phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file.

If you wish to inspect the DEA's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II each year. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The DEA established the 2014 aggregate production quotas for substances in schedules I and II on September 9, 2013 (78 FR 55099). Subsequently, on October 10, 2013, the DEA published in the **Federal Register** a notice of intent to temporarily place three synthetic phenethylamines (25I-NBOMe, 25C-NBOMe, and 25B-NBOMe) in schedule I of the CSA (78 FR 61991). On November 15, 2013, the DEA published in the **Federal Register** a final order to temporarily place these three synthetic phenethylamines in schedule I of the CSA (78 FR 68716), making all regulations pertaining to schedule I controlled substances applicable to the manufacture of these three synthetic phenethylamines, including the establishment of an aggregate production quota pursuant to 21 CFR 1303.11.

25I-NBOMe, 25C-NBOMe, and 25B-NBOMe were non-controlled substances when the aggregate production quotas for schedule I and II substances were established, therefore, no aggregate production quotas for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe were established at that time.

In determining the 2014 aggregate production quotas of these three phenethylamines, the Deputy Administrator considered the following factors in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11: (1) Total estimated net disposal of each substance by all manufacturers; (2) estimated trends in the national rate of net disposal; (3) total estimated inventories of the basic class and of all substances manufactured from the class; (4) projected demand for each class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and (5) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Deputy Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

The Deputy Administrator, therefore, proposes that the year 2014 aggregate production quotas for the following temporarily controlled schedule I controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class–schedule I	Proposed 2014 quota
2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15 g
2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15 g
2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15 g

Comments

Pursuant to 21 CFR 1303.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Deputy Administrator may hold a public hearing on one or more issues raised. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments and after a hearing, if one is held, the Deputy Administrator will publish in the **Federal Register** a Final Order establishing the 2014 aggregate production quota for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe.

Dated: January 17, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014–01778 Filed 1–29–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–40]

House of Medicine; Decision and Order

On October 2, 2013, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (R.D.). Therein, the ALJ found that there was no dispute over the material fact that Respondent does not possess authority under the laws of California, the State in which it has applied for a DEA Certificate of Registration as a Retail Pharmacy, to dispense controlled substances. R.D. at 5–6. Accordingly, the ALJ held that Applicant does not meet the statutory definition of a practitioner, *see* 21 U.S.C. 802(21), and therefore is not entitled to be registered under 21 U.S.C. 823(f). *Id.* at 6. The ALJ thus granted the Government's Motion for Summary Disposition and recommended that the Administrator deny Respondent's application. *Id.* at 7. Neither party filed exceptions to the Recommended Decision.

Having reviewed the record, I have decided to adopt the ALJ's Recommended Decision in its entirety except as discussed below.[1]

[1] In the R.D., the ALJ found that the Order to Show Cause was issued on August 6, 2013. R.D. at 2. The ALJ then found that ''[o]n December 26, 2012, Respondent . . . filed a timely request for

Continued

Accordingly, I deny Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 0.104, I order that the application of House of Medicine for a DEA Certificate of Registration as a Retail Pharmacy be, and it hereby is, denied. This Order is effective immediately.

Dated: January 17, 2014.

Thomas M. Harrigan,

Deputy Administrator.

Brian Bayly, Esq., for the Government
Jahangir S. Janfaza, Pro Se, for the Respondent

Order Granting the Government's Motion for Summary Disposition and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Nature of the Case and Procedural History

Christopher B. McNeil, Administrative Law Judge. On June 16, 2009, House of Medicine, the respondent in this case, submitted an application to the Drug Enforcement Administration seeking a new DEA retail pharmacy registration.[1] Respondent, acting through its owner and apparent sole proprietor, Jahangir S. Janfaza, sought this registration for use at 9025 Wilshire Boulevard, Suite 200, Beverly Hills, California.[2] The pending DEA application number for this application is W09156272A.[3]

On August 6, 2013, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application pursuant to 21 U.S.C. 823(f). As grounds for revocation, the Government alleges that Respondent does not have the authority to handle controlled substances in the State of California and it alleges that Respondent's registration would be inconsistent with the public interest.[4]

On December 26, 2012, Respondent, through its sole owner, Jahangir S. Janfaza, filed a timely request for hearing.[5] Respondent does not dispute that the required professional license that had permitted House of Medicine to provide retail pharmacy services in California expired effective March 13, 2013, and does not dispute that it has not submitted a renewal or new application for such license.[6] He argues, however, he has provided pharmacy services to the community for 50 years, that he is attempting to resolve a pending dispute with the California pharmacy licensing authority, that such a resolution requires that he pay $57,900 in fines and other costs to that licensing authority, and that due to financial hardship due to medical conditions he has not been able to reach a resolution with that licensing authority.[7]

In my order of September 6, 2013, I directed the Government to provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances. I received the Government's Motion for Summary Disposition on September 19, 2013, with proof of service upon Respondent, accompanied by supporting documentation. The factual premise relied upon by the Government in support of its motion is that Respondent does not have a pharmacy license issued by the California State Board of Pharmacy, the state in which Respondent seeks to be registered.[8]

In my Order of September 6, 2013, I provided to Respondent the opportunity to respond to the Government's Motion for Summary Disposition. That response was due by September 25, 2013.[9] I have not received Respondent's response, nor have I received any request to enlarge the time for filing such a response.

