Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methamphetamine (1105)	II
Pentobarbital (2270)	II
Nabilone (7379)	II

With regard to Gamma Hydroxybutyric Acid (2010), Tetrahydrocannabinols (7370), and Methamphetamine (1105) only, the company manufactures these controlled substances in bulk solely for domestic distribution within the United States to customers engaged in dosage-form manufacturing.

With regard to Nabilone (7379) only, the company presently manufactures a small amount of this controlled substance in bulk solely to conduct manufacturing process development within the company. It is the company's intention that, when the manufacturing process is refined to the point that its Nabilone bulk product is available for commercial use, the company will export the controlled substance in bulk solely to customers engaged in dosage-form manufacturing outside the United States. The company is aware of the requirement to obtain a DEA registration as an exporter to conduct this activity.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Norac, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Norac, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 9, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21073 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 13, 2011, and published in the **Federal Register** on April 20, 2011, 76 FR 22146, Stepan Company, Natural Products Dept., 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Cocaine (9041)	II
Ecgonine (9180)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Stepan Company to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Stepan Company to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21081 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 25, 2011, and published in the **Federal Register** on May 4, 2011, 76 FR 25375, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methylphenidate (1724)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Oripavine (9330)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for conversion and sale to dosage form manufacturers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Rhodes Technologies to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Rhodes Technologies to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21080 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–16]

Lyle E. Craker, PhD; Order Regarding Officially Noticed Evidence and Motion for Reconsideration

Lyle E. Craker, PhD (Respondent) has requested that I reconsider the Final Order I issued on January 7, 2009 (74 FR 2101), which denied his application to

become registered as a bulk manufacturer of marijuana. For the reasons provided below, Respondent has failed to demonstrate that the Final Order contains any erroneous material findings of fact or conclusions of law. Accordingly, Respondent's motion for reconsideration does not provide a basis for altering the decision in the Final Order to deny his application.

I. Post-Final-Order Proceedings

Following the issuance of the January 7, 2009, Final Order, Respondent submitted a letter to me dated January 21, 2009, noting that, in several places in the Final Order, I indicated I was taking official notice of certain documents that were not submitted during the administrative hearing. With respect to such documents, the Final Order states: ''To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.'' Thus, Respondent had until January 23, 2009, to file a motion for reconsideration of the facts of which I took official notice. In his January 21, 2009, letter, Respondent requested an extension of this filing deadline until January 30, 2009. I granted this request for an extension by letter dated January 22, 2009.

On January 30, 2009, Respondent submitted to me a document entitled ''Request for Opportunity Under 5 U.S.C. 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration.'' In this document, Respondent provided a preliminary response to those documents of which I took official notice. However, Respondent asked for additional time to supplement his preliminary response, given the length of the Final Order as well as that of the documents of which I took official notice. I granted this request, allowing Respondent until March 11, 2009, to supplement his response and motion. I further instructed that counsel for the Government would have to submit its response no later than 15 days after being served with Respondent's submission.

On March 11, 2009, Respondent submitted ''Respondent's Supplemental Brief in Support of Request Under 5 U.S.C. 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration.'' In this document, Respondent provided the legal and factual bases for his motion for reconsideration of the Final Order. Also in the document, Respondent requested that the administrative hearing be reopened so that he may call additional witnesses in view of certain documents of which I took official notice in the final order. The Government submitted its response on April 13, 2009. In view of these submissions, and to clarify Respondent's request, I issued an interim order on May 18, 2009, directing Respondent to submit a list of all witnesses he would call if his request to reopen the administrative hearing were granted and to provide a summary of the proposed testimony for each witness. This interim order further instructed Respondent to indicate precisely which documents he sought to introduce for purposes of his motion for reconsideration and, for each document, whether he wanted me to take official notice of it, or whether he wished to introduce it through witnesses if his request to reopen the hearing were granted.

On June 5, 2009, Respondent submitted his ''Witness List and Document List in Support of Motion for Reconsideration.'' On December 2, 2010, I issued an order granting in part, and denying in part, Respondent's request that I take official notice of certain documents. The order denied Respondent's request that I reopen the hearing to allow him to call additional witnesses. Having ruled on which new documents would be considered part of the record (through my taking official notice thereof), the order then gave Respondent an additional opportunity to file a final brief in support his motion for reconsideration. The order stated that Respondent was required to submit such brief on or before March 7, 2011, and that the Government's responsive brief was due no later than 30 days after receipt of Respondent's brief. Respondent submitted his brief on March 7, 2011 (hereafter, ''Respondent's latest submission''), and the Government submitted its responsive brief on April 1, 2011.

II. Respondent's Additional Proposed Documentary Exhibits

Respondent's request to introduce additional documents for purposes of his motion for reconsideration was addressed at length in my December 2, 2010, Order. For each such document Respondent sought to introduce, the December 2, 2010, Order stated (pages 23–27) whether I would take official notice of the document, and the reasons therefor. Only *one* category of documents that Respondent sought to introduce was left unresolved by the December 2, 2010, Order. As to this category, the order stated (page 26):

> If Respondent submits all of the correspondence between Chemic and HHS (or any of its components) relating to this application [Chemic's application to HHS to receive marijuana for research] that he has in his possession or can reasonably access (including, but not limited to, any such correspondence on the MAPS website, such as the January 23, 2009, letter from HHS to Chemic), I will take official notice of all such correspondence.

Thus, the only additional documents that might be considered at this juncture for inclusion in the record (by my taking official notice thereof) are the ''correspondence between Chemic and HHS'' described in the above-quoted sentence. Respondent's latest brief seeks to introduce 11 new documents (which Respondent labels Exhibits A–K). However, only four of these documents (Exhibits C, I, J, and K) appear to be correspondence between Chemic and HHS. The remaining seven documents (A, B, D, E, F, G, and H) do not appear to be correspondence between Chemic and HHS, and Respondent makes no assertion in his brief that they are such. The Government asserts in its responsive brief that these Exhibits A, B, E, F, G, and H are not ''correspondence'' and further that ''Respondent has not laid any foundation to demonstrate that these exhibits were provided to HHS by Chemic.'' For this reason, among others, the Government objects to including these documents in the record.

Accordingly, I rule as follows with respect to these latest proposed exhibits:

(1) I will take official notice of Exhibits C, I, J, and K; and

(2) As Exhibits A, B, D, E, F, G, and H do not comport with the instructions contained in the December 2, 2010, Order, I will not take official notice of these documents, and they will not be considered part of the administrative record considered by the agency in this adjudication.

III. Respondent's Motion for Reconsideration

Given the number of written submissions made by Respondent following the issuance of the January 7, 2009, Final Order, along with the Government's responses thereto and the interim orders I issued regarding these submissions, it is important to reiterate here the purpose for which Respondent was given an opportunity to file a motion for reconsideration. That purpose was stated in the January 7, 2009, Final Order: ''To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall

commence with the mailing of the order.'' 74 FR at 2108 n.24. This was restated in the interim orders I issued following the Final Order. As explained in the Final Order and the December 2, 2010, Order, this opportunity to seek reconsideration of facts of which the agency takes official notice is derived from the Administrative Procedure Act (5 U.S.C. 556(e)) and the DEA regulations (21 CFR 1316.59(e)).

