	8/8/02	9/27/02	11/26/03	
02-44	Santucci	6/14/02	8/12/02	9/18/02	10/28/02	
01-20	Aboumarboub	4/17/02	8/15/02	9/18/02		Terminated <sup>1</sup> - Joint Motion filed 12/6/04 Published 8/1/03
02-46	Mercedith	6/26/02 <sup>4</sup>	9/13/02	10/24/02	07/31/2003 <sup>5</sup>	
02-50	Serai	7/23/02	9/18/02	10/28/02	7/28/03	
02-52	Goswitz	7/24/02	10/8/02	11/12/02	4/21/03	

<sup>1</sup> The administrative law judge will terminate a case either because (1) it has become moot (e.g., the respondent's registration expired during the course of the proceedings and the respondent did not file a renewal application); (2) the parties settle all outstanding issues; or (3) the respondent failed to comply with a directive from the judge and was therefore deemed to have waived his right to a hearing. If a case is terminated for the first or second reason listed above, no further action is required by either this office or the Deputy Administrator. If a case is terminated for the third reason, the investigative file should be forwarded to the Deputy Administrator for issuance of a final order based on that file. A case may also become moot or may be settled while pending before the Deputy Administrator, in which case it will be terminated.

<sup>4</sup> On June 26, 2002, the hearing clerk received a letter from respondent in which he "requests an extension of time re: his above cause hearing until the registrant [sic] federal complaint is adjudicated." This letter was filed as a request for an extension of time to respond to the order to show cause on the docket sheet, but was treated as a request for hearing.

<sup>5</sup> This date represents when the document was filed at the Federal Register. The date the Final Order was signed is unknown.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
01-15	Ashland	3/1/01	10/28/02			Terminated 11/7/06 <sup>5</sup>
01-23	FCC	3/1/01	10/28/02			Terminated 11/17/06 <sup>6</sup>
02-11	Davis	12/13/01	11/21/02	1/21/03	12/18/03	
01-10	Branex	1/26/01	12/4/02	1/21/03	2/10/04	
03-4	Dinozzi	10/21/02	1/13/03	2/19/03	11/13/03	
03-2	Lusman	10/9/02	1/13/03	2/20/03	11/13/03	
03-9	Perry	11/26/02	2/25/03	3/18/03	11/13/03	
03-14	Prescriptionline.com	1/22/03	3/19/03	4/22/03	1/7/04	
02-24	Kruger	4/9/02	4/23/03	5/28/03	1/20/04	
02-10	Morall	12/17/01	4/28/03	7/24/03	9/28/04	
02-7	Davenport	12/10/01	6/13/03	8/6/03	11/26/03	
02-35	Chaundry	3/25/02	6/13/03	8/6/03	10/5/04	
03-27	Edwin	5/22/03	7/18/03	8/20/03	9/13/04	
03-19	Katz	4/28/03	8/8/03	9/12/03	3/29/04	
03-22	Boone	4/28/03	8/29/03	11/24/03	5/17/04	
03-36	Ankonsson	Unknown <sup>7</sup>	9/23/03	11/13/03	1/7/04	
03-41	Impram	8/18/03	11/7/03	12/15/03	4/7/04	
02-40	Hale	5/13/03	11/26/03	1/15/04	11/10/04	
03-51	Jones	9/23/03	12/4/03	1/16/04	6/21/04	
03-48	Strauss	9/11/03	12/8/03	1/16/04	5/17/04	

<sup>6</sup> At the Government's request, Ashland and FCC were ultimately terminated without being submitted to the Deputy Administrator. These cases were part of a series of proceedings (including *Indace* and *Mallard*) involving PDK Laboratories, Inc.

<sup>7</sup> See fn. 5.

