

burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395-5806. 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 This Information Collection

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

(2) *Title of the Form/Collection:* Procedures for the Administration of Section 5 of the Voting Rights Act of 1965.

(3) *None.* Civil Rights Division.

(4) *Affected Public:* State, Local, or Tribal Governments

Brief Abstract: Jurisdictions covered under the Voting Rights Act may request preclearance from the Attorney General (AG) before instituting changes affecting voting. They must convince the Attorney General that voting changes are not racially discriminatory.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take 10,103 respondents under the Procedures for the Administration of Section 5 of the Voting Rights Act of 1965 approximately 47,365 burden hours to complete the submission of voting changes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual burden hours to complete the submission of voting changes is 47,365 hours.

If additional information is required contact: Robert B. Briggs, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, D Street NW., Washington, DC 20530.

Dated: February 27, 2006.

Robert B. Briggs,

Clearance Officer, Department of Justice.

[FR Doc. 06-1937 Filed 3-31-06 8:45am]

BILLING CODE 4410-18-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04-8]

Wedgewood Village Pharmacy; Revocation of Registration

On September 8, 2003, the Deputy Assistant Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause to Wedgewood Village Pharmacy in Sewell, New Jersey. The Order to Show Cause proposed to revoke the DEA Certificate of Registration AW1289126, issued to Wedgewood Village Pharmacy as a retail pharmacy and deny any pending applications for renewal of such registration. The Order alleged that the continued registration of the pharmacy would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f).

The Order to Show Cause specifically alleged that Wedgewood Village Pharmacy was not acting as a traditional retail pharmacy but, was holding itself out as a compounding pharmacy that manufactured controlled substances without a DEA registration, in violation of the Controlled Substances Act (CSA) and provisions of the Federal Food Drug and Cosmetic Act (FD&C). It also alleged that the pharmacy was distributing controlled substances and listed chemicals without being registered with DEA to conduct those activities. The Order to Show Cause further alleged that a DEA investigation of the pharmacy determined that the pharmacy was not maintaining complete and accurate records and inventories of the controlled substances that it handled, and was unable to accurately account for the bulk controlled substances and listed chemicals it had received.

By letter dated October 16, 2003, the pharmacy, through counsel, requested a hearing in the matter. On October 21, 2003, the pharmacy submitted a written request to the DEA requesting a modification of its registration to a new location in Swedesboro, New Jersey. DEA responded to the pharmacy's request via letter dated October 27, 2003, informing the pharmacy that their requested address change constituted a modification of the registration and would be considered as part of the matters considered at the hearing on the Order to Show Cause.

On November 5, 2003, Wedgewood Village Pharmacy filed a motion for a temporary restraining order (TRO) in the United States District Court for the District of New Jersey seeking to enjoin DEA from denying its request to change location pending the hearing on the Order to Show Cause. The District Court denied the TRO on November 7, 2003, and further denied a Motion for Preliminary Injunction on December 15, 2003, concluding that Wedgewood did not meet its burden of proving all the elements required for a preliminary injunction including that, "Wedgewood is unlikely to succeed on the merits of the case." *Wedgewood Village Pharmacy v. Ashcroft*, 293 F.Supp.2d 462, 474 (D.N.J. 2003).

The hearing on the Order to Show Cause was held at the DEA Headquarters in Arlington, Virginia, on January 26-28, 2004, before a DEA Administrative Law Judge (ALJ). No witnesses were called to testify at the hearing by either party. However, documentary evidence was submitted by both the Agency and Respondent and admitted into the record by the ALJ.

The ALJ issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge on March 4, 2005. The Respondent filed exceptions to the ALJ's Recommended Rulings on April 29, 2005. The record was transmitted by the ALJ to the DEA Deputy Administrator on May 18, 2005.

The Deputy Administrator has reviewed the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge, the Respondent's Exceptions to the Recommended Rulings, and the record in this matter. The Deputy Administrator hereby adopts the Findings of Fact and Conclusions of Law of the Administrative Law Judge. The ALJ concluded that the agency had clearly met its burden of proof, demonstrating that Respondent's continued registration with DEA is inconsistent with the public interest. The Deputy Administrator concurs with

that Recommendation and finds as follows.