Respondent's post-Final-Order submissions have, in many respects, gone beyond seeking reconsideration of facts of which I took official notice. Respondent has essentially sought broad reconsideration of the factual and legal bases for the Final Order—generally without predicating such arguments on the taking of official notice of any fact. Neither the Controlled Substances Act (CSA) nor the DEA regulations provide for such a broad-based motion for reconsideration of a Final Order.[1] Nonetheless, in the exercise of my discretion, taking into account the complex and sometimes novel issues involved in this matter, I have considered all of the arguments Respondent has submitted in his post-Final-Order submissions—including those that go beyond the scope of what is permitted by 5 U.S.C. 556(e) and 21 CFR 1316.59(e).

The arguments contained in Respondent's post-Final-Order submissions are, for the most part, reiterations of the same arguments that were addressed at length and rejected in the Final Order. In a few instances, as noted below, Respondent does present some slightly different assertions than he previously offered. However, even in these instances, Respondent's core contentions remain those that I previously rejected. Furthermore, Respondent fails in these latest submissions to rebut the fundamental reasons that were provided in the Final Order for denying his application.

[1] The CSA appeal provision, 21 U.S.C. 877, states: ''All final determinations, findings, and conclusions of the [Administrator of DEA] under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the [Administrator] may obtain review of the decision in the United States Court of Appeals * * *.'' This provision suggests that—outside of the scenario provided by the DEA regulations and APA in which a party, on timely request, seeks the opportunity to controvert facts of which the agency took official notice—DEA is not obligated to allow parties to seek reconsideration of final orders regarding applications for registration. DEA also adheres to the Supreme Court's decision in *Interstate Commerce Comm'n* v. *Bhd. of Locomotive Eng'rs,* 482 U.S. 270 (1987), regarding the reopening of proceedings where it is alleged that new evidence or changed circumstances render the agency's original order inappropriate. *See also Fry* v. *DEA,* 353 F.3d 1041, 1044 (9th Cir. 2003).

A. Respondent's Arguments Relating to the Review of Research Protocols by the Department of Health and Human Services

In his post-Final-Order submissions, Respondent continues to focus on what was his primary theme throughout the adjudication proceedings leading up to the Final Order: his desire to have the Public Health Service and the National Institute on Drug Abuse (NIDA) removed from the process by which the Department of Health and Human Services (HHS) carries out its statutory duty to review proposed research involving marijuana. For purposes of context, it is repeated here, as explained in the Final Order, that under the CSA (21 U.S.C. 823(f)), the Secretary of HHS is responsible for reviewing all proposed research involving schedule I controlled substances. Specifically, section 823(f) provides that, with respect to applications for registration by practitioners wishing to conduct research with schedule I controlled substances, ''the Secretary * * * shall determine the qualifications and competency of each practitioner requesting registration, *as well as the merits of the research protocol.''* (Emphasis added.) Thus, under section 823(f), a research proposal involving marijuana may only go forward where the Secretary both (1) Deems the practitioner qualified and competent and (2) determines the research protocol to be meritorious. Or, as stated by HHS in its 1999 announcement of its policies for providing marijuana to researchers: ''To receive such a registration [under § 823(f)], a researcher must first be determined *by HHS* to be qualified and competent, and the proposed research must be determined *by HHS* to have merit.'' 74 FR at 2120 n.70 (emphasis added in Final Order).

Respondent does not dispute that the statute assigns the foregoing functions to the Secretary of HHS. However, Respondent objects to the manner in which these functions are carried out within HHS. In particular, Respondent seeks to have the Public Health Service and NIDA stripped of any role in this process.[2]

For purposes of addressing this issue, it is useful to repeat the following parts of the Final Order, which discussed the scientific review process that has been utilized by HHS since 1999 to evaluate marijuana research proposals:

> [I]n 1999, due in part to an increased interest in marijuana research and taking into account the IOM report, HHS decided to change the procedures by which it would supply marijuana to researchers. The new procedures were announced in a document released by NIH on May 21, 1999. In the announcement, ''HHS recognize[d] the need for objective evaluations of the potential merits of cannabinoids for medical uses[,]'' and that ''[i]f a positive benefit is found, * * * the need to stimulate development of alternative, safer dosage forms.'' Toward this end, NIH explained that the new procedures were designed to increase the availability of marijuana for research purposes by, among other things, making such marijuana ''available on a cost-reimbursable basis.'' This new procedure allowed researchers who were privately funded to obtain marijuana from HHS by reimbursing the NIDA contractor for the cost of the marijuana. This was a departure from the prior practice (pre-1999), whereby HHS only made marijuana available to persons who received NIH funding. The new procedures implemented by HHS in 1999 remain in effect today.
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> At the administrative hearing in this case, Steven Gust, PhD, Special Assistant to the Director of NIDA, explained that, in addition to seeking to facilitate research into the possible medical utility of marijuana, the new procedures implemented by HHS in 1999 were intended ''to make the process more standardized, and to * * * provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved * * * the use of marijuana * * * for treatment of diseases.'' Accordingly, HHS ''established a separate peer review process that * * * moved the review into the Public Health Service [a component of HHS] * * * where additional expertise from other NIH Institutes and other Federal agencies'' could be utilized in reviewing the scientific merit of the applications. Dr. Gust further explained that the members of the review committee are drawn from the various specialty institutes of NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA). Dr. Gust also testified that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana.'' As of April 2004, HHS had approved at least seventeen pre-clinical or clinical studies of marijuana, which were sponsored by the California Center for Medical Cannabis Research (CMCR). According to one witness who testified on behalf of Respondent, all of the CMCR-sponsored researchers who applied to NIDA for marijuana did in fact receive marijuana from NIDA.
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> In his testimony, Dr. Gust explained the term ''peer review'' as follows: ''Peer review is a process that has been used, certainly by NIH, and I think in other agencies in the Department of Health and Human Services, and probably the Federal Government, where outside expertise is acquired and outside opinions on the scientific merit of specific research proposals.'' Dr. Gust added that the NIH peer review committees ''review

[2] *See, e.g.,* 74 FR at 2106 (noting testimony of Rick Doblin, the Director of MAPS, that ''what we're trying to do is get the Public Health Service and NIDA out of the picture'').

proposals three times a year for the NIH, and there are—occasionally a Federal employee participates in one of those reviews, but probably 90 percent or more of the participants are researchers who are in the private sector, for the most part in academic institutions.''

74 FR at 2015, 2119 n.67 (footnotes and citations omitted).

Again, it is Respondent's contention that the involvement of the Public Health Service and NIDA in reviewing proposed marijuana research protocols has the effect of blocking legitimate research into marijuana. Indeed, the primary argument Respondent puts forth in support of his proposed registration is that the current system by which the United States Government makes marijuana available to researchers fails to provide an adequate supply of marijuana within the meaning of 21 U.S.C. 823(a)(1)—precisely because, in Respondent's opinion, the Public Health Service and NIDA have ''institutional biases'' against certain types of marijuana research.

