

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Eastern District of California, 4-200 Robert T. Matsui United States Courthouse, 501 I Street, Sacramento, California 95814. In addition, the proposed Consent Decree may be viewed at http://www.usdoj.gov/enrd/Consent_Decrees.html.

Stephen Samuels,

Assistant Chief, Environmental Defense Section, Environment & Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated January 11, 2006 and published in the **Federal Register** on January 23, 2006, (71 FR 3545), Cody Laboratories, Inc., 601 Yellowstone Avenue, Cody, Wyoming 82414-9321, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Raw Opium (9600)	II.
Poppy Straw (9650)	II.
Concentrate of Poppy Straw (9670).	II.

The company plans to import narcotic raw materials for manufacturing and further distribution to its customers. The company is registered with DEA as a manufacturer of several controlled substances that are manufactured from raw opium, poppy straw, and concentrate of poppy straw.

Comments, objections, and requests for a hearing were received. However, after a thorough review of this matter DEA has concluded that, per 21 CFR 1301.34(a), the objectors are not entitled to a hearing. As explained in the Correction to Notice of Application dated January 25, 2007, pertaining to Cody Laboratories *et al.* (72 FR 3417), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Cody Laboratories, Inc. to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or

protocols in effect on May 1, 1971. DEA investigated Cody Laboratories, Inc. to ensure that the company's registration would be consistent with the public interest. The investigation 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. After investigating these and other matters, I have concluded that registering Cody Laboratories, Inc. to import raw opium, poppy straw, and concentrate of poppy straw is consistent with the factors set forth in 21 U.S.C. 823(a)(2)-(6), as incorporated in 21 U.S.C. 958(a).

The DEA also considered whether the registration of Cody Laboratories, Inc. would be consistent with 21 U.S.C. 823(a)(1) that requires the DEA to limit the importation of certain controlled substances (including raw opium, poppy straw, and concentrate of poppy straw) "to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions* * *." I find that the establishments currently registered with DEA to import raw opium, poppy straw, and concentrate of poppy straw provide an adequate and uninterrupted supply of those substances. The DEA found no evidence that the supply of such substances was inadequate or interrupted in supplying the needs of the United States for legitimate medical, scientific, research, and industrial purposes.

However, I find that the adequate and uninterrupted supply of these substances did not occur under adequately competitive conditions. Specifically, I find that Cody Laboratories, Inc. has demonstrated that the current importers of raw opium, poppy straw, and concentrate of poppy straw have, in some cases, refused to sell these substances to Cody Laboratories, Inc. Some of the current importers also use their position to demand restrictive contractual terms when selling narcotic raw material to Cody Laboratories, Inc. Many of the current importers also manufacture active pharmaceutical ingredients or have corporate ties to firms that manufacture active pharmaceutical ingredients from raw opium, poppy straw, and concentrate of poppy straw. These importers have a direct financial interest in refusing to sell narcotic raw material to Cody Laboratories, Inc. or in demanding significant contractual restrictions when selling narcotic raw material to Cody Laboratories, Inc.

Based on the information in the investigative file that is summarized herein, I find that the current importation of raw opium, poppy straw, and concentrate of poppy straw is not being conducted under adequately competitive conditions. Therefore, under 21 U.S.C. 823(a)(1), DEA may grant the application of Cody Laboratories, Inc. to import raw opium, poppy straw, and concentrate of poppy straw. Having already found that registering Cody Laboratories, Inc. to import raw opium, poppy straw, and concentrate of poppy straw is consistent with the factors set forth in 21 U.S.C. 823(a)(2)-(6), I find that the statutory factor set forth in 21 U.S.C. 823(a)(1) also weighs in favor of granting the application.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: July 18, 2008.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 13, 2008 and published in the **Federal Register** on February 21, 2008, (73 FR 9592), Johnson Matthey, Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066-1742, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Lisdexamfetamine (1205), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance in bulk for sale 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 Johnson Matthey, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Johnson Matthey, 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, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: July 15, 2008.

Joseph T. Rannazzisi,

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

[FR Doc. E8-16905 Filed 7-23-08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08-29]

Laurence T. McKinney; Revocation of Registration

On February 5, 2008, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Laurence T. McKinney, M.D. (Respondent), of Philadelphia, Pennsylvania. The Order immediately suspended and proposed the revocation of Respondent's DEA Certificate of Registration, BM7201267, as a practitioner, on the grounds that his continued registration was "inconsistent with the public interest" and "constitute[d] an imminent danger to public health and safety." Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4) & 824(d)).