Although Respondent has not directly responded to the factual and legal premises raised by the Government, its initial pleading does set forth facts and arguments in support of its application for a Certificate of Registration. Drawing what I can from the premises appearing in Respondent's request for a hearing, I find as follows.

Issue

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's application must be summarily denied because Respondent does not have a pharmacy license issued by the state in which it intends to operate. Under DEA precedent, an application for a retail-pharmacy DEA Certificate of Registration must be summarily denied if the applicant is not authorized to handle controlled substances in the state in which it seeks DEA registration.[10] Unless from the pleadings now before me there is a material issue regarding Respondent's authority to handle controlled substances in California, the application must be denied summarily, without a hearing.

Respondent's Contentions

Respondent sought a hearing on its application to explain why it currently does not have a pharmacy license in California.[11] This explanation is clear and cogent, and was succinctly presented by Mr. Janfaza in Respondent's request for Hearing dated September 3, 2013. In this letter, Mr. Janfaza asked for a hearing, and asked that it be held close to his home, due to his age and medical condition.[12] He explained that he is 76 years old, and currently is receiving disability benefits after undergoing emergency heart surgery in August 2012.[13] His medical condition has left him unable to work, and his condition is described in detail through supporting documentation accompanying Respondent's request for a Hearing.[14] Mr. Janfaza noted as well the medical condition of his wife, whose diagnosis of breast cancer and related surgery in 2012 contributed to the poor financial condition of his family.[15]

Mr. Janfaza also explained the connection between his family's financial condition and the circumstances that currently prevent him from obtaining a license to operate a pharmacy in California.[16] He stated

hearing.'' *Id.* However, in a footnote, the ALJ cited Respondent's request for a hearing and noted that it was dated September 3, 2013 and received by DEA two days later. *See id.* at n.5. Having reviewed the record, I find that the actual date on which Respondent filed its hearing request was September 5, 2013. *See* Letter of Jahangir S. Janfaza to Hearing Clerk, Office of Administrative Law Judges (Sept. 3, 2013).

[1] Order to Show Cause dated August 6, 2013 at 3.

[2] *Id.*

[3] *Id.* at 1.

[4] *Id.*

[5] Respondent's Request for Hearing dated September 3, 2013, received by DEA September 5, 2013, at 1–2.

[6] *Id.*

[7] *Id.* at 2.

[8] Government's Motion for Summary Disposition at 1.

[9] Order for Briefing on Allegations Concerning Respondent's Lack of State Authority at 2.

[10] *See* 21 U.S.C. 801(21), 823(f), 824(a)(3); *see also Deanwood Pharmacy,* 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.,* 77 FR 67669–02 (DEA November 13, 2012); *Alan H. Olefsky, M.D.,* 72 FR 42127–01 (DEA August 1, 2007); *Layfe Robert Anthony, M.D.,* 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA–C,* 64 FR 15811–02 (DEA April 1, 1999); *Shahid Musud Siddiqui, M.D.,* 61 FR 14818–02 (DEA April 4, 1996); *Michael D. Lawton, M.D.,* 59 FR 17792–01 (DEA April 14, 1994); *Abraham A. Chaplan, M.D.,* 57 FR 55280–03 (DEA November 24, 1992). *See also Bio Diagnosis Int'l,* 78 FR 39327–03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other ''practitioners'' in the context of summary disposition analysis).

[11] Respondent's Request for hearing at 1–2.

[12] *Id.*

[13] *Id.* at 2.