This argument was carefully examined in the Final Order. *See* 74 FR at 2107–08, 2119–20. Respondent's post-Final-Order submissions as to this issue are not materially different from the claims that were rejected in the Final Order. In fact, the new documents that Respondent has submitted following the Final Order, and of which I have taken official notice, provide further confirmation of certain determinations made in the Final Order. Respondent's latest submission contains no citations to actual *evidence* in the record that supports his claims of ''institutional biases'' or ''political'' motivation on the part of the Public Health Service and NIDA.

As to this issue, the Final Order stated, among other things:

> Respondent also introduced into evidence a letter from the President of Chemic to HHS responding to several points raised by the PHS Committee in denying Chemic's application. Respondent's letter does not, however, establish that HHS impermissibly denied Chemic's application for marijuana. To the contrary, *the evidence supports the conclusion that HHS (acting through the PHS Committee) made its determination not to supply marijuana on this occasion based on scientific considerations, finding that Chemic's then-latest proposed study was duplicative of prior and ongoing research and not likely to provide useful data.*

74 FR at 2109 (emphasis added; footnote and citation omitted). As noted, I granted Respondent's post-Final-Order request to introduce additional correspondence between Chemic and HHS relating to Chemic's proposed research protocol involving marijuana. Respondent produced six additional pieces of correspondence between Chemic and HHS relating to this matter that were not produced in the administrative hearing. As indicated above and in the December 2, 2010, Order, I have taken official notice of all six of these documents. Each of these documents further confirms that HHS's rejection of the Chemic protocol was—as the Final Order found—based purely on scientific merit.

It is difficult to understand why Respondent would seek to introduce at this juncture six letters between Chemic and HHS that reaffirm what was found in the Final Order—and how Respondent construes these letters as ''rebuttal'' evidence. The statements by HHS in these letters are, without question, focused entirely on the scientific inadequacies of various iterations of Chemic's research proposal. The letters demonstrate that the HHS scientists have actively engaged in a dialogue with Chemic for many years, and have gone to great lengths to explain to Chemic each of the areas in which Chemic needs to revise its protocol so that it can be deemed scientifically meritorious. The letters thereby reaffirm that HHS (including, but not limited to, the Public Health Service and NIDA) has never indicated any opposition (political, philosophical, or otherwise) to any *category* of marijuana research. To the contrary, the letters—particularly the most recent one submitted by Respondent, dated January 23, 2009—actually show that HHS is interested in Chemic's proposal and willing to supply Chemic with marijuana, provided that Chemic provides validation data that is necessary to support Chemic's scientific measurements. In short, the evidence continues to point squarely to the conclusion that HHS is doing precisely what it is required to do under 21 U.S.C. 823(f): Allow only those schedule I research proposals that it determines to be scientifically meritorious to go forward. As the Final Order stated: ''That Respondent finds this process to be scientifically rigorous—and thereby not automatically accepting of any proposed study sponsored by MAPS—provides no basis for any valid objection or any contention that the HHS supply of marijuana is inadequate.'' 74 FR at 2120 (footnotes omitted).[3]

Moreover, Respondent's ''institutional bias'' theory is belied by the following crucial fact. As stated in the Final Order: ''The record reflects that since HHS changed its policies in 1999 to make marijuana more readily available to researchers (by, among other things, allowing privately funded researchers to obtain marijuana), every one of the 17 CMCR [California Center for Medical Cannabis Research]-sponsored pre-clinical or clinical studies that requested marijuana from NIDA was provided with marijuana.'' 74 FR at 2119. Despite the enormity of this fact in relation to Respondent's ''institutional bias'' claim, Respondent makes only the following vague reference to it in his latest submission (page 9): ''Though the DEA points to other marijuana research that NIDA has allowed, none of these studies aimed to develop marijuana into a legal prescription medicine.'' What Respondent downplays as ''other marijuana research that NIDA has allowed'' is, in fact, *seventeen* different clinical trials involving marijuana proposed by CMCR—*all* of which were approved by the Public Health Service and NIDA. As stated in the Final Order:

> Any suggestion that the HHS scientific review process is unduly rigorous is belied by the testimony of Dr. Gust that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana'' (Tr. at 1700–01) as well as the uncontroverted evidence that every one of the 17 CMCR-sponsored research protocols submitted to HHS was deemed scientifically meritorious by HHS and was supplied with marijuana (GX 31, at 3; Tr. 694–95).

74 FR at 2120 n.71.

As for Respondent's contention that ''none of these studies aimed to develop marijuana into a legal prescription medicine,'' this too is contradicted by the record. As stated in the Final Order:

> The California research studies were conducted pursuant to a law enacted by California in 1999 known as the Marijuana Research Act of 1999. Cal. Health & Safety Code § 11362.9. This state law established the ''California Marijuana Research Program'' to develop and conduct studies on the potential medical utility of marijuana. *Id.* (The program is also referred to as the ''Center for Medicinal Cannabis Research'' (CMCR). Tr. 396.) The state legislature

[3] It is unclear whether Respondent is suggesting that I should refuse to accept at face value what HHS stated in its correspondence with Chemic and instead conclude—without any evidentiary basis for doing so—that the HHS scientists who are responsible for reviewing proposed marijuana research have conspired for years to carry out an elaborate ruse aimed at thwarting marijuana research. If this is Respondent's mind-set, adopting it would be the antithesis of the principle inherent to the Administrative Procedure Act (APA) that agency action must be presumed to be valid where a reasonable basis exists for its decision. *See, e.g., Kern County Farm Bureau* v. *Allen,* 450 F.3d 1072, 1076 (9th Cir. 2006). It is also at odds with the APA concept that bars a reviewing court—much less a member of the public—from substituting its judgment for that of the agency. *Id.*

appropriated a total of $9 million for the marijuana research studies. Tr. 397.

74 FR at 2105–06 n.16. It is thus beyond question that the CMCR studies were aimed at what Respondent characterizes as ''develop[ing] marijuana into a legal prescription medicine.'' [4]

For the same reasons, the record contradicts Respondent's related claim that the involvement of the Public Health Service and NIDA in determining the scientific merit of proposed marijuana research ''renders the supply [of marijuana] inadequate because entire categories of legitimate medical research are effectively foreclosed.'' Respondent fails to explain what ''categories of legitimate medical research'' are supposedly being foreclosed. Again, it seems (but is unclear) that Respondent is suggesting that the Chemic research proposal, and/or Dr. Russo's proposal (see below), were more geared toward ''develop[ing] marijuana into a legal prescription medicine'' than were the 17 CMCR studies. In other words, Respondent appears to be suggesting that the Public Health Service and NIDA went into their alleged ''institutional bias'' mode when reviewing the Chemic and Russo proposals, but turned off that mode when reviewing the 17 CMCR proposals because the latter were less geared toward developing marijuana into an FDA-approved medicine. If this is what Respondent is suggesting, there is no evidentiary foundation for such a claim as neither Chemic's proposal nor Dr. Russo's could be characterized as closer than the CMCR studies to the goal of obtaining FDA approval of marijuana as a drug.[5]

To address further the portion of Respondent's latest submission pertaining to Dr. Russo, the following part of the Final Order is recited:

> [Dr. Ethan Russo] sought funding from NIDA to study the use of marijuana to treat migraine headaches beginning around 1996. The precise dates of the events related to Dr. Russo are somewhat unclear as Respondent presented these events through the testimony of Mr. Doblin. (Dr. Russo did not testify.) Based on Mr. Doblin's testimony, it appears that during 1996–97, NIDA twice rejected Dr. Russo's protocol for reasons which are not clearly established by the record. However, according to Mr. Doblin, Dr. Russo conceded that, on both of these two occasions when NIDA rejected his protocol, NIDA's bases for doing so did include ''some valid critiques.'' Mr. Doblin testified that Dr. Russo subsequently attempted for a third time to obtain marijuana from NIDA, but on this third occasion he decided not to seek government funding but to seek private funding to purchase the marijuana from NIDA. According to Mr. Doblin, this third protocol submitted by Dr. Russo was approved by both the FDA and Dr. Russo's institutional review board, but NIDA again refused to supply marijuana. When asked when this last denial by NIDA occurred, Mr. Doblin testified: ''I think it was 1999.''
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> As noted above, NIH announced on May 21, 1999, HHS's new procedures for making marijuana available to researchers. Bearing in mind that Respondent had the burden of proving any proposition of fact that he asserted in the hearing, 21 CFR 1301.44(a), nothing in Mr. Doblin's testimony, or any other evidence presented by Respondent, established that HHS denied Dr. Russo's request for marijuana under the new procedures implemented by the agency in 1999. Indeed, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines.

74 FR at 2108 (citations omitted).

In his post-Final-Order submissions, Respondent submitted a letter dated February 1, 2000, from the Public Health Service and NIDA to Dr. Russo (Exhibit C to Respondent's March 11, 2009, Supplemental Brief). In the December 2, 2010, Order, I granted Respondent's request to take official notice of this document. As Respondent indicates, this letter was issued after HHS announced in 1999 its new procedures for providing marijuana to researchers. Even assuming, arguendo, that this letter demonstrates that the third protocol submitted by Dr. Russo was evaluated by HHS under the new procedures established in 1999,[6] this does not materially alter the conclusions in the Final Order. This is because the Final Order stated, in essence, that even if Dr. Russo's proposal had been evaluated by HHS under the post-1999 procedures, ''the evidence indicates that the denials involving * * * Dr. Russo were based on HHS finding [his] protocols to be lacking in scientific merit.'' *See* 74 FR at 2119 n.68.

The most recent document submitted by Respondent regarding Dr. Russo (the February 1, 2000, letter from Public Health Service to Dr. Russo) confirms yet again that the Public Health Service and NIDA focus on *scientific merit* in reviewing proposed marijuana research. The February 1, 2000, letter advised Dr. Russo that a scientific review of his protocol had been conducted by the Center for Scientific Review (CSR) of the National Institutes of Health on behalf of the Public Health Service, and that the CSR recommended certain changes to the protocol. If, the letter continued, such changes were incorporated into a new protocol and submitted by Dr. Russo, the Public Health Service would reconsider his request. Among the specific changes that Dr. Russo was advised to make were the following: Including a placebo arm; taking steps to account for possible attrition of research subjects; and ensuring that research subjects received equivalent doses of THC. These are quintessentially scientific refinements that the researcher was being asked to make—not, as Respondent alleges, a refusal to allow a category of research to take place.

Thus, even when viewing Respondent's newly submitted evidence regarding Dr. Russo as an example of a denial by HHS of marijuana under the post-1999 HHS procedures, it is in the same category as the Chemic protocols: A denial based on scientific merit under the post-1999 procedures. This would bring the total figures under the post-1999 procedures to the following: 17 studies approved and supplied with marijuana; two studies denied until the researcher makes certain changes in the protocol to render the proposal scientifically meritorious. Stated alternatively, under the post-1999 procedures, HHS's approval rate for marijuana studies is at least 89.5 percent, with the possibility of that figure rising to 100 percent if two of the researchers were willing to make adjustments to their protocols to make them scientifically meritorious.

Respondent's latest submission also refers to certain documentary and testimonial statements by NIDA officials, which Respondent contends support his claim of ''institutional bias.'' As these statements were part of the record that the parties addressed in their pre-Final-Order submissions, and since the Final Order already addressed this type of argument by Respondent, it is not necessary to reexamine this issue at length here. Moreover, the *actions* by HHS in response to actual research proposals are by far the best evidence of the agency's true willingness to supply marijuana to researchers, and these actions render inconsequential any attempt by Respondent to surmise ''institutional bias'' from abstract statements isolated from the documents

[4] The process by which FDA approves new drugs for marketing is summarized in the Final Order. 74 FR at 2106 n.21.

[5] As stated in the Final Order, no clinical trials involving marijuana—not even the 17 CMCR studies—have advanced beyond Phase 1 of the three phases required for FDA approval of a new drug. 74 FR at 2107 n.23. The proposed Chemic study does not even appear to be a clinical trial, let alone a study more advanced in the phases of FDA approval than the CMCR studies.

[6] While the letter itself is dated February 1, 2000, Respondent failed to present evidence indicating when Dr. Russo submitted his third protocol, or when HHS began its review of that protocol. Thus, it remains uncertain whether this third protocol was evaluated under the pre-1999 or post-1999 HHS procedures.

and testimony. The same considerations apply with respect to Respondent's argument that NIDA's mission stands as an obstacle to allowing legitimate marijuana research to take place. This argument was addressed in the Final Order and is overwhelmingly refuted by the evidence of HHS's actual track record in supplying marijuana to researchers.[7]

Respondent also asserts that two provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) and an FDA regulation mandate that the FDA—and not NIDA—must carry out the Secretary of HHS's responsibility under 21 U.S.C. 823(f) to determine the scientific merit of proposed marijuana research. Specifically, Respondent cites 21 U.S.C. 393(b) (FDA's mission statement), 21 U.S.C. 355 (new drug approval process), and 21 CFR 312.22(a) (general principles of submission of an investigational new drug application (IND)), in support of this assertion.

This assertion is mistaken in a number of respects, including, but not limited to, the following. First, the fact that the FDA's statutory mission statement lists certain functions by no means precludes other agencies within HHS from having overlapping functions.[8] Second, while FDA is indeed the agency within HHS that is chiefly responsible for administering the new drug approval process under 21 U.S.C. 355, this is a distinctly different function than the determination under 21 U.S.C. 823(f) of the scientific merit of proposed research involving schedule I controlled substances. There is certainly no basis for Respondent (or any other member of the public) to dictate to the Secretary that the same agency within HHS that carries out the former function must also carry out the latter.[9] Third, although the review by FDA of an IND may (depending on the phase of the investigation) be similar in certain respects to the review under § 823(f) of a schedule I research proposal, the two types of reviews are distinct administrative functions carried out within HHS. This is evident from the first sentence of the very regulation that Respondent cites, 21 CFR 312.22(a), which states: ''FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety.'' Thus, in reviewing an IND for a Phase 1 investigation, FDA's primary objective is to assure the *safety and rights of subjects*—not to assess the scientific quality of the clinical investigation. This is especially notable since, as stated above, none of the clinical trials involving marijuana that have been proposed to HHS has advanced beyond Phase 1.

