

April 2005



New Jersey Board of Pharmacy

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www.state.nj.us/lps/ca/boards.htm

Published to promote voluntary compliance of pharmacy and drug law.

License Renewal

All New Jersey pharmacists' licenses expire April 30, 2005. The Division of Consumer Affairs sent every New Jersey-licensed pharmacist a notice in February 2005 regarding the option to renew his or her license online through the Division's Web site at www.njconsumeraffairs.gov. The letter contained the username and password necessary to renew via the Web. Pharmacists are the first professional group in the state to be able to electronically renew their licenses.

All licensees will also be sent a standard renewal application, which should be disregarded if you complete the renewal online. Renewals must have been completed online by March 31, 2005, to guarantee that you will receive your license prior to the expiration date. As a requirement for license renewal, licensees must complete a minimum of 30 credits of continuing education (CE) during each biennial period. All documentation concerning the completion of CE must be maintained for a period of five years. A pharmacist may elect to have his or her license placed on inactive status if he or she does not plan to engage in the practice of pharmacy in New Jersey during the next biennial period. Please refer to N.J.A.C. 13:39-2.18 for the specifics regarding "Inactive Licensure."

If a license is not renewed prior to its expiration date, it may be renewed within 30 days of the expiration date by submitting a renewal application and paying the renewal and late fees. If a license is not renewed within 30 days of its expiration date, it will be suspended without a hearing and can only be renewed after the licensee has gone through a reinstatement process. Any individual who continues to practice with an expired license more than 30 days following its expiration shall be deemed to be engaged in the unlicensed practice of pharmacy.

Minimum Equipment: References

The New Jersey Board of Pharmacy requires that each pharmacy have certain reference texts or computerized versions of references readily accessible (N.J.A.C. 13:39-5.8). If a pharmacy is using a computerized version, the pharmacist must be able to access and demonstrate the use of the reference to the Bureau of Enforcement inspector during an inspection.

New Pharmacy Rules

Chapter 39 of the State Board of Pharmacy Regulations expires every five years and must be reviewed, amended where necessary, proposed for public comment, and adopted. The proposed changes to Chapter 39 were published in the New Jersey Register on July 19, 2004. The Chapter was rearranged in an attempt to place the regulations in a more logical order. The final regulations were adopted and published in the January 18, 2005 New Jersey Register. The proposed and adopted regulations may be found at the Board of Pharmacy Web site at www.state.nj.us/lps/ca/medical/pharmacy.htm. Some of the

changes to the regulations were made in order to comply with the New Jersey Pharmacy Practice Act (N.J.S.A. 45:14-40 et seq). One of the general changes is a requirement that, for the biennial renewal period beginning May 2005, each New Jersey pharmacist must obtain at least three (3) CE credits in pharmacy law applicable to the practice of pharmacy in New Jersey. It is your responsibility to be familiar with the current laws; each licensee and permit holder should review these regulations at his or her earliest convenience.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site (see above) or by calling the License Verification Line at 973/273-8090.

License Suspensions/Surrenders

Burt Friedman, RPh – Engaged in gross malpractice, gross negligence, or gross incompetence, which resulted in the untimely death of a patient. As the registered pharmacist-in-charge (PIC) he failed to properly interpret the prescription issued, failed to observe the warnings for the use of the drug, failed to observe the usual supply of the drug and instead dispensed a supply forty (40) times greater than that prescribed, and failed to properly consult with the physician issuing the prescription. Respondent's license to practice pharmacy shall be suspended for five (5) years; the first three (3) years of the suspension shall be active, the last two (2) years shall be served in a probationary status and the respondent shall pay a civil penalty of \$10,000.

Thomas M. Clancy, RPh – Respondent diverted methadone from his part-time workplace, Boyt Drugs, Metuchen, NJ, for his own consumption. The respondent's license to practice pharmacy was suspended. Upon application for reinstatement, respondent shall submit documentation satisfactory to the Board that shall include weekly, random witnessed urine screens; complete treatment records of all therapy; and a current, in-depth evaluation from a Board-approved psychiatrist/psychologist. (Filed on September 13, 2004)

License Reinstatements

Scott Ruzich, RPh – Respondent diverted Schedule II Controlled Dangerous Substances from the unlicensed premises of his pharmacy, Ridge Road Pharmacy, for his own use from approximately January 2001 to April 2002. On April 12, 2002, respondent entered into a Consent Order with the Board of Pharmacy whereby he agreed to the voluntary surrender of his pharmacy license pending further Order of the Board upon respondent's application for re-licensure. After respondent has submitted documentation of his successful completion