Respondent, Wedgewood Village Pharmacy, is registered by the DEA as a retail pharmacy. The registration was last renewed on May 18, 2000. They have submitted a form to renew the registration. The pharmacy was registered at that time, and is still registered with DEA at an address in Sewell, New Jersey. The Respondent is not, nor has it been, registered with DEA as a distributor or manufacturer of controlled substances or listed chemicals.

Respondent holds itself out as a compounding pharmacy, both through advertising in various medical publications and on its Web site, www.wedgewoodpharmacy.com. The pharmacy was the subject of an inspection by investigators from the DEA in March 2003. The investigators collected records of controlled substance and listed chemical activity by Respondent which were entered into evidence in this matter by both parties. The investigators also conducted an audit of selected controlled substances, and the results are in the record showing that there were overages and shortages in the accountability. There are also theft reports, DEA-106 forms, in evidence in the record documenting two thefts of controlled substances from Wedgewood Pharmacy.

Following the inspection, the Special Agent in Charge of the DEA Newark Division sent a letter to Wedgewood Village Pharmacy dated August 21, 2003, advising the pharmacy that it was operating beyond the scope of its registration as a retail pharmacy and was, in fact, acting as a manufacturer and distributor of controlled substances and listed chemicals without the appropriate DEA registration. The pharmacy was also advised that its recordkeeping with regard to controlled substances and listed chemicals was "inadequate." By letter addressed to the DEA offices in Newark and Mt. Laurel, New Jersey, dated September 17, 2003, Respondent's counsel Howard M. Hoffman responded to the August 21st letter. Respondent's counsel disagreed that Respondent is a manufacturer of controlled substances and listed chemicals and stated that Respondent acts as a compounder and is operating in compliance with New Jersey law. Respondent continued its activity and did not submit any applications to DEA for registration as a distributor or a manufacturer.

A review of Respondent's "Log of Prescriptions" for the period January 1, 2002, through December 31, 2002, and for a period in early 2003 indicates that

the overwhelming majority of its "prescriptions" list the prescribing doctor as the patient. Although the Respondent refers to these documents as prescriptions, they are not prescriptions as defined in DEA regulations. Prescriptions for controlled substances are required to "bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." See 21 CFR 1306.05(a). The DEA regulations also provide that a "prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients." See 21 CFR 1306.04(b). Unless the physicians are the patients, these documents are not prescriptions for purposes of the Controlled Substances Act.

Owner George Malmberg's own admissions in an inquiry before the New Jersey State Board of Pharmacy in October 2002 indicate that over 80% of the Respondent's sales were made directly to a physician or veterinarian and not to an individual patient. Examples include individual sales of 1080 stanozolol 50 mg/ml injectable to one veterinarian on January 2, 2002; 1800 boldenone undecylenate 50 mg/ml injectable to a veterinarian on September 3, 2002; and 1350 diazepam 5 mg/ml injectable to a physician on September 10, 2002. During 2002 the Respondent made 7,445 sales of controlled substances for a total of 1,083,154 doses of controlled substances. Over 95% of these sales were to physicians or veterinarians documented by what the pharmacy called prescriptions which contained the name of the physician or veterinarian as the patient.

The majority of Respondent's controlled substance sales were for the Schedule III anabolic steroids stanozolol and boldenone undecylenate and the Schedule IV tranquilizer diazepam. The Respondent also sells buprenorphine troches and testosterone injection, as well as the listed chemical phenylpropanolamine (PPA). The Respondent distributes or dispenses few other controlled substances. A large portion of Respondent's sales of controlled substances and listed chemicals were to physicians and veterinarians outside the State of New Jersey. DEA and the New Jersey State Board of Pharmacy received complaints regarding Respondent's compounding activities. The New Jersey State Board of Pharmacy conducted an inquiry in

October 2002 and the DEA conducted an investigation in March 2003.

The main issue in this case is whether the controlled substance business activity of Respondent pharmacy was compounding as an adjunct to dispensing controlled substances in the course of retail pharmacy practice or manufacturing and distributing controlled substances as those terms are defined in the Controlled Substances Act (CSA), 21 U.S.C. 801 *et. seq.* If the Respondent was compounding as an adjunct to dispensing controlled substances to specific patients, it was properly registered as a retail pharmacy. If the Respondent was manufacturing and distributing controlled substances, the Respondent was and is not properly registered to conduct that activity. The Order to Show Cause also alleges that the Respondent failed, in a number of specific ways, to maintain complete and accurate records of the controlled substances and listed chemicals it handled.