The foregoing discussion also sheds light on another assertion made by Respondent in his latest submission: That ''several research projects have been blocked by NIDA in spite of FDA-approved protocols.'' [10] Preliminarily, it should be noted that Respondent fails to specify exactly what he means here by ''several research projects.'' The record reveals only *two* clinical research proposals submitted to HHS involving marijuana that did not receive marijuana: Dr. Abrams's proposal (in the pre-1999 era) and Dr. Russo's proposal.[11] In addition, it is important at this juncture to correct an error in terminology. *FDA does not ''approve'' INDs.* Rather, the IND process works as follows. An investigator seeking to use an investigational new drug in a clinical trial must submit an IND for the drug to the FDA. 21 CFR 312.40. The IND automatically goes into effect 30 days after the FDA receives the IND,[12] unless the FDA notifies the sponsor that the investigation is subject to a clinical hold. *Id.*

Thus, it is incorrect for Respondent to state that the FDA ''approved'' any ''protocols'' for proposed marijuana research.[13] More accurately stated, the most that can be inferred from the evidence is that the FDA *reviewed INDs* submitted by Dr. Abrams and Dr. Russo, and that the FDA did not place a clinical hold on either proposed investigation.[14] However, as just explained, the FDA regulations indicate that, for Phase 1 investigations, FDA's review of an IND focuses primarily on the safety and rights of subjects—not the scientific quality of the clinical investigation. Thus, while the FDA appears to have concluded that allowing Dr. Russo's and Dr. Abrams's Phase 1 studies to proceed would not have presented an unacceptable risk of harm to the human research subjects,[15] there is no evidentiary basis to conclude that FDA evaluated the scientific quality of either proposal—and particularly no basis to conclude that FDA determined that the studies were scientifically meritorious within the meaning of 21 U.S.C. 823(f).

As stated in the Final Order, under the procedures implemented by HHS in 1999 for reviewing proposed marijuana research, the review by FDA on an IND is *one part* of that process.[16] Yet, Respondent seems to want FDA's

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[7] Although HHS's actual record in supplying marijuana to researchers is the best evidence of its willingness to do so, the following testimony of Dr. Gust at the hearing explains how HHS took steps in 1999 to ensure the availability of marijuana to researchers—including those interested in pursuing medical uses of marijuana—irrespective of NIDA's mission:

It was about this time [1999] when there was some increased interest in research, in pursuing the medical use of marijuana, and in an effort to make the process more standardized, and to basically provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved primarily the use of marijuana or any other substance for that matter for treatment of diseases, which did not really fall within NIDA's mission, the department [HHS] established a separate peer review process that made the review—that moved the review into the Public Health Service at the time where additional expertise from other NIH Institutes and other Federal agencies could be brought to bear to help—and help provide reviews, appropriate reviews, of the scientific merit of these applications.

Tr. 1632–33. Thus, Respondent's attempt to focus on NIDA's particular mission, without regard to the mission of other components of HHS involved in review of marijuana research proposals, and without regard to the overall aims of the procedures established by HHS in 1999 for providing marijuana to researchers, is misplaced.

[8] Moreover, not even those functions expressly listed in FDA's statutory mission statement are carried out solely by the FDA. As stated in the very next subsection after the one cited by Respondent, 21 U.S.C. 393(c), which is entitled ''Interagency collaboration'': ''The Secretary [of HHS] shall implement programs and policies that will foster collaboration between the [FDA], the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies. * * *''

[9] Under 21 U.S.C. 823(f), Congress assigned to the Secretary of HHS sole discretion to determine how HHS carries out its responsibility to review the scientific merit of schedule I research proposals.

[10] Respondent uses this particular wording on page 9 of his latest submission, and he reiterates the assertion numerous times in the document.

[11] As Respondent seems to concede, Chemic's proposed research involving marijuana is *not* a clinical trial. Accordingly, Respondent does not appear to be suggesting that Chemic submitted an IND to the FDA for its research proposal. Thus, it does not appear that Respondent is including the Chemic situation in his category of ''research projects [that] have been blocked by NIDA in spite of FDA-approved protocols.''

[12] The FDA may also notify the investigator that the clinical investigation may begin earlier than 30 days after the FDA receives the IND. 21 CFR 312.40(b)(2).

[13] The word ''approve'' (or ''approval'') is a term of art in the FDCA. The FDA ''approves'' new drug applications upon an adequate showing of safety and efficacy for the uses in the proposed labeling, which allows a drug to be legally marketed. 21 U.S.C. 355; 21 CFR 314. An effective IND is considered ''accepted,'' not ''approved,'' by FDA.

[14] I am assuming, for the sake of discussion, that Dr. Russo and Dr. Abrams submitted INDs and that the FDA did not issue clinical holds, even though Respondent did not introduce such INDs or call Dr. Russo or Dr. Abrams to testify.

[15] *See* 21 CFR 312.42(b) (grounds for imposition of a clinical hold of a Phase 1 study under an IND).

[16] *See* 74 FR at 2105.

review of an IND for Phase 1 investigations—which focuses on the safety and rights of subjects, rather than the scientific quality of the clinical investigation—to serve as the entire review process, *i.e.,* to supplant the full-fledged evaluation of the scientific merit required by 21 U.S.C. 823(f). Had Congress intended such a result, it could have easily stated in 21 U.S.C. 823(f) that the only scientific prerequisite to conducting research with a schedule I controlled substance is that an IND be in effect with respect to such research.[17] But it is evident from the language of § 823(f) that Congress intended HHS to conduct a different type of evaluation of the scientific merit of research proposals than that which will suffice for purposes of an IND. It is unclear whether Respondent fails to understand this distinction between the review by FDA of a Phase 1 IND and the review of the scientific merit of a research proposal under § 823(f), or if Respondent does understand this distinction and simply wishes that the less rigorous review (the Phase 1 IND review) would suffice so that even those marijuana research proposals that lack scientific merit could be carried out.[18] For the reasons noted above, neither of the foregoing is a legally valid position.

In sum, Respondent's motion for reconsideration provides no basis for deviating from the conclusions in the Final Order relating to the process by which HHS determines the scientific merit of proposed marijuana research pursuant to 21 U.S.C. 823(f). Congress assigned to the Secretary of HHS responsibility for deciding how to carry out that function within HHS, and the evidence demonstrates that the procedures established by HHS in 1999, including the Public Health Service interdisciplinary review process, properly focus on the scientific merit of research proposals. As the Final Order indicated, that process makes marijuana available to all researchers who meet the criteria of § 823(f), and Respondent's post-Final-Order submissions provide no evidence suggesting otherwise. Respondent's desire to substitute his opinion for that of the Secretary as to what type of scientific review should be carried out under § 823(f), and who within HHS should carry it out, is legally untenable.