<sup>8</sup> The respondent (Ankonsson) requested an extension of time to respond to the Order to Show Cause on July 3, 2003. No formal hearing request was received. On July 29, 2003, the Government requested for a Stay of Proceedings and Motion for Summary Disposition. The Opinion and Recommended decision of the ALJ was made on September 21, 2003.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
04-10	RX Network of South Florida, LLC	11/5/03	12/17/03	1/29/04	10/5/04	
04-7	Pripstein	10/15/03	12/19/03	1/28/04		Terminated 8/17/05
02-28	Prakasam	3/6/02	1/30/04	3/2/04	5/25/05	
04-9	Orzanne	11/10/03	2/4/04	3/15/04	9/8/04	
03-1	Hoxie.	10/4/02	4/7/04	5/26/04	7/27/04	
01-31	Bordeaux	7/3/01	5/4/04	6/7/04	11/10/04	
03-5	Express Wholesale	11/8/02	5/18/04	6/24/04	10/5/04	
04-2	Yagub	10/6/03	5/14/04			Terminated 7/12/04
04-22	Townsend	5/10/04	6/28/04			Terminated 11/15/04
04-34	Price	5/3/04	6/28/04	8/10/04	10/5/04	
04-38	Chalfoux	5/12/04	6/28/04	8/10/04	10/5/04	
04-40	Mirza	5/17/04	8/10/04	9/15/04	10/5/04	
03-35	Joy's Ideas	8/26/03	9/29/04	11/8/04	5/25/05	
03-25	Elk Int'l, Inc.	5/14/03	10/7/04	11/16/04	5/22/05	
04-27	Bradway	4/5/04	10/15/04			Terminated 11/16/04
04-30	Gooberman	4/13/04	10/15/04		5/9/05	
04-63	Siddall	8/16/04	11/4/04	12/7/04	12/15/05	
05-1	Ryziel	Unknown <sup>9</sup>	11/22/04	1/11/05	5/9/05	
03-24	TNT Distributors, Inc.	4/28/03	12/3/04	1/11/05	2/14/05	
03-26	H&R Corp.	5/20/03	12/3/04	1/11/05	5/5/06	
04-62	Kobrin	7/28/04	12/27/04	2/2/05	5/25/05	
05-5	Goodrich	11/8/04	12/29/04	2/2/05	5/2/05	

<sup>9</sup> No formal request for hearing was received. The Respondent requested for an extension of time to respond to the Order to Show Cause.



Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
03-81	Nearing	3/10/03	1/3/05	2/2/05	5/25/05	
01-45	Chattam Chemicals, Inc.	9/7/01	2/16/05	6/6/05	2/17/06	
03-39	D&S Sales	7/21/03	2/11/05	3/22/05	6/12/06	
05-9	Rodriguez	11/17/04	2/16/05	3/22/05	5/25/05	
04-8	Wedgewood Village Pharmacy	10/16/03	3/4/05	5/17/05	3/22/06	
05-2	Bergman	10/29/04	3/8/05	4/14/05	5/25/05	
05-17	Graham	1/6/05	3/25/05	4/26/05	5/25/05	
02-47	Kennedy	7/15/02	4/13/05	6/14/05	6/12/06	
03-8	Krishna-Iyer	1/12/02	4/15/05	7/27/05	8/22/06	
05-7	Yeates	1/1/04/4	5/9/05	6/14/05	6/13/06	
05-15	Oakland Medical Pharmacy	12/13/04	5/27/05	8/17/05	8/15/06	
05-28	The Medicine Shoppe	5/6/05	6/29/05	8/2/05	7/20/06	
05-27	Michael's Discount Pharmacy	5/6/05	7/1/05	8/2/05	8/15/06	
04-4	Tri-County Distributors	10/8/03	7/6/05	8/9/05	8/22/06	
02-9 & 02-43	Chlein	12/13/01	7/28/05	12/23/05	1/19/07	
05-36	Dillard	8/3/05	9/23/05	10/26/05	8/22/06	
04-16	T. Young Associates, Inc.	1/20/04	10/28/05	11/30/05	9/14/06	
03-12	Koller	12/26/02	11/15/05	12/21/05	11/3/05	
04-48	Lockridge	6/14/04	11/18/05	12/23/05	12/8/05	
04-68	Miritone	9/2/04	3/2/06	4/12/06		Terminated 3/30/07 by Deputy Administrator