The Controlled Substances Act (CSA) "creates a comprehensive, closed regulatory regime * * *" *Gonzales v. Oregon*, ___ U.S. ___, 126 S.Ct. 904, 911 (2006). This regime makes it "unlawful to manufacture, distribute, dispense or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, ___ U.S. ___, 125 S.Ct. 2195, 2203 (2005). An essential component of that closed regulatory system requires any person who handles controlled substances to obtain a registration with the DEA. See 21 U.S.C. 822. Those who manufacture and distribute controlled substances must obtain a registration annually. See 21 U.S.C. 822(a)(1). Those that dispense controlled substances must obtain a registration every three years as required by regulation. See 21 U.S.C. 822(a)(2) and 21 CFR 1301.13. The requirements for registration of manufacturers and distributors of controlled substances are more stringent than for those registered as practitioners to dispense controlled substances. See 21 U.S.C. 823(d)-(f). Recordkeeping, reporting and security requirements are also more rigorous for those who manufacture and distribute controlled substances. The Respondent is not registered as a manufacturer or a distributor. The Respondent is registered as a retail pharmacy, defined as a practitioner, and is authorized by that registration to dispense controlled substances and act as a retail distributor of listed chemicals.

A practitioner is defined in the CSA to include a pharmacy which is licensed in the jurisdiction in which it practices "to distribute, dispense, conduct research with respect to, administer, or

use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” See 21 U.S.C. 802(21). A practitioner is the last link in the closed distribution system for controlled substances created by the CSA. The primary role of a practitioner in this system is to provide controlled substances to patients or ultimate users by dispensing, which includes administering and prescribing.

Manufacturing is defined by in the CSA at 21 U.S.C. 802(15) as:

The production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substances or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable state or local law by a practitioner as an *incident to his administration or dispensing of such drug or substance in the course of his professional practice*. [Emphasis added]

Distribution is defined as “to deliver (other than by administering or dispensing) a controlled substance or listed chemical.” See 21 U.S.C. 802(11). Dispense “means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for delivery.” See 21 U.S.C. 802(10).

The CSA clearly permits pharmacies to compound controlled substances as part of the act of dispensing, and exempts such compounding from the definition of manufacture. The FD&C similarly exempts pharmacies that compound as part of retail pharmacy practice from the manufacturing requirements of that statute. However, in recent years some pharmacies have increased their compounding activities to such an extent that the Food and Drug Administration (FDA) became concerned that some pharmacies are using compounding as a guise to manufacture drugs.

In response to that concern, in 1997 Congress passed the Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115. Included in the statute at Section 127 was a provision which amended the FD&C at 21 U.S.C. 353a. This provision was entitled “Application of Federal Law to the Practice of Pharmacy Compounding,” which exempted pharmacies from drug approval provisions of the FD&C

relating to manufacturing when they compounded drugs under certain circumstances. The legislative history of this provision found in the House Conference Report states that “[i]t is the intent of the conferees to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding.” 1997 U.S.C.C.A.N. 2880.

A number of compounding pharmacies, including the Respondent, challenged the constitutionality of the portion of the section that prohibited advertising of specific compounded drugs, in the United States District Court for the District of Nevada. The District Court found that the provision imposed an unconstitutional restriction on commercial speech, but held that the advertising provision was severable from the rest of the compounding provision. *Western States Medical Center v. Shalala*, 69 F.Supp.2d 1288 (D.Nev.1999). The United States Court of Appeals for the Ninth Circuit affirmed that decision, but held that the advertising provision was not severable from the rest of the compounding provision. *Western States Medical Center v. Shalala*, 238 F.3d 1090 (9th Cir. 2001). Review was granted by the Supreme Court on the advertising issue, but not on the severability issue. The Supreme Court found the advertising provision to be an unconstitutional restriction on commercial speech. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). The Court did not address the other provisions of the section. The Supreme Court defined compounding as follows:

Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to *the needs of an individual patient*. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass produced product. [Emphasis added] *Id.* at 361.