Respondent's claim that the supply of marijuana is inadequate is dependent on his supposition that the current HHS process for supplying marijuana to researchers improperly denies marijuana to researchers. That supposition was found in the Final Order to be without merit, and his latest submission warrants no departure from that finding, as explained above. Accordingly, Respondent has provided no basis to change the conclusion in the Final Order that he failed to meet his burden of proving that the supply of marijuana is inadequate within the meaning of 21 U.S.C. 823(a)(1).

B. Respondent's Arguments Relating to the Single Convention on Narcotic Drugs, 1961

Respondent seeks reconsideration of the determinations in the Final Order relating to the Single Convention on Narcotic Drugs, 1961 (Single Convention). Respondent's post-Final-Order arguments relating to the Single Convention are not predicated on the taking of official notice of any fact. Nonetheless, as indicated, I have considered these arguments. Respondent's core contentions regarding the Single Convention were addressed in the Final Order and, therefore, it is unnecessary to repeat all of that discussion here. However, in view of his latest submissions, a few points warrant reiteration and/or clarification.

Under 21 U.S.C. 823(a), DEA must deny an application by a person seeking to become registered as a bulk manufacturer of a schedule I controlled substance if the agency determines that such registration would be inconsistent with United States obligations under applicable international drug control treaties—*i.e.,* the Single Convention. When it comes to marijuana (referred to under the treaty as ''cannabis''), one of the key principles of the Single Convention is that the federal government maintain a monopoly over the wholesale distribution of the drug. As to this point, the Final Order recited the following statement from the Official Commentary to the Single Convention:

> Countries * * * which produce * * * cannabis * * *, [i]n so far as they permit private farmers to cultivate the plants * * *, cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the crops to private traders, they would not be in a position to ascertain with reasonable exactitude the amounts which enter their controlled trade. The effectiveness of their control régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. * * * [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 * * * and article 28 * * * therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

74 FR at 2115 (citing Commentary at 278).

As indicated in the Final Order, the United States has, since 1968, implemented this aspect of the treaty through the following system carried out within HHS. NIDA enters into a contract with a private grower, with the grower being obligated under the contract to produce the amount and quantity of marijuana specified by NIDA and to produce marijuana cigarettes to supply researchers as directed by NIDA.[19] Throughout the 44 years since the United States ratified the Single Convention in 1967, the entire United States supply of marijuana for researchers has been distributed through this system. In this manner, the United States Government has always monopolized the wholesale trade in marijuana, consistent with its obligations under the treaty.

It is true, as Respondent points out in his post-Final-Order submissions, that the Single Convention (article 23, paragraph 3) calls upon parties to carry out the functions of article 23 by a single government agency. It is also true, as Respondent indicates, that the United States fails to adhere strictly to this provision of the treaty as both DEA and HHS carry out certain functions set forth in article 23, paragraph 2.[20] Specifically, DEA carries out those functions of article 23 paragraph 2 that are encompassed by the DEA registration system, and HHS (through NIDA) carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution. That these

[17] Several provisions of the CSA reference the IND provision of the FDCA. For example, 21 U.S.C. 827(c)(2)(A) expressly excludes ''research conducted in conformity with an exemption granted under [21 U.S.C. 355(i)]'' from the CSA's recordkeeping requirements.

[18] Illustrative of this point is Respondent's statement in his latest submission (page 14) that ''if a research protocol is good enough for the FDA, it should be good enough to be carried out.''

[19] Prior to 1999, NIDA entered into two contracts: one with the grower and one with the entity that produced the cigarettes. In 1999, NIDA decided that a single contract should be awarded for both activities, which resulted in the contractor (a division of the University of Mississippi) continuing to grow the marijuana, but subcontracting to Research Triangle Institute the responsibility of producing the cigarettes. 74 FR at 2122 n.79.

[20] Respondent is incorrect, however, in asserting that the Final Order stated that NIDA carries out all the functions under article 23, paragraph 2. No such statement appears in the Final Order.

functions are divided among the two agencies—rather than being carried out by a single agency—is a result of the existing statutes, regulations, and Congressional appropriations.[21] Nonetheless, when evaluating an application for registration under 21 U.S.C. 823(a), DEA must attempt to conform with the provisions of the Single Convention to the fullest extent possible under the existing statutory and regulatory framework. Accordingly, even in the absence of a single government agency carrying out all the functions referred to in article 23, paragraph 2, DEA must seek to adhere to the other provisions of this article that are attainable within the existing statutory and regulatory framework, including that which calls upon the United States Government to monopolize the wholesale distribution of marijuana.[22]

Therefore, for the reasons detailed in the Final Order, Respondent's stated goal of becoming registered for the purpose of ending the Government monopoly on the wholesale distribution of marijuana to researchers is directly at odds with the Single Convention, which independently warrants denial of his application. Respondent seems to continue to either ignore and/or misunderstand this fundamental aspect of the treaty. In his latest submission, Respondent states (pages 20–21): ''It is certainly true Dr. Craker seeks to cultivate marijuana outside *NIDA's* monopoly, but it does not follow that Dr. Craker seeks to cultivate marijuana outside the structures of *any government regulation.* * * * Dr. Craker and [Mr. Doblin] are in no way opposed to the regulation of marijuana by [DEA].'' (Emphasis in original.) This statement suggests that Respondent believes incongruously that as long as he agrees to comply with the DEA regulations relating to registration and security, his proposed registration should be deemed consistent with the Single Convention. Based on this flawed assumption, Respondent is effectively arguing that the provision of the Single Convention requiring a Government monopoly over the wholesale distribution of marijuana may be jettisoned whenever an applicant for registration promises to comply with the DEA regulations governing registration and security.

Respondent also continues to argue that the marijuana he seeks to grow is ''exempt'' from the Single Convention requirement of a government monopoly over the wholesale distribution of marijuana. According to Respondent, because he is seeking to supply marijuana to researchers for the purpose of conducting research that he hopes will someday lead to the FDA approval of marijuana as medicine, the marijuana he is seeking to grow should be deemed ''medicinal cannabis'' within the meaning of the Single Convention and thus the government monopoly set forth in article 23, paragraph 2(e) should be considered inapplicable to his proposed activity. The Government correctly suggests in its responsive brief (pages 8–9) that Respondent's interpretation would vitiate the language of article 23, paragraph 2(e). As I stated in the December 2, 2010, Order, it is theoretically possible that a marijuana-derived drug might be approved by the FDA in the future that would constitute ''medicinal cannabis'' within the meaning of the Single Convention. However, no drug product derived from marijuana has been approved by the FDA and, therefore, there is currently no such thing as ''medicinal cannabis'' in the United States. For this reason, the exception in article 23, paragraph 2(e) for ''medicinal cannabis'' has no bearing on this adjudication.

For purposes of the Single Convention, the marijuana that Respondent seeks to produce is clearly ''cannabis'' subject to the government monopoly under article 23, paragraph 2(e). As to this point, the Final Order observed:

> In its 2005 Annual Report, the [International Narcotics Control Board] reiterated: ''Articles 23 and 28 of the [Single] Convention provide for a national cannabis agency to be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is used for research purposes only.''

74 FR at 2115 (footnote omitted).

Respondent also makes the following statement in his latest submission (pages 15–16): ''Additionally, the conduct of the one currently DEA-licensed manufacturer, who has been permitted by DEA to grow large amounts of marijuana *outside* of the NIDA contract, disproves the theory that marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention.'' (Emphasis in original.) Respondent is referring here to the cultivation of marijuana by the National Center for Natural Products Research (National Center), a division of the University of Mississippi.[23] As explained in the Final Order, in 1999, DEA and the National Center entered into a Memorandum of Agreement (MOA) under which the National Center was granted an additional registration to manufacture marijuana and THC independent of its contract with NIDA. 74 FR at 2104 n.13. The Final Order further explained:

> As set forth in the MOA, the purpose of the registration was ''to allow the Center to develop a new product formulation for effecting delivery of THC in a pharmaceutically acceptable dosage form suppository * * * and to provide crude THC extract to a DEA-registered manufacturer of THC for further purification.'' The MOA further stated that, under the terms thereof, the Center would ''manufacture marijuana for the purpose of extracting THC therefrom.'' Subsequently, the Center submitted a new application for a registration to bulk manufacture marijuana and THC ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' DEA has not yet issued a final order as to this application. (DEA publishes in the Federal Register all final orders on applications for registration to bulk manufacture schedule I and II controlled substances.)
>
> *The MOA further provided that ''[i]n accordance with articles 23 and 28 of the Single Convention on Narcotic Drugs * * * private trade in 'cannabis' is strictly prohibited. Therefore, the Center shall not distribute any quantity of marijuana to any person other than an authorized DEA employee.''* Continuing, the MOA explained that ''[t]he Single Convention does not prohibit private trade in 'cannabis preparations,''' and noted that this term, ''within the meaning of the Single Convention, is a mixture, solid or liquid containing cannabis, cannabis resin, or extracts or tinctures of cannabis.'' Because ''[t]he THC that the Center will extract from marijuana [is] considered such a 'cannabis preparation[,]' * * * the Center may, in accordance with the Single Convention, distribute the crude THC extract to private entities'' provided the Center otherwise complies with the CSA and DEA regulations. The MOA also set forth a detailed series of controls to maintain accountability of the marijuana from acquisition of the seeds through the extraction of THC from the harvested material.

Id. (emphasis added; citations omitted). The Final Order further stated:

[21] Whether, in the absence of Congressional action, DEA could promulgate regulations that would result in DEA alone carrying out all the functions of article 23 is beyond the scope of this adjudication.

[22] Although Respondent argues that the Government does not take actual physical possession of the marijuana grown by the NIDA contractor (as contemplated by article 23, paragraph 2(d)), one could conclude that the NIDA contract process does fulfill this obligation. For the reasons indicated above, this does not compel DEA to abandon the provision of article 23 requiring a government monopoly on the wholesale distribution of marijuana. *See* 74 FR at 2114 (''taking possession and engaging in wholesale distribution are two separate activities under the Convention'').

[23] For ease of understanding, the National Center is sometimes referred to here and in the Final Order as ''the University of Mississippi.''

In 2005, the University of Mississippi applied for a new registration to manufacture marijuana ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' DEA has not yet issued a final order as to this application and the University therefore does not currently have DEA authorization to undertake such activity. As with Respondent's application, DEA may only grant the pending University of Mississippi application if the agency determines that the University has demonstrated that the registration would be consistent with United States treaty obligations and the public interest. In making such determinations, DEA will not simply rely on the prior issuance of registration under the 1999 MOA but will consider the application anew, in view of the current circumstances and consistent with this final order. Among other things that must be considered with respect to the pending University of Mississippi application, I note that the Commentary to the Single Convention states the following with respect to the exemption for ''opium preparations'' under Article 23, paragraph (e): ''Opium-producing countries may thus authorize private manufacture of, and private international and domestic wholesale trade in, medicinal opium and opium preparations. *The opium other than medicinal opium needed for such manufacture must however be procured from the national opium agency.''* Commentary at 284 (emphasis added). Whether the University of Mississippi's proposed registration would be consistent with this aspect of the treaty has not yet been determined by DEA and is not the subject of this adjudication.

74 FR at 2118 n.61 (emphasis in original; citations omitted).

When viewing the foregoing statements from the Final Order in juxtaposition with Respondent's latest assertions regarding the National Center, two points should be considered. First, the above statements reflect that as part of the 1999 MOA with the National Center, DEA insisted—as it has in Respondent's case—on adherence to the principle under the Single Convention of prohibiting private trading in cannabis. The National Center has never been permitted to distribute marijuana to any persons except upon the specific instructions of NIDA through the system described above. Second, contrary to Respondent's assertion, DEA has never taken the position that ''marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention.'' Rather, as just noted, DEA has consistently taken the position that, in accordance with the Single Convention, the Government must maintain a monopoly on the wholesale distribution of cannabis.

One other argument made by Respondent in his latest submission warrants a brief response. Respondent repeatedly makes erroneous assertions about the legal and factual circumstances surrounding his application, then denounces the situation as a ''catch-22.'' For example, on page 17 of his latest submission, Respondent describes the following as a ''catch-22'': ''Medical marijuana does not exist, according to DEA, unless it is an FDA-approved medicine, but Dr. Craker's license to supply marijuana for the research necessary to test such a medicine and secure FDA approval cannot be granted because medical marijuana does not exist.'' In fact, not only DEA, but also the United States Supreme Court, interpreting the text of the CSA, has stated—*unanimously*—that marijuana is not medicine. In *United States* v. *Oakland Cannabis Buyers' Cooperative,* 532 U.S. 483, 491 (2001), the Court stated: ''[F]or purposes of the [CSA], marijuana has 'no currently accepted medical use' at all.'' Moreover, Respondent, in denouncing the notion that marijuana must gain FDA-approval to be considered medicine, is objecting to what has been a cornerstone of the FDCA for 50 years—that a drug may not be marketed as medicine in this country unless the FDA has determined, based on submissions of scientific evidence established in clinical trials, that the drug is safe and effective for the treatment of a disease or condition. As for Respondent's contention that marijuana research cannot go forward unless he becomes registered to grow marijuana, as explained above in section A., this is flatly refuted by the fact that HHS and DEA authorized 17 of the last 17 marijuana research proposals submitted by CMCR—all of which were aimed at establishing a scientific foundation for the FDA approval of marijuana. Thus, Respondent's use of the term ''catch-22'' is empty rhetoric.

C. Respondent's Arguments Relating to the Involvement of Rick Doblin in Respondent's Proposed Activities

Respondent also seeks reconsideration of my determinations in the Final Order relating the involvement of Rick Doblin in Respondent's application and proposed activities. Again, in the exercise of my discretion, I have considered Respondent's post-hearing submissions as to this issue, even though they do not arise out of the taking of official notice of any fact.