More specifically, the Show Cause Order alleged that Respondent was "one of the largest prescribers of schedule II controlled substances in the Philadelphia area[,]" and that "[f]rom October 5, 2004 to November 30, 2007 [had written] 3,101 prescriptions for schedule II narcotics." *Id.* Next, the Show Cause Order alleged that Respondent sold prescriptions for narcotics for \$100 per prescription, that he had issued prescriptions to undercover law enforcement officers on five separate dates between December 14, 2007, and January 30, 2008, that he had either failed to perform a physical examination or had conducted only a "cursory physical examination" on the Officers, and that he had also written a prescription for one of the undercover Officer's fictitious wife. *Id.* at 1-2. The Show Cause Order further alleged that these "prescriptions were not issued for a legitimate medical purpose or in the

normal course of professional practice" and thus violated both Federal and state laws and regulations. *Id.* at 2 (citing 21 U.S.C. 841(a); 21 CFR 1306.04(a)).

Based on the above, I also made the preliminary finding that Respondent had "deliberately diverted controlled substances" and that his "continued registration during the pendency of these proceedings would constitute an imminent danger to the public health or safety because of the substantial likelihood that [he would] continue to divert controlled substances." *Id.* at 2. I therefore also ordered the immediate suspension of Respondent's registration. *Id.*

On February 15, 2008, Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Following pre-hearing procedures, a hearing was held on April 7, 2008 in Arlington, Virginia, at which both parties introduced testimonial and documentary evidence.¹ Upon conclusion of the hearing, both parties submitted briefs containing their proposed findings, conclusions of law and argument.

On May 5, 2008, the ALJ issued her recommended decision (ALJ). In her decision, the ALJ specifically rejected Respondent's testimony regarding his prescribing to the undercover patients finding that he was not credible. ALJ at 29. With respect to factor two (Respondent's experience in dispensing controlled substances), the ALJ concluded that "the record establishes * * * that Respondent issued prescriptions to the undercover Officers for controlled substances without any meaningful physical examination or gathering sufficient information from the patients to arrive at a reasoned diagnosis or * * * to determine whether they had any condition at all warranting treatment with the drugs he prescribed to them." *Id.* at 29-30. The ALJ thus found "that all the prescriptions Respondent issued to the undercover officers were not issued for a legitimate medical purpose." *Id.* at 30.

The ALJ further noted that various patient files introduced into evidence by the Government demonstrated that Respondent had not provided "individualized attention" to other patients. *Id.* Relatedly, while noting that Respondent had "introduced into evidence patient files containing considerably more detailed information than those the Government offered," the ALJ reasoned that even if these files

¹ The Government also introduced recordings of several undercover visits.

showed that Respondent had "legitimately treated" some patients, the files predated November 26, 2007, the date on which the Philadelphia Police Department had received a complaint about Respondent and did not "diminish the weight of the evidence that he improperly prescribed controlled substances after it." *Id.*

With respect to factor four (Respondent's compliance with applicable laws), the ALJ concluded that Respondent had failed to comply with Pennsylvania law because he had issued prescriptions for controlled substances without doing proper physical examinations, taking adequate medical histories, documenting the patient's symptoms, his diagnosis and treatment recommendations, and that he had failed to counsel his patients regarding how the drugs should be taken, the appropriate dosage, and their side effects. *Id.* at 31. The ALJ thus concluded that "Respondent violated applicable Pennsylvania law and also violated 21 CFR 1306.04, and thereby 21 U.S.C. 829(b)." *Id.*

With respect to factor five (other conduct), the ALJ rejected Respondent's contention that he had prescribed pursuant to a good-faith belief that the undercover patients were in pain. *Id.* More specifically, the ALJ expressed her disbelief "that Respondent did not know that the undercover Officers were not in pain but were trying to obtain controlled substances for other than a legitimate medical reason." *Id.* at 31. The ALJ further found that Respondent had "refus[ed] to acknowledge his wrongdoing," and that there was "little hope" that "he will act more responsibly in the future." *Id.*²

Based on her findings with respect to three of the factors, the ALJ concluded "that Respondent is unwilling or unable to accept the responsibilities inherent in a DEA registration." *Id.* at 32. The ALJ thus recommended the revocation of Respondent's registration and the denial of any pending applications. *Id.*

Respondent filed exceptions to the ALJ's recommended decision. In this filing, Respondent raised thirty-three exceptions to the ALJ's decision.³

² The ALJ also found that Respondent had retained his state medical license and that this factor supported a finding "that his continued registration would be in the public interest." ALJ at 29. The ALJ explained, however, that this factor was not dispositive because "state licensure is a necessary but not sufficient condition for DEA registration." *Id.* The ALJ further found that while Respondent had been convicted of a felony, his offense did not involve an offense related to controlled substances. *Id.* at 30-31. The ALJ thus found that this factor supported his continued registration although it too was not dispositive.

³ Respondent's Exceptions did not, however, comply with DEA's regulation which requires