



New Jersey State Board of Pharmacy

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Dr Marc Sturgill

The New Jersey State Board of Pharmacy would like to thank and publicly recognize Dr Marc Sturgill for his many years of dedicated service to the Board and the citizens of New Jersey. Dr Sturgill was a member of the Board for nine years, having been appointed in March 2005. He is presently the chair of the Department of Pharmacy Practice and Administration at the Ernest Mario School of Pharmacy at Rutgers University. During his tenure on the Board, Dr Sturgill, most notably, was the source of clinical expertise and experiential practice. He was the Board's liaison to the National Association of Boards of Pharmacy® (NABP®) for publication of *New Jersey State Board of Pharmacy Newsletter* items and topics. He actively participated in the development of test questions for the NABP Multistate Pharmacy Jurisprudence Examination® and was instrumental in promulgating rules and regulations for sterile compounding, collaborative practice, technician registration, and continuing education (CE). He reviewed CE programs for content and applicability to the profession of pharmacy. His presence on the Board and his many contributions will be missed. The Board wishes Dr Sturgill well in all of his future endeavors and extends a heartfelt thank you to him for his service to the Board.

Mandatory Security Requirements for Prescription Blanks

On February 18, 2014, the New Jersey Office of the Attorney General published new mandatory security requirements for prescription blanks. As of May 18, 2014, all state-approved printer vendors of prescription blanks will stop selling the old blanks and will begin to exclusively sell the new blanks. State-licensed prescribers must stop writing prescriptions on the old blanks no later than August 18, 2014. Pharmacists will likely begin to see the new prescription blanks within the next few months, but physicians can continue to write valid prescriptions using the old blanks until August 18, 2014. Enhanced

security measures for the new prescription blanks are summarized below:

1. A small "Rx" on the front written in thermochromic (heat-activated) ink that changes color or disappears as the prescription is handled;
 - ◆ Tip: If your hands are cold, the thermochromic ink may not activate. Try rubbing them together before testing or rub the "Rx" letters between two fingers.
2. A line of microprint on the front that becomes illegible when scanned or photocopied;
3. A hollow "VOID" that is invisible on a genuine prescription blank but will be visible on a scanned or photocopied prescription;
4. A unique identification number for each blank; and
5. A scannable barcode matching the unique identification number that allows the prescription to be identified in the New Jersey Prescription Monitoring Program.

The new blanks will be green on the front and blue on the back, and will have a complete list of security enhancements printed on the back.

Licensing/Registration of Pharmacists and Technicians

As a reminder, the registered pharmacist-in-charge (RPIC) is responsible for ensuring that all personnel who work in the pharmacy are properly licensed or certified and that these licenses/certifications are current. N.J.A.C. 13:39-6.2(f) states,

A pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

The pharmacy is staffed by sufficient, competent personnel in keeping with the size, scope and com-



New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

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can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

plexity of the pharmaceutical services provided by the pharmacy. . .

The pharmacy and all pharmacy personnel provide pharmaceutical services in accordance with acceptable professional standards and comply with all Federal and State statutes, rules and regulations governing the practice of pharmacy.

In the case of technicians, RPIC responsibilities include the assurance that registered technicians renew their registration in a timely manner, and in the case of newly employed technicians, that they apply for and complete the registration process in a timely manner.

N.J.A.C. 13:39-6.6(b) states, "By March 2, 2008, a pharmacy shall only employ a person registered with the Board as a pharmacy technician pursuant to (a) above, or a pharmacy technician applicant, consistent with (c) below, to perform pharmacy technician functions."

N.J.A.C. 13:39-6.6(c) states, "By March 2, 2008, any person who is hired as a pharmacy technician who is not registered with the Board shall be designated a pharmacy technician applicant. A person may only be considered a pharmacy technician applicant one time and only for a maximum of 180 consecutive days. During the first 10 days of employment, the pharmacy technician applicant shall file an application with the Board to begin the pharmacy technician registration process. The applicant shall retain proof of filing the application until he or she receives his or her registration. If at the conclusion of the 180 day period, the pharmacy technician applicant has not completed the pharmacy technician registration process, consistent with (a) above, the applicant shall cease performing pharmacy technician functions in the pharmacy."

Compounding Sterile and Nonsterile Preparations in Retail and Institutional Pharmacies

The substantially modified N.J.A.C. 13:39-11 (Compounding Sterile and Non-Sterile Preparations in Retail and Institutional Pharmacies) is now in effect, and can be accessed in the updated "Pharmacy Regulations" hyperlink at www.njconsumeraffairs.gov/pharm/phar_rules.htm, which was last revised on June 3, 2013. The new regulation divides the subchapter into sterile compounding (N.J.A.C. 13:39-11.1-24) and nonsterile compounding (N.J.A.C. 13:39-11A.1-15), and brings New Jersey regulations into agreement with the practice standards established by the United States Pharmacopeia (USP) General Chapter 797 (Pharmaceutical Compounding of Sterile Preparations) and General Chapter 795 (Pharmaceutical Compounding of Nonsterile Preparations). The Board urges all licensees to become familiar with the new regulation.

This is the fourth article in a series of issues summarizing critical changes in the new regulation and will

cover N.J.A.C. 13:39-11.14-15 of the sterile compounding regulations, describing cleaning, disinfection, and garbing requirements for personnel and the cleanroom, buffer area, and ante area.

- ◆ The new regulation **N.J.A.C. 13:39-11.14** addresses the cleansing and garbing requirements for personnel who engage in compounding sterile preparations.
 - ◇ 13:39-11.14(a) defines the cleansing and garbing requirements for such personnel before entering the buffer area.
 - ◇ 13:39-11.5(b) defines the steps that must be taken once inside the buffer area.
 - ◇ 13:39-11.12(c) defines the **steps** required for disposal of garb upon exiting the cleanroom.

13:39-11.14 Personnel cleansing and garbing requirements

- (a) All personnel who engage in compounding sterile preparations shall comply with the following requirements before entering the buffer area:
 1. Personnel shall remove personal outer garments (for example, bandanas, coats, hats, jackets, scarves, sweaters, vests), all cosmetics, and hand, wrist, and other visible jewelry or piercings (for example, earrings, or lip or eyebrow piercings);
 2. The wearing of artificial nails or extenders is prohibited while working in the compounding area. Natural nails shall be kept neat and trimmed;
 3. Personnel protective equipment shall be donned in the following order:
 - i. Dedicated shoes or shoe covers;
 - ii. Head and facial hair covers (for example, beard covers in addition to face masks);
 - iii. Face masks; and
 - iv. Eye shields, if required;
 4. A hand and forearm cleansing procedure shall be performed. Personnel shall remove debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing for at least 30 seconds. Hands and forearms to the elbows shall be completely dried using either lint-free disposable towels or an electric hand dryer; and
 5. Personnel shall wear non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck, that are designed for buffer area use.

(b) Following the completion of all steps in (a) above, and once inside the buffer area, personnel shall perform antiseptic hand cleansing, using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Once hands are dried thoroughly, personnel shall don sterile gloves. Gloves shall be routinely inspected for holes, punctures, or tears, and shall be replaced immediately if any are detected.

1. Gloves become contaminated when they make contact with non-sterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70 percent Isopropyl Alcohol (IPA) on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70 percent IPA shall occur throughout the compounding process and whenever non-sterile surfaces (for example, vials, counter tops, chairs, and carts) are touched.

(c) When compounding personnel exit the cleanroom during a work shift, the exterior gown may be removed and retained in the cleanroom if not visibly soiled, and may be re-donned during that same work shift only. Shoe covers, hair and facial hair covers, face masks/eye shields, and gloves, however, shall be replaced with new ones before re-entering the buffer area, and proper hand hygiene shall be performed, consistent with (a) and (b) above.

◆ The new regulation **N.J.A.C. 13:39-11.15** defines the cleaning and disinfection requirements for the cleanroom, buffer area, and ante area. The rule requires that all cleaning and disinfection procedures be

performed consistent with the standards established in USP Chapter 797, Appendix II.

13:39-11.15 Cleaning and disinfection requirements for cleanroom, buffer area, and ante area

(a) The cleanroom, buffer area, and ante area shall be cleaned and disinfected consistent with the following requirements:

1. All surfaces in laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators shall be cleaned and disinfected at the beