

opportunity, he will violate the Act again." *Koller*, 71 FR at 66983.

Like the registrant in *Koller*, the Respondent's repeated and continuing violations in the face of—and even motivated by—his disagreement with his obligations as a registrant, undermine the confidence that can be placed in him to execute his responsibilities in compliance with the law. See *Koller, D.V.M.*, 71 FR at 66983 ("Respondent's repeated violations of the CSA provide ample grounds to deny his application.").

Following the guidance of *Koller*, it is clear that the Government has sustained its burden of showing that Respondent committed acts inconsistent with the public interest. Accordingly, the burden shifts to the Respondent to show that he can be entrusted with a DEA registration. As discussed above, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.*, 75 FR at 8236. The present record does not present transgressions on a level that could not have been overcome by a credible and persuasive acceptance of responsibility coupled with a cogent plan for coming into compliance and avoiding future violations; but inasmuch as neither demonstration was convincingly offered by the Respondent, under current Agency precedent, he cannot prevail.

Here, while Respondent has nominally⁸⁴ acknowledged that his conduct was wrongful, Tr. 763, 765, he has failed to outline any steps he has taken to prevent the reoccurrence of the infractions. Generally, actions speak louder than words, and the Respondent's actions speak volumes about his level of responsibility acceptance. By his own admission, the Respondent continues to dispose of controlled substances down his office drains without DEA authorization, and continues to administer drugs at his unregistered Avon location. Tr. 764. The Respondent has also failed to outline any steps which he has taken (or even intends to take) that would tend to prevent controlled substances from being left unsecured during mornings at the unregistered Avon Office. Clear on

⁸⁴ Though the Respondent acknowledged wrong doing, he also testified, in essence, that "everybody does it." These ministrations echo the righteous protests put forth in *Koller*; and are no more compelling here. Accordingly, the evidence here, as in *Koller*, leaves "the firm impression that, if given the opportunity, [Respondent] will violate the [CSA] again." *Koller*, 71 FR at 66983.

the evidence presented here, is that far from demonstrating acceptance and contrition, the Respondent has violated the law, disagrees with the law, and has continued to violate the law even after the Agency served him with an OSC. Thus, in this case, the Respondent has failed to sustain his burden of showing that he can be entrusted with the responsibilities incumbent upon a DEA registrant. *Koller*, 71 FR at 66983; *Jeri Hassman, M.D.*, 75 FR at 8236.⁸⁵

Where, as here, the Government has made out a *prima facie* case that the Respondent has committed acts that render registration inconsistent with the public interest, Agency precedent has firmly placed acknowledgement of guilt and acceptance of responsibility as conditions precedent to merit the granting or continuation of status as a registrant. *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.*, 75 FR 78745, 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.*, 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.*, 74 FR 17529, 17543 (2009); *Steven M. Abbadessa, D.O.*, 74 FR 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009); *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008). As explained above, Respondent has not rebutted the Government's *prima facie* case to the extent that he can avoid the sanction of a revocation of his registrations. Accordingly, the Respondent's Certificate of Registrations should be *revoked*, and any pending renewal applications should be *denied*.

Dated: December 21, 2011.

John J. Mulrooney II,
Chief Administrative Law Judge.

[FR Doc. 2012-29333 Filed 12-4-12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Amy S. Benjamin, N.P.; Decision and Order

On April 20, 2012, the Deputy Assistant Administrator, Office of

⁸⁵ In its Posthearing Brief the Government contends that "the agency has recently admitted and considered testimony with regard to community impact [of revocation]." Gov't Posth'g Brf. at 33. However, the Agency has recently once again re-affirmed its view that "community impact evidence is not relevant in determining whether to * * * revoke an existing registration under the various authorities provided in 21 U.S.C. 824(a)." *Cheek, M.D.*, 76 FR at 66972. Accordingly, community impact has not played a role in this recommended decision. *Id.*

Diversions Control, Drug Enforcement Administration, issued an Order to Show Cause to Amy S. Benjamin, N.P. (Respondent), of Wheeler, Mississippi. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration MB1536171, and the denial of any pending applications to renew or modify the registration, on the ground that Respondent lacks authority to handle controlled substances in Mississippi, the State in which she is registered with the Agency. Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(3)). Specifically, the Show Cause Order alleged that on June 10, 2011, the State of Mississippi Board of Nursing issued a final order, which suspended her nursing license, to include her authority to handle controlled substances in the State. *Id.*

The Show Cause Order notified Registrant of her right to request a hearing on the allegations, or in lieu of a hearing, to submit a written statement regarding the matters of fact and law asserted therein; the procedures for doing either; and the consequences for failing to do either. *Id.* at 2 (citing 21 CFR 1301.43(a), (c), (d), & (e)). The Show Cause Order was personally served on Registrant by members of the DEA New Orleans Field Division-Oxford Resident Office on April 23, 2012. GX 2, at 2; GX 6. Since the date of service of the Show Cause Order, thirty days have now passed and neither Registrant, nor anyone purporting to represent her, has requested a hearing or submitted a written statement in lieu of a hearing. I therefore find that Registrant has waived her right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d).

I further find that Registrant's DEA registration was due to expire on July 31, 2012, and that Registrant has failed to submit a renewal application. See Gov. Notification of Registration Expiration, at Ex. B. Therefore, I find that Registrant's registration expired on July 31, 2012.

It is well settled that "[i]f 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 *William W. Nucklos*, 73 FR 34330 (2008). Moreover, in the absence of an application (whether timely filed or not), there is nothing to act upon. See *Donald Brooks Reece II, M.D.*, 77 FR 35054 (2012). Because Registrant's registration has expired and there is no pending application to act upon, I conclude that this case is now moot and will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that the Order to Show Cause issued to Amy S. Benjamin, N.P., be, and it hereby is, dismissed.

Dated: November 16, 2012.

Michele M. Leonhart,
Administrator.

[FR Doc. 2012-29302 Filed 12-4-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Application, Mylan Pharmaceuticals, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on October 8, 2012, Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, 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
Amphetamine (1100)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Methadone (9250)	II
Morphine (9300)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in

quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than January 4, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic classes of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: November 27, 2012.

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

[FR Doc. 2012-29410 Filed 12-4-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Fisher Clinical Services, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on October 16, 2012, Fisher Clinical Services, Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106, made application to the Drug Enforcement Administration (DEA) for registration as an importer of levorphanol (9220), a basic class of controlled substance in schedule II.

The company plans to import the listed controlled substance for analytical research and clinical trials.

The import of the above listed basic class of controlled substance would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act 21 U.S.C.

952(a)(2)(B) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than January 4, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: November 27, 2012.

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

[FR Doc. 2012-29404 Filed 12-4-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Siemens Healthcare Diagnostics, Inc.

Pursuant to § 1301.33(a) Title 21 of the *Code of Federal Regulations* (CFR), this is notice that on November 7, 2012, Siemens Healthcare Diagnostics, Inc., Attn: RA, 100 GBC Drive, Mail Stop 514, Newark, Delaware 19702, 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
Ecgonine (9180)	II
Morphine (9300)	II