13 *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

that he currently owes the California State Board of Pharmacy $28,950 personally, and that House of Medicine owes $28,950 as well, resulting in a debt of $57,900. He explained that he offered to make payments of $500 per month (or $6,000 per year) toward retiring this obligation, but that ''it appears that they are not willing to accept my hardship as noted herein.'' [17] Mr. Janfaza concluded by observing that ''I have suffered greatly and lost most if not all of my business over the last few years. Any assistance from your office will be greatly appreciated.'' [18]

Scope of Authority

The case before me is presented under a grant of authority to recommend that the Administrator either grant or deny Respondent's application for a DEA retail-pharmacy license. Pursuant to 21 U.S.C. 823(f), the DEA may grant such an application only to a pharmacy ''practitioner.'' Under 21 U.S.C. 802(21), a ''practitioner'' must be ''licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]'' Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to grant a registration to a practitioner if that practitioner is not authorized by to dispense controlled substances.[19]

Facts

Given this body of law, the material fact here, indeed the sole fact of consequence, is whether Respondent is authorized by the State of California to dispense controlled substances. Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate.[20] The sole question of fact before me can be addressed, and has been addressed, by the pleadings submitted to me by the parties. Our record includes a declaration by Mr. Janfaza that his authority and that of Respondent to dispense controlled substances in California expired in 2012 and has not been renewed.[21] The reasons for nonrenewal are not material, given the statutory language set forth above.

Analysis, Findings of Fact and Conclusions of Law

In determining whether to grant the Government's motion for summary disposition, I am required to apply the principle of law that holds such a motion may be granted in an administrative proceeding if no material question of fact exists:

> It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory—even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks (citations omitted).[22]

In this context, I am further guided by prior decisions before the DEA involving certificate holders who lacked licenses to distribute or dispense controlled substances. On the issue of whether an evidentiary hearing is required, ''it is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing.'' [23] Under this guidance, the Government's motion must be sustained unless a material fact question has been presented.

The Government argues that the sole determinative fact now before me is that Respondent lacks a California pharmacy license. I agree. In order for a pharmacy to receive a DEA registration authorizing it to dispense controlled substances under 21 U.S.C. 823(f), it must meet the definition of ''practitioner'' as found in the Controlled Substances Act.[24] Such an entity must be ''licensed, registered, or otherwise permitted by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' [25] Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only to ''practitioners'' as defined by the Controlled Substances Act.[26]

As cited by the Government in its Motion for Summary Disposition, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that an application for a retail pharmacy DEA registration is dependent upon the applicant having a state license to dispense controlled substances.[27] Under the doctrine before me, the Government meets its burden of establishing grounds to deny an application for registration upon sufficient proof establishing the applicant's state pharmacy license has expired and has not been renewed. That proof is in the record before me, and it warrants the summary denial of Respondent's application for a DEA Certificate of Registration.

I am mindful of the arguments raised by Respondent in its Request for a Hearing, including the fact that Respondent's lack of a pharmacy license is based on financial obligations Respondent and Mr. Janfaza have incurred with the California Board of Pharmacy, and with the difficulties Mr. Janfaza faces in meeting those obligations. These difficulties do not, however, change the fact that without a state pharmacy license, Respondent is not a ''practitioner'' and cannot be granted a Certificate of Registration.

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. I have examined the parties' contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent's contentions. While the details of these circumstances may explain why Mr. Janfaza has been unable to renew his pharmacy's California license, the facts or allegations in his request for a hearing are not material in the administrative proceedings now before the DEA. In the proceedings now before me, the only material question was answered by Respondent in its Request for Hearing. Further, while the Order to Show Cause sets forth a non-exhaustive summary of facts and law relevant to a determination that granting this application would be inconsistent with the public interest under 21 U.S.C. 823(f), the conclusion, order and recommendation that follow are based solely on a finding that Respondent is not a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and I make no finding regarding whether granting this application would or would not be inconsistent with the public interest.

[17] *Id.*

[18] *Id.*

[19] *See Abraham A. Chaplan, M.D.,* 57 FR 55280–03, 55280 (DEA 1992), and cases cited therein.

[20] *See Michael G. Dolin, M.D.,* 65 FR 5661 (DEA February 4, 2000); *see also Philip E. Kirk, M.D.,* 48 FR 32887 (DEA July 19, 1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984).

[21] Respondent's Request for Hearing at 1.

[22] *NLRB v. International Assoc. of Bridge,* 549 F.2d 634, 638 (9th Cir. 1977) (quoting *United States* v. *Consolidated Mines & Smelting Co., Ltd.,* 455 F.2d 432, 453 (9th Cir. 1971)).

[23] *See Michael G. Dolin, M.D.,* 65 Fed. Reg. 5661 (DEA February 4, 2000); *Jesus R. Juarez, M.D.,* 62 FR. 14945 (DEA March 28, 1997); *see also Philip E. Kirk, M.D.,* 48 FR 32887 (DEA July 19, 1983), *aff'd sub nom. Kirk v. Mullen,* 749 F.2d 297 (6th Cir. 1984).

[24] 21 U.S.C. 802(21).

[25] *Id.*

[26] 21 U.S.C. 823(f).

