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Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Notice of Proposed Settlement Agreement Under the Park System Resource Protection Act

Notice is hereby given that the U.S. Department of Justice, on behalf of the U.S. Department of Interior, National Park Service has reached a settlement with University of Miami, on behalf of itself and the R/V F.G. Walton Smith regarding claims for response costs and damages under the Park System Resource Protection Act, 16 U.S.C. 19jj.

The United States' claims arise from the grounding of the vessel F.G. Walton Smith in Biscayne National Park on October 13, 2007. The grounding injured Park resources. Pursuant to the Agreement, the United States will recover a total of $508,708.

The U.S. Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Settlement Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 and should refer to the Settlement Agreement between the United States and University of Miami and the R/V F.G. Walton Smith, DJ No. 90–5–1–1–10168.

The proposed settlement agreement may be examined at Biscayne National Park, at 9700 SW 328 Street, Homestead, Florida 33033, and at the Department of the Interior, Office of the Solicitor, Southeast Regional Office, Richard B. Russell Federal Building, 75 Spring Street SW., Atlanta, Georgia 30303. During the public comment period, the Settlement Agreement may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Settlement Agreement may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or emailing a request to ''Consent Decree Copy'' (*EESCDCopy.enrd@usdoj.gov*), fax number (202) 514–0097, phone confirmation number (202) 514–5271. In requesting a copy from the Consent Decree Library, please refer to the Settlement Agreement between the United States and University of Miami and the R/V F.G. Walton Smith (proposed Settlement Agreement, DOJ Ref. No. 90–5–1–1–10168), and enclose a check in the amount of $3.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2012–19251 Filed 8–6–12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0014]

Agency Information Collection Activities: Proposed Collection; Comments Requested: Application for Registration; Application for Registration Renewal; Affidavit for Chain Renewal; Application for Modification of Registration for Online Pharmacies DEA Forms 224, 224a, 224b, 224c

ACTION: 60-Day Notice of Information Collection Under Review.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted until October 9, 2012. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact John W. Partridge, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; (202) 307–7297.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of Information Collection 1117–0014

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Registration; Application for Registration Renewal; Affidavit for Chain Renewal; Application for Modification of Registration for Online Pharmacies.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* DEA Forms 224, 224a, 224b, 224c. Component: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit.

Other: Not-for-profit institutions; State, local, or tribal government.

Abstract: All firms and individuals who dispense controlled substances must register with the DEA under the Controlled Substances Act. Pharmacies wishing to be online pharmacies must apply to modify their registrations. Such registration is mandatory under the law and needed for control measures over legal handlers of controlled substances and to monitor their activities.

(4) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

	Number of annual respondents	Average time per response	Total annual hours
DEA–224 (paper)	5,867	0.2 hours (12 minutes)	1,173.4
DEA–224 (electronic)	79,057	0.13 hours (8 minutes)	10,540.9
DEA–224a (paper)	66,200	0.2 hours (12 minutes)	13,240
DEA–224a (electronic)	323,758	0.07 hours (4 minutes)	21,583.8
DEA–224b (chain renewal)*	32	5 hours	160
DEA–224c	0	0.25 hours (15 minutes)	0
Total	474,914		46,698.1

* In total, 64 chain pharmacies represent 36,660 individual pharmacy registrants. Pharmacies register for a three-year registration period. In calendar year 2011, the year for which estimates are calculated, 32 chains registered 6,472 individual pharmacies.

(6) *An estimate of the total public burden (in hours) associated with the collection:* It is estimated that there are 46,698 annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Suite 2E–508, Washington, DC 20530.

Dated: August 1, 2012.

Jerri Murray,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2012–19228 Filed 8–6–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–52]

Physicians Pharmacy, L.L.C.; Decision and Order

On December 15, 2011, Administrative Law Judge Timothy D. Wing issued the attached recommended decision.[1] Thereafter, the Government filed Exceptions to the ALJ's decision.

Having carefully considered the ALJ's recommended decision and the record in light of the Government's Exceptions, I have decided to adopt the ALJ's rulings, findings of fact, and conclusions of law except as discussed below.[2] Accordingly, I will order that Respondent's application be granted.

[1] All citations to the ALJ's opinion are to the slip opinion as originally issued.