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-42	Champaign Urbana Public Health District	1/29/05	3/7/06	5/22/06		No Final Order Issued <sup>10</sup> Terminated 3/30/07 by Deputy Administrator
02-6	Houba	11/20/01	3/8/06	6/5/06		
06-39	Dariah	11/16/05	4/17/06	06/1/06	1/19/07	
05-26	Tank Wholesale	4/19/05	4/24/06	6/1/06		Pending Final Order
05-22	Planet Trading, Inc. d/b/a United Wholesale Distributors, Inc.	3/24/05	4/23/06	6/5/06	2/28/07	
04-41	Jackson	5/18/04	5/26/06	6/29/06	4/24/07	
03-21	Medicine Shoppe Jonesborough	4/18/03	6/9/06	7/14/06		Remanded 4/28/07
05-8	Rick's Picks, L.L.C.	11/15/04	8/9/06	9/22/06	3/30/07	
06-52	Green Acres, Farm, Inc.	3/14/06	8/9/06	9/18/06	4/25/07	
06-58	Patel	6/19/06	8/28/06	10/2/06	3/30/07	
06-46	Miliciano	2/27/06	8/28/06			Terminated 10/27/06
04-36	Lewis	5/4/04	9/26/06	11/2/2006	1/19/07	
06-68	Bourne Pharmacy	8/29/06	11/6/06	12/11/06	3/30/07	
05-24	The Lawsons Inc., v/a The Medicine Shoppe	5/13/05	11/6/06	3/14/07		Pending Final Order
04-58	RX Direct Pharmacy, Inc.	6/22/04	11/21/06	1/17/07		Pending Final Order

<sup>10</sup> A final order was prepared but it was not published in the Federal Register because the case became moot.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-4	Trinity Healthcare Corp, d/b/a Ovedo Discount Pharmacy	9/23/05	10/2/06	11/13/06	5/21/07	
05-3	Fotinosopoulos	11/1/04	10/11/06	11/15/06	4/25/07	
05-33	Holloway Distributing, Inc.	6/30/05	12/19/06	2/1/07		Pending Final Order
07-3	Elite Pharmacy	11/1/06	1/23/07	2/15/07		Terminated on 4/3/07
05-16	Craker	2/7/05	2/12/07	5/15/07		Pending Final Order
05-24	The Lawsons, Inc., v/a/ The Medicine Shoppe Pharmacy	5/13/05	2/12/07 Supplemental II	3/14/07		Pending Final Order
07-19	CRJ Pharmacy, Inc. & YPM Total Care Pharmacy, Inc.	3/2/07	3/22/07	4/19/07	5/21/07	
07-7	Southwood Pharmaceuticals, Inc.	1/3/07	3/30/07	5/8/07	6/22/07	
07-23	Newcare Home Health Services	3/12/07	4/3/07	5/4/07		Pending Final Order

<sup>11</sup> Pursuant to the November 6 issuance of the ALJ's Opinion and Recommended Ruling, an exception to this opinion was filed on November 26 and Counsel for the Respondent filed a motion for reconsideration. This Motion was granted, however neither party filed briefs. Consequently, a Supplemental Opinion and Recommended Ruling were issued.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-19 & 06-20	Saran	10/20/05	4/30/07			Pending Parties Exceptions, then to Deputy Administrator <sup>12</sup>
07-18	Wood	2/21/07	4/27/07	6/4/07		Pending Final Order
07-21	United Prescription Services, Inc.	3/6/07	5/31/07	6/26/07		Pending Final Order
06-45	Volkman	6/20/07	6/20/07			Pending Parties Exceptions, then to Deputy Administrator
05-38	Memphis Wholesale Company	8/18/05	6/20/07	7/23/07		Pending Final Order

<sup>12</sup> At respondent's request, the judge granted an extension until October 1, 2007, for the filing of exceptions. The exceptions will then be transmitted to the Office of the Deputy Administrator.