[27] Government's Motion for Summary Disposition at 4 and cases cited therein.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which it seeks to operate under a DEA Certificate of Registration. I find no other material facts at issue, for the reasons set forth in the Government's Motion for Summary Disposition. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I RECOMMEND the Administrator DENY Respondent's application for a DEA Certificate of Registration.

Dated: October 2, 2013.

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2014–01794 Filed 1–29–14; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–21]

Ralph J. Chambers, M.D.; Decision and Order

On February 11, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Ralph J. Chambers, M.D. (Applicant), of Sanford, Florida. GX 3. The Show Cause Order proposed the revocation of Applicant's DEA Certificate of Registration BC2172485, on the ground that his continued ''registration would be inconsistent with the public interest.'' *Id.* at 1 (citing 21 U.S.C. 823(f)). The Order also sought the denial of Applicant's June 2, 2010 pending application for a DEA registration at an address in Orange City, Florida.[1] *Id.*

The Show Cause Order alleged that, from June 2006 through January 2009, Applicant ''inappropriately prescribed excessive quantities and combinations of controlled substances'' to eight confidential informants. *Id.* The Show Cause Order also alleged that a ''medical expert'' reviewed patient files seized from Applicant's practice and determined that ''for more than eighty patients, [he] inappropriately prescribed excessive quantities and combinations of controlled substances and failed to maintain proper medical documentation containing a legitimate medical purpose for [his] course of actions for those patients.'' *Id.* at 2.

On March 11, 2013, Applicant filed a request for a hearing, and the matter was assigned to an Administrative Law Judge (ALJ). GX 4. However, on June 13, 2013, Applicant submitted a letter to the ALJ, wherein Applicant ''decided to waive [his] rights [sic] to a hearing regarding the revocation of my DEA Certificate.'' *Id.* at 2. The next day, the ALJ found that Applicant waived his request for a hearing and terminated the proceeding. *Id.* Subsequently, the Government forwarded the Investigative Record along with a Request for Final Agency Action to this Office, seeking the revocation of Applicant's DEA registration as well as the denial of any pending applications. Based on Applicant's letter of June 13, 2013, I find that he has waived his right to a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on the record submitted by the Government and make the following findings of fact.

Applicant's Registration and Licensure Status

On August 25, 2010, Applicant was issued DEA Certificate of Registration BC2172485, pursuant to which he was authorized to dispense controlled substances as a practitioner in schedules II through V; this registration's expiration date was August 25, 2013. GX 1. On August 1, 2013, Applicant submitted a renewal application for this registration.[2]

Under an Agency regulation applicable to those applicants who are subject to an Order to Show Cause:

> [i]n the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the Applicant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the Applicant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

21 CFR 1301.36(i). Because Applicant had previously been served with an Order to Show Cause, and he did not apply to renew his registration until twenty-four days before it was due to expire, pursuant to the above regulation, I conclude that his registration expired on August 25, 2013. Having reviewed the record, I further conclude—for reasons explained below—that the extension of Applicant's registration during the pendency of this proceeding would be ''inconsistent with the public health and safety.'' *Id.* I therefore hold that Applicant's registration expired on August 25, 2013. *See Paul H. Volkman,* 73 FR 30630, 30641 (2008). However, I further hold that Applicant's renewal application remains pending before the agency. *See id.*

Applicant is also the holder of a Florida state medical license, ME58544. However, he has been subjected to discipline by the Florida Board of Medicine on two occasions.

Applicant's first brush with the Board occurred in 2001. GX 2, at 1. That year, the Board filed an administrative complaint against Applicant, alleging, *inter alia,* that with respect to a patient, who had suffered a stroke, he ''fail[ed] to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances,'' as well as that he ''failed to keep written medical records justifying the course of treatment'' for that patient. *Id.* at 9–10 (citing Fla. Stat. § 458.331(1)(m)). Applicant did not dispute the facts, and following a hearing, he agreed to: (1) Pay a $5,000 fine, (2) pay $1,728, this sum being the Board's costs in the case, (3) complete twenty hours of continuing medical education, (4) complete a medical records course, and (5) submit to a Quality Assurance Review. *Id.* at 2.

In 2010, the Board filed a new complaint, and in 2011, the Board filed two more complaints; these complaints culminated in a single final settlement order in 2012. *Id.* at 13. The 2010 complaint[3] alleged that, between December 16, 2009 and May 27, 2010, Applicant ''dispensed medicinal drugs

[1] Notwithstanding this allegation, no evidence was put forward establishing that any such application is pending before the Agency.

[2] I have taken official notice of the Agency's registration records which show that Applicant filed a renewal application on August 1, 2013. *See* 5 U.S.C. 556(e); 21 CFR 1316.59(e); *Attorney General's Manual on the Administrative Procedure Act* § 7(d) (1947).

[3] State of Florida Department of Health Case number 2010–03851.