To briefly recap, the Final Order listed the various ways in which Mr. Doblin was involved in Respondent's application process and how Mr. Doblin would have a role in Respondent's activities if the application were granted. 74 FR at 2126. The Final Order then stated:

> In short, Mr. Doblin has mapped out and assisted in most acts, if not every act, that Respondent has taken toward applying for a registration to manufacture marijuana and, if the registration were granted, Mr. Doblin would continue to maintain responsibility for managing and monitoring the activities of the registrant. Given this level of involvement by Mr. Doblin—and the passive, if not subservient, nature of Respondent's involvement—it is appropriate under factor six to consider the following conduct by Mr. Doblin relating to controlled substances. First, Mr. Doblin admits that he smokes marijuana for ''recreational use'' on a weekly basis. Thus, Mr. Doblin violates federal and state laws relating to controlled substances on a weekly basis. This demonstrates that Mr. Doblin has disregard for the controlled substances laws. It is simply inconceivable that DEA would—consistent with its obligations under the CSA—grant a registration to engage in certain activities involving controlled substances where it is clear that a person who will have *any* role in the oversight and management of such activities routinely engages in the illegal use of controlled substances. It is still more untenable where that person has the level of oversight and management that Mr. Doblin would have—and where the controlled substance he illegally uses is the very controlled substance the applicant seeks to produce. Indeed, it is remarkable that Mr. Doblin would—given his admitted illegal involvement in controlled substances—ask DEA to effectively grant him permission to take on such a prominent role in the manufacture of the most widely abused illegal controlled substance in the United States.

Id. (emphasis in original; citations and footnotes omitted).

In his latest submission, Respondent points out that in the Final Order, under the fifth public interest factor (21 U.S.C. 823(a)(5)), I concluded that if the registration were granted, Respondent would have in the establishment (*i.e.,* in his growing facility) effective controls against diversion. 74 FR 2125–26. Respondent contends that this conclusion precludes me from concluding under the sixth public interest factor (21 U.S.C. 823(a)(6)) that Mr. Doblin's involvement in Respondent's activity weighs against granting his application.

It is plain when comparing the text of factor five with that of factor six that a favorable finding with respect to factor five does not preclude an unfavorable finding under factor six. As explained in the Final Order, under public interest factor five, ''the existence in the establishment of effective control against diversion'' includes, among other considerations, appropriate physical security and employee screening as required by the DEA

regulations as confirmed through a DEA on-site inspection of the premises. 74 FR at 2128 (citing 21 CFR 1310.71–1301.93). Factor six, in contrast, is a catchall category that is designed to give DEA wide latitude to consider all evidence that might reasonably bear on the suitability of an applicant for registration. In other words, even if a registrant has promised to undertake security procedures sufficient to obtain a favorable finding under factor five, if other evidence (not covered by factors one through five) casts doubt on whether the applicant can be entrusted with the responsibility of a DEA manufacturing registration, such evidence may be considered under factor six.

Consider, for example, if a person were seeking to become registered as a manufacturer of oxycodone, and the applicant promised to install and maintain in the facility all the physical security measures and employee screening procedures required by the regulations. Assume further that evidence came to light that the main investor in the facility, who planned to make the decisions as to how the facility would distribute oxycodone, admitted that he obtains oxycodone illegally and uses it for ''recreational'' purposes on a weekly basis. In such circumstances, it would certainly be appropriate for DEA to draw an adverse inference under factor six based on such person's illicit activity involving oxycodone—regardless of whether the applicant made assurances that it would comply with the security regulations. Thus, I cannot adopt Respondent's suggestion that Mr. Doblin's regular marijuana use should be ignored as a factor relevant to his application.

Nonetheless, it bears repeating that the ultimate decision in this matter did not turn on consideration of Mr. Doblin's marijuana activity. As stated in the Final Order, two other independent grounds existed for denying the application and, therefore, the same result would have been reached had I determined that Mr. Doblin's marijuana activity were irrelevant.

To be clear, if I determined that the proposed registration were consistent with United States obligations under the Single Convention and further that the supply of marijuana available to researchers in the United States were inadequate within the meaning of 21 U.S.C. 823(a)(1), it is conceivable that arrangements could have been made to mitigate the concerns regarding Mr. Doblin's marijuana activity. For example, under a conditional grant of registration or memorandum of agreement, sufficient terms perhaps could have been imposed to ensure that Mr. Doblin would not be allowed to have access to the growing facility and would have no role in any decision making relating to management of the facility or the distribution of marijuana. However, consideration of such an approach was not feasible here given the other grounds for denying the application.

IV. Conclusion

For the foregoing reasons, Respondent's motion for reconsideration is hereby denied. The administrative record is modified as indicated herein and in my December 2, 2010, order. The January 14, 2009, Final Order, as supplemented by this order, is effective on September 7, 2011.

Dated: August 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21064 Filed 8–17–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Joe C. Fermo, M.D.; Revocation of Registration

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Joe C. Fermo, M.D. (Registrant), of Tulsa, Oklahoma. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration, BF7430781, as well as the denial of any pending applications to renew or modify his registration, on the ground that his ''continued registration would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that on February 23, 1990, Registrant was convicted in the District Court for Oklahoma County, State of Oklahoma, of ten counts of submitting false claims to the Oklahoma Department of Human Services in violation of Oklahoma law, and that on June 20, 1990, the United States Department of Health and Human Services excluded him from participating in federal health care programs under 42 U.S.C. 1320a–7(a). *Id.* at 1–2. The Order further alleged that based on his convictions, on June 21, 1990, the Oklahoma State Board of Medical Licensure placed his medical license on probation and that Registrant materially falsified three separate applications (in 1991, 1994, and 1997) to renew his DEA registration by failing to disclose the state board's action. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).[1]

Finally, the Show Cause Order alleged that on August 27, September 24, and September 26, 2007, an undercover officer had obtained prescriptions from Registrant for alprazolam (at all three visits) and propoxyphene (at the first two visits), both of which are schedule IV controlled substances. *Id.* The Order further alleged that these prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice in violation of Federal and State laws. *Id.* (citing 21 CFR 1306.04 and Okla. Admin. Code 475.30–1–3(a)).

On or about October 5, 2009, the Show Cause Order, which also notified Registrant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing so, and the consequence if he failed to do so, was served on Registrant by certified mail addressed to him at the address of his registered location. *Id.* at 2–3 (citing 21 CFR 1301.43). Since service of the Show Cause Order, more than thirty days have now passed and neither Registrant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(b)–(d). Accordingly, I find that Registrant has waived his rights to a hearing or to submit a written statement. *Id.* 1301.43(d). I therefore issue this Decision and Final Order without a hearing based on relevant evidence contained in the investigative record submitted by the Government.

Findings

Registrant is the holder of DEA Certificate of Registration, BF7430781, which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered location of 5970 E. 31 St., Suite O, Tulsa, Oklahoma. While his registration was to expire on September 30, 2010, on August 13, 2010, Registrant filed a renewal application. In accordance with the Administrative Procedure Act and DEA regulations, I find that Registrant's registration remains in effect pending the issuance

[1] The Show Cause Order alleged that in March 2001, Registrant and DEA entered into a Memorandum of Agreement (MOA) which settled a Show Cause Proceeding filed in April 2000 based on the allegations described above. Show Cause Order at 2. The Show Cause Order also alleged that under the MOA, Registrant surrendered his registration and was allowed to reapply no earlier than March 2004, and that in October 2004, DEA issued him a new registration. *Id.*