Prior to passage of the 1997 legislation, and after the Supreme Court’s decision which acted to invalidate the entire pharmacy compounding provision of the 1997 Act, the FDA has published on its Web site, <http://www.fda.gov>, and elsewhere, its policy on this issue. The Compliance Policy Guide issued by the FDA in 1992, “warned that pharmacies could not dispense drugs to third parties for resale to individual patients without losing their status as retail entities.” 535 U.S. at 363. Since the Supreme Court’s

decision, the FDA has issued Compliance Policy Guides related to pharmacy compounding for both human and veterinary drugs. The Guides continue to express FDA’s concern that certain pharmacies are using their retail licenses to conduct manufacturing and distribution activities under the guise of compounding.

Against this backdrop, the Deputy Administrator finds that to be exempt from the definition of manufacturer under the CSA a DEA practitioner registrant must be engaged in compounding controlled substances on an individual patient basis. That is, a pharmacy must receive a prescription for a specific patient from a physician or other individual practitioner and must deliver or dispense that medication to the patient. Since the evidence in this case clearly demonstrates that the Respondent is not preparing or compounding medications containing controlled substances on an individualized patient basis, the Respondent’s activities constitute manufacturing under the CSA and it must be registered as a manufacturer to conduct such activity.

The Deputy Administrator also finds that in order to dispense controlled substances, those substances must be delivered to the patient or ultimate user by the dispenser. Sending controlled substances to another DEA practitioner for dispensing is distribution, not dispensing. The Respondent argues in its Post Hearing Brief that “Wedgewood dispenses controlled substances to physicians for administration to their patients.” Respondent argues that since the physicians are not dispensing, but administering, that Respondent is dispensing to the physician and not distributing. The Respondent’s analysis is incorrect. Dispensing controlled substances, by definition, includes administering and prescribing. See 21 U.S.C. 802(15). The essence of dispensing, and by incorporation administration, is delivery of a controlled substance to the patient or ultimate user. The physician or other individual practitioner who receives controlled substances from the Respondent is not the ultimate user, but another DEA practitioner registrant, who is also authorized by DEA registration to dispense, prescribe and administer controlled substances. Therefore, the Respondent is not dispensing, but distributing controlled substances to these physicians or other individual practitioners such as veterinarians.

DEA regulations permit the Respondent to distribute up to five percent of “the total number of dosage

units of all controlled substances distributed and dispensed by the practitioner during the same calendar year." See 21 CFR 1307.11(a)(1)(iv). This is to ensure that those practitioners registered to dispense controlled substances do not become distributors of controlled substances without being properly registered, to permit them to distribute limited quantities to other practitioners for office use. By its own admission, and documented by its own records, the Respondent is distributing controlled substances to physicians and other individual practitioners throughout the United States for further dispensing by these individual practitioners. The Respondent is rarely dispensing controlled substances to specific patients or ultimate users, and, in the majority of cases, has no documentation of the identity of the patients to whom the controlled substances will ultimately be dispensed or administered.

Evidence in the record shows that the Respondent is distributing identical products to many different individual practitioners and therefore not compounding on a patient by patient basis. For example, records in evidence indicate that the Respondent made several lots of stanolazolol 50 mg/ml injection. This is a Schedule III anabolic steroid. Each lot produced approximately 10,000 ml or 300, 30 ml vials of product. Many times, the yield of each lot would be divided and shipped to several different physicians or veterinarians.

While the Deputy Administrator does not rely on FDA's position on compounding, her interpretation of the CSA is consistent with the legislative history of the pharmacy compounding provisions of the Food and Drug Administration Modernization Act of 1997 and with FDA's current guidelines regarding compounding by pharmacies. Retail pharmacies may compound and avoid the requirements of regulation by the FDA and the DEA when they do so for a specific patient on a patient by patient basis. The traditional definition of compounding, found in the Supreme Court's decision in *Thompson v. Western States Medical Center*, *supra* is also consistent with this statement. Respondent's practice, by its own evidence and admission, does not consist of compounding a specific formulation containing a controlled substance on a patient by patient basis. It consists of manufacturing and distributing controlled substances for office use by other DEA practitioners.

The Respondent maintains that the State of New Jersey approves of its practice because it issued the

Respondent a new pharmacy registration at the new business location. The Deputy Administrator notes that the New Jersey statutes included by the Respondent as part of the record do not specifically address the issue of compounding controlled substances; however, New Jersey does have a State Controlled Dangerous Substances Act. The definitions of manufacture, distribute, and dispense are the same as those in the Federal statute. Also included in the New Jersey Administrative Code is a provision that states, "[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients." N.J.A.C. 8:65-7.4(b). The Deputy Administrator does not seek to interpret the laws of the State of New Jersey. The Deputy Administrator notes that the record does reflect that the State of New Jersey has not taken action against the Respondent and has renewed its pharmacy license at its new location.

