

Respondent intends to both import and distribute its product to end users. [FOF 22, 24]. In that regard, the Respondent has already provided the DEA with a customer list of its retail distributors, as it has only one: itself. In addition, not only has the DEA verified that customer, it has specifically investigated that customer to ensure that it has protocols in place to protect against diversion. [FOF 28, 29, 34]. Accordingly, both the purpose behind the CMEA and DEA's policy are met by the disclosure that the Respondent has made in this case, and the Respondent's failure to disclose its retail customers does not otherwise weigh against its registration. [See FOF 3 (describing purpose behind CMEA); FOF 19 (describing purpose behind requiring customer list)].³⁴

However, under this factor, I find Mr. Pierce's reaction to the Better Bodies shipment into the United States, and his general credibility weigh in favor of denial. When asked whether he still conducted business with Better Bodies after the customs seizure, he stated, "[w]e have no control over them buying the product from us and shipping it without our knowledge. [Health Canada] . . . has been informed." [FOF 73]. However, GFR *does* have control over to whom it sells its product, and GFR's decision to continue to supply a company that has illegally handled its product reflects a general apathy towards diversion. As Mr. Pierce is the President and CEO of GFR, and the principle owner of the Respondent, this factor raises a concern that he would similarly turn a blind eye to the misuse of the Respondent's product in the United States.

Furthermore, Mr. Pierce's testimony throughout this proceeding raises credibility concerns and consequently concerns about whether he could be trusted with a DEA registration. Specifically, during the hearing Mr. Pierce testified that he conducted no market research on the Respondent prior to investing in it, yet was certain that there was a need for its product in the United States as a bronchodilator and that individuals would purchase it over the internet for that purpose. [FOF 116–122]. I find the assertion that he invested in the Respondent blindly, in light of his extensive business experience at GFR and other companies,

highly unlikely. [See FOF 47, 77, 81, 87]. In addition, I find it more likely that he was aware of the market for ephedrine as a dietary supplement in the United States based on Mr. Schiefelbein's experience selling it as such prior to the FDA's ban in 2004, as well as his own experience selling it for that purpose in Canada. [FOF 83, 53, 54]. Such knowledge likely motivated his investment, a fact he made efforts to conceal during this proceeding. Such lack of candor weighs against the Respondent's registration. [Net Wholesale, 70 FR 24,626, 24,627 (DEA 2005)].

V. Conclusion and Recommendation

In light of the foregoing, I find that the Government has proved by a preponderance of the evidence that the Respondent's registration would be inconsistent with the public interest due to its current inability to comply with state and FDA law, its lack of candor, and its attitude towards diversion. Once the Government has met its burden of proof, the burden shifts to the Respondent to establish that its Registration would otherwise be consistent with the public interest.

Here, the Respondent argues that its registration is consistent with the public interest because, among other reasons, it has completed its due diligence to ensure compliance with all applicable laws and regulations. [See Resp. Brief at 10 (stating "4 OTC has expended a great amount of time and resources in ensuring that its intended activities relating to the import and distribution of ephedrine containing products within the United States will be in compliance with all pertinent federal and state laws")]. However, it is clear that the Respondent has yet to grasp those laws, because its stated practices stand contrary to them, and its SOPs otherwise fail to adequately address them.

Accordingly, it is my recommendation that the Respondent's application be denied.

Dated: September 22, 2011

/s/Gail A. Randall

Administrative Law Judge

[FR Doc. 2012–14307 Filed 6–11–12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–13]

Donald Brooks Reece II, M.D.; Dismissal of Proceeding

On November 19, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Donald Brooks Reece II, M.D. (Respondent), of Morehead City, N.C. The Order proposed the revocation of Respondent's DEA Certificate of Registration as a practitioner, and the denial of any pending application to renew or modify the registration, on the ground that Respondent's registration is inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f). Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)).