[2] I do not, however, adopt footnote 20 of the ALJ's opinion. *See Kwan Bo Jin,* 77 FR 35021, 35021 n.2 (2012). Moreover, to the extent the ALJ's decision suggests that a practitioner does not have an obligation to maintain effective controls against diversion of controlled substances because this is not a statutory factor under the public interest standard of section 823(f), *see* ALJ at 25–26, it should be noted that factor four authorizes the Agency to consider an applicant's compliance with applicable federal and state laws ''relating to controlled substances'' and DEA regulations require that an applicant or registrant ''provide effective controls and procedures to guard against theft and diversion of controlled substances.'' 21 CFR 1301.71(a).

However, I agree with the ALJ's rejection of the Government's contention that ''in assessing the public interest, the nature and amount of diversion of controlled substances in a geographical area is a legitimate area of inquiry and concern when determining whether an applicant should be granted a DEA registration.'' ALJ at 25 (quoting Gov. Br. 4). Contrary to the Government's understanding, DEA has held that the public interest inquiry is not a free-wheeling inquiry but is guided by the specific factors set forth by Congress for the applicable category of registration. *Gregory D. Owens,* 74 FR 36751, 36757 (2009). With respect to a practitioner (which includes a pharmacy), *see* 21 U.S.C. 823(f), these factors primarily focus on an applicant's past conduct and the likelihood of future compliance. Nothing in the texts of any of the five factors set forth in section 823(f) remotely suggests that Congress granted the Agency the authority to deny an application based on its assessment of ''the nature and amount of diversion of controlled substances in a geographical area.'' Gov. Br. 4.

Indeed, this is simply the other side of the community impact coin. However, in multiple cases, DEA has held that such evidence is not relevant to any of the public interest factors and further noted that a rule which takes into account the impact on the community caused by not registering (or de-registering through a revocation proceeding) a particular practitioner is completely unworkable. *See Linda Sue Cheek,* 76 FR 66972, 66973 n.4 (2011) (quoting *Owens,* 74 FR at 36757) (''the ALJ's reasoning begs the question of how many patients from underserved areas would a practitioner have to treat to claim the benefit of the rule'').

The Government's Exceptions

The Government's principal contention is that Mr. Lawrence James, Respondent's pharmacist-in-charge, ''will not adequately fulfill his corresponding responsibility to prevent drug diversion.'' Exceptions at 1. Ignoring that Mr. James has nearly forty years of experience as a registered pharmacist and has never been cited for any violation of state or federal laws, the Government argues that various portions of Mr. James' testimony support its contention.

First, the Government's argues that ''[i]n testifying how he would prevent diversion and fraud, [its pharmacist-in-charge's] testimony focused on fraudulent prescriptions, including prescriptions that had been altered, stolen or forged by the prospective patient.'' *Id.* at 1–2 (citing Tr. 51). Continuing, the Government argues that ''Mr. James did not address the significant diversion problem that exists with pill-pushing physicians and [which] is the exact type of pernicious drug diversion that plagues southern Ohio and surrounding areas.'' *Id.* at 2. The Government based this contention on the following colloquy:

> Q [by Government Counsel]: Are you aware of any diversion schemes where the doctor was in cahoots with the patient to issue a prescription that wasn't for a legitimate medical purpose?
>
> A That question is also very tough because it relies upon basically the equivalent of hearsay evidence. I have heard of and been told of some of those things, but at the same difference—and I am sure somewhere in Ohio, somewhere in the United States, there probably are doctors, like down in Florida, that will have an arrangement with a patient where they will supposedly—the doctor will write them a prescription, they'll get it filled, and the doctor either gets a cut of the pills or whatever. Have I ever actually seen any of that or am I totally aware of like any specifics? No, I am not.

Tr. 52.

While the Government finds this testimony remarkable in light of Mr. James' extensive experience as a Registered Pharmacist and the scope of the diversion problem in southern Ohio, it did not ask Mr. James any further questions regarding his awareness of doctors writing unlawful prescriptions. Nor did the Government pose to Mr. James any hypothetical questions regarding how he would handle prescriptions which raise red flags due to the quantity and strength of the drug or combination of drugs prescribed, as well as other relevant circumstances. Thus, to the extent Mr. James did not address to the Government's satisfaction the problems posed by prescriptions issued by pill-pushing physicians, the Government ignores that it (and not Respondent) had the burden of proof in this proceeding, *see* 21 CFR 1301.44(d), and that Mr. James was only required to