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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of 30 CE credits, his license to practice pharmacy shall be reinstated and placed on a probationary status for two (2) years. If the respondent violates any of the provisions outlined in the Order, the Board may initiate proceedings to revoke his license to practice pharmacy. In addition, respondent shall submit to random urine monitoring a minimum of two (2) times per week for the duration of the probation. Respondent is prohibited from holding a registered PIC position for a period of five (5) years and is debarred forever from being a permit holder directly or indirectly. (Filed on September 13, 2004)

Satish R. Shah, RPh – Order of Limited Reinstatement with Conditions. On December 2, 1997, by Order of the Board, respondent’s license was revoked based upon respondent’s conviction in the District of Maryland, United States District Court, of Conspiracy to commit an offense against the US and of making a false statement to a federal agency. After respondent has submitted documentation of his successful completion of 75 current CE credits and successful passage of the law exam, his license to practice pharmacy will be reinstated subject to certain limitations and conditions. Respondent must complete a practicum of 1,000 hours as an intern under the immediate supervision of a Board-approved preceptor. Respondent is prohibited from acting as a PIC in any pharmacy or having ownership interest in any pharmacy. Respondent must present a copy of this Order to any employer prior to commencing work and his employer must notify the Board in writing that he or she has received and understands the terms of the Order. (Filed on September 13, 2004)

Consent Orders

Mohammad Ismail, RPh – On February 5, 2003, respondent was convicted of the crime of Grand Larceny in Superior Court of New York, County of Kings. Respondent submitted fraudulent claims to Medicaid in the State of New York. The respondent’s license to practice pharmacy in the State of New Jersey was revoked with no right to request reinstatement for three (3) years from the entry of the order. (Filed on October 7, 2004)

Final Orders

Adebowale Oyenusi, RPh – Respondent was convicted for submitting fraudulent claims to Medicaid. The respondent’s license to practice pharmacy in the State of New Jersey was revoked. (Filed on December 21, 2004)

Other Orders

Michelle Paradiso, RPh, Colfax Pharmacy – Order of Licensing – Colfax Pharmacy and Michelle Paradiso shall not permit any former employee, independent contractor, or equity holder of the following former pharmacies: “Avon Pharmacy,”

“Spring Lake Heights Super Pharmacy,” “Belmar Hometown Pharmacy,” and “Wall Pharmacy” to engage in any operation of Colfax, including but not limited to advertising and/or marketing, purchasing, and managing or conducting any business with insurers or third party payors on behalf of the pharmacy, on or off the permitted premises. Michelle Paradiso shall not transfer the permit to operate Colfax, nor any percentage of the ownership through any transaction, without prior approval of the Board. Should the respondent violate any of the terms outlined in the Order, the Board reserves the right to actively suspend the permit. (Filed on January 7, 2004)

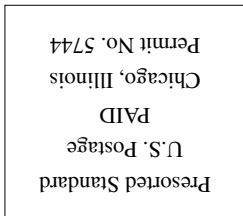
Roy Thomas Presciotta, RPh – Arrested on November 13, 2003, in Dover Township and charged with possession of 25 oxycodone tablets, marijuana, and drug paraphernalia. Respondent represents that he was only in possession of oxycodone pursuant to valid prescriptions and denies possession of marijuana and drug paraphernalia. For six (6) months and two (2) weeks from the date of entry of this Interim Order respondent shall submit to random urine sampling a minimum of twice a week which shall include at least one (1) weekend per month. All test results shall be provided to the executive director of the Board. Respondent consents to the entry of the Order of Automatic Suspension of his license without notice upon the Board’s receipt of any reliable information. (Filed on February 11, 2004)

Abdul S. Borges, Inc d/b/a MLK Pharmacy – Respondent has made application to the Board of Pharmacy for a new permit. MLK Pharmacy shall not permit any former employee, independent contractor, or equity holders of the following pharmacies: “L & S Pharmacy,” “Clinton-Bergen Pharmacy,” “Crast Drugs,” “Ampere Pharmacy,” “Ironia,” “Quicksript Pharmacy,” “Billstra Pharmacy,” “Rawal Pharmacy,” “Family Pharmacy,” and “Bayway Pharmacy” to engage in any operation of MLK Pharmacy on or off the permitted premises. Respondent shall not transfer the permit to operate nor any percentage of the ownership through any transaction without the prior, express approval of the Board. Any violation of this Order and the Board will actively suspend the permit. (Filed on May 13, 2004)

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The *New Jersey Board of Pharmacy News* is published by the New Jersey Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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