The Deputy Administrator finds that the Respondent's activities with regard to controlled substances are manufacturing and distributing as those terms are defined in the CSA, and that the Respondent is not registered with the DEA to conduct either activity, and was acting outside the bounds of its registration as a retail pharmacy. The activity conducted by the pharmacy which it argues is compounding, is not patient specific, but rather manufacturing and distribution to physicians or other practitioners for their dispensing to an individual patient. The Respondent appears to dispute this reading of the CSA and has refused to comply with the August 21, 2003, letter from DEA advising that it is in violation of the statute.

The Respondent pharmacy also obtains bulk phenylpropanolamine (PPA), a listed chemical under the CSA, and sells PPA capsules, which it produces, to veterinarians. In a two-year period Respondent purchased a total of 131 kilograms of PPA from one supplier. In 2002 Respondent sold over 700,000 dosage units of PPA to veterinarians for which they had no records for over threshold or regulated transactions. The Respondent may act as a retail distributor of listed chemicals under its DEA pharmacy registration. A retail distributor of listed chemicals is defined as a drug store who distributes PPA products for personal use and that such distribution is primarily to "walk-in customers or in face-to-face" transactions. A separate registration is required to manufacture and distribute

PPA which is a List I chemical. The Deputy Administrator notes that the record indicates that since being notified by DEA Investigators, the Respondent has begun to keep records for regulated transactions with PPA products.

The Respondent filed extensive exceptions in this matter in which it alleged that the outcome of the Order to Show Cause proceeding was "pre-ordained," that the agency's record was "farcical," and that the Administrative Law Judge's Recommendation was "fraught with a legion of legal and factual errors." Respondent raises a number of issues, many of which the Deputy Administrator has already addressed in this decision. Most of the facts upon which the Deputy Administrator relies are not in dispute. The Deputy Administrator would note that while the agency did not present witnesses in its case, the Respondent was not precluded from doing so, and also presented no witnesses.

The Deputy Administrator recognizes that the agency has the burden of proof and she concludes that the agency has met the burden of demonstrating by a preponderance of the evidence that the Respondent's registration was inconsistent with the public interest because the Respondent was acting as a manufacturer and distributor of controlled substances without being registered to do so. The Respondent's own exhibits, which consist of all the records seized by the DEA during its inspection in March 2003, demonstrate the nature of the Respondent's business with regard to controlled substances and listed chemicals. The sworn testimony of the Respondent's owner, George Malmberg, before the New Jersey State Board of Pharmacy on October 9, 2002, also demonstrates the specific activities which the Respondent was conducting. Mr. Malmberg testified in response to a question about the nature of his business that, "[i]t's virtually all compounding today." The Respondent contends its activities constitute compounding and dispensing, the agency argues that this conduct is manufacturing and distributing controlled substances and listed chemicals. The Respondent has been on notice by both the FDA and DEA that their activities were manufacturing and distribution, but has chosen to contest the position of the agencies.

The Respondent also takes exception to agency references to the high volume of its business. The Respondent is correct that volume alone does not show that its activity is manufacturing rather than compounding. It is one of many factors that describe the nature of its

business. The Deputy Administrator notes that the DEA registers many mail order and high volume retail pharmacies that dispense quantities of controlled substances far in excess of those distributed by the Respondent. These pharmacies also ship nationwide as does the Respondent. They differ from the Respondent, however, because they dispense controlled substances directly to the patient or ultimate user. These retail pharmacies do not manufacture or even compound the majority of the controlled substances that they handle. They do not distribute controlled substances to physicians and other practitioners. The Respondent's high volume and out-of-state shipping are included as descriptions of the nature of its business.

The Respondent also objects to the Administrative Law Judge's use of a DEA Report of Investigation, which was entered into evidence, as the source of many factual findings in the ALJ's Findings of Fact. While the report is the record of a diversion investigator's findings, those conclusions are supported by the records submitted into evidence by both the agency and the Respondent. The Deputy Administrator does not accord significant weight to the many recordkeeping violations cited in the report and the Order to Show Cause. The primary focus of this decision rests on the Respondent's acting outside the scope of its DEA registration even after being advised that it was doing so by DEA. The facts supporting this conclusion are not in dispute.

The Deputy Administrator concludes that the Respondent's activities of manufacturing and distributing controlled substances without the appropriate DEA Certificate of Registration, of its continued activity even when advised by the agency in writing that its activities were in violation of the statute, demonstrate that the Respondent's continued registration with DEA is inconsistent with the public interest. The Respondent is distributing more than one million dosage units of controlled substances a year to customers across the country. Because it is not registered as a manufacturer or distributor of controlled substances, it is not subject to the security and recordkeeping requirements for that type of registrant. The evidence in the record documents two thefts of controlled substances from the Respondent during 2002. Security requirements for dispensers of controlled substances are fairly minimal and include that the controlled substances may be intermingled with non-controlled substances. No type of alarm system is required. Manufacturers

of controlled substances are required to store Schedule III through V raw materials, bulk materials awaiting processing, and finished products in a safe, vault, a building, room or caged area with limited access and self-closing, self-locking doors. These areas must be equipped with an electronic alarm system which is connected to a central station. Recordkeeping and reporting requirements required of manufacturers are much more stringent than those for dispensers of controlled substances.

Accordingly, the Deputy Administrator of the DEA, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.014, hereby orders that DEA Certificate of Registration AW1289126, issued to Wedgewood Village Pharmacy, be, and is, hereby revoked. The Deputy Administrator further orders that any pending application for renewal or modification of such registration be, and they hereby are, denied.

This order is effective May 3, 2006.

Dated: March 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6-4771 Filed 3-31-06; 8:45 am]

BILLING CODE 4410-09-P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act; Meeting

March 22, 2006.

TIME AND DATE: 10 a.m., Thursday, April 6, 2006.

PLACE: The Richard V. Backley hearing Room, 9th Floor, 601 New Jersey Avenue, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The commission will consider and act upon the following in open session: *Secretary of Labor on behalf of Wendell McClain, Coy McClain, Wade Dameron, and Gary Conway v. Misty Mountain Mining, Inc., Stanley Osborne, and Simon Ratliff*, Docket Nos. KENT 2005-96-D, KENT 2005-97-D, KENT 2005-98-D, and KENT 2005-99-D. (Issues include whether the Administrative law Judge properly awarded back pay in an amount reduced from that sought by the Secretary, and properly concluded that the complainants were not entitled to a further reinstatement offer once they had turned down such offers).

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform

the Commission in advance of those needs, subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

FOR FURTHER INFORMATION CONTACT: Jean Ellen, (202) 434-9950/(202) 708-8300 for TDD Relay/1-800-8339 for toll free.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 06-3184 Filed 3-29-05; 4:34 pm]

BILLING CODE 6735-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 06-022]

U.S. Space-Based Positioning, Navigation, and Timing Advisory Board; Notice of Establishment of a NASA Advisory Committee, pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. §5 1 et seq.

AGENCY: National Aeronautics and Space Administration (NASA).

Explanation of Need: The President authorized a new national policy on December 8, 2004 that establishes guidance and implementation actions for space-based positioning, navigation, and timing programs, augmentations, and activities for U.S. national and homeland security, civil, scientific, and commercial purposes. The policy supersedes Presidential Decision Directive/National Science and Technology Council-6, U.S. Global Positioning System Policy, dated March 28, 1996. The new national policy states that a space-based Positioning, Navigation, and Timing Advisory Board shall be established. The Advisory Board shall be comprised of experts from outside the United States Government, and shall be chartered as a Federal Advisory Committee. In accordance with the new national policy, the NASA Administrator is establishing the U.S. Space-Based Positioning, Navigation, and Timing Advisory Board. This notice follows consultation with the Committee Management Secretariat, General Services Administration.

Name of Committee: U.S. Space-Based Positioning, Navigation, and Timing (PNT) Advisory Board.

Purpose and Objective: The U.S. Space-Based Positioning, Navigation, and Timing Advisory Board will provide advice on U.S. space-based PNT policy, planning, program management, and funding profiles in relation to the current state of national and international space-based PNT services. The U.S. Space-Based Positioning, Navigation, and Timing Advisory Board