Respondent requested a hearing on the allegations and an Administrative Law Judge (ALJ) conducted a hearing on May 9–13, 2011. Thereafter, on September 30, 2011, the ALJ issued his decision, which concluded that "Respondent's continued registration would be fully inconsistent with the public interest," and recommended that his registration be revoked and that any pending application to renew or modify his registration be denied. ALJ at 33. Respondent filed Exceptions, and on November 21, 2011, the ALJ forwarded the record to this Office for final agency action.¹

Upon review of the record, it was noted that Respondent's registration was due to expire on April 30, 2012. GX 1. Because in the absence of a timely renewal application, Respondent's registration would expire, *see* 5 U.S.C. 558(c), pursuant to 5 U.S.C. 556(e) and 21 CFR 1316.59(e), I have taken official notice of Respondent's registration record with the Agency.² According to

¹ On February 9, 2012, the Government also filed a pleading entitled: "Notice To The Administrator Regarding State Authority," with attachments. Therein, the Government observed that Respondent had entered into a Consent Order with the North Carolina Medical Board, pursuant to which he agreed to cease the practice of medicine or surgery in North Carolina, the State in which he held his DEA registration. Notice to the Administrator Regarding State Authority, at 3. This Order was effective on December 8, 2011. *Id.*, Attachment 5, at 6.

² In accordance with the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled to timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To

³⁴ However, to ensure that the Respondent doesn't evade the customer list disclosure laws by acting as both a retailer and a distributor, I would recommend that if the Respondent's registration is granted, it should be limited to importation and retail sales *only* and the Respondent should be precluded from selling its product to other distributors without first coordinating such registration modification with the DEA. [FOF 117, 118].

this record, Respondent has not filed a renewal application. I therefore find that Respondent's registration has expired.

Under DEA precedent, "if a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke." *Ronald J. Riegel*, 63 FR 67132, 67133 (1998); *see also Thomas E. Mitchell*, 76 FR 20032, 20033 (2011). Moreover, in the absence of an application (whether timely filed or not), there is nothing to act upon. Accordingly, because Respondent has allowed his registration to expire and has not filed either a renewal or a new

application, this case is now moot and will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I hereby order that the Order to Show Cause issued to Donald Brooks Reece II, M.D., be, and it hereby is, dismissed. This Order is effective immediately.

Dated: June 2, 2012.

Michele M. Leonhart,
Administrator.

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BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Lipomed, Inc.

By Notice dated April 2, 2012, and published in the **Federal Register** on April 12, 2012, 77 FR 21998, Lipomed, Inc., One Broadway, Cambridge, Massachusetts 02142, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
4-methyl-N-methylcathinone (1248)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Fenethylamine (1503)	I
Aminorex (1585)	I
4-Methylaminorex (cis isomer) (1590)	I
Gamma Hydroxybutyric Acid (2010)	I
Methaqualone (2565)	I
Mecloqualone (2572)	I
1-Pentyl-3-(1-naphthoyl)indole (7118)	I
1-Butyl-3-(1-naphthoyl)indole (7173)	I
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl) indole (7200)	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (7297)	I
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (7298)	I
Lysergic acid diethylamide (7315)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Parahexyl (7374)	I
Mescaline (7381)	I
3,4,5-Trimethoxyamphetamine (7390)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
3,4-Methylenedioxyamphetamine (7400)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-N,N-dimethyltryptamine (7431)	I
Alpha-methyltryptamine (7432)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
5-Methoxy-N,N-diisopropyltryptamine (7439)	I
N-Ethyl-1-phenylcyclohexylamine (7455)	I
1-(1-Phenylcyclohexyl)pyrrolidine (7458)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine (7473)	I
N-Ethyl-3-piperidyl benzilate (7482)	I
N-Methyl-3-piperidyl benzilate (7484)	I
N-Benzylpiperazine (7493)	I
3,4-methylenedioxypyrovalerone (7535)	I
3,4-methylenedioxy-N-methylcathinone (7540)	I

allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file

a motion for reconsideration within fifteen calendar

days of service of this order which shall commence on the date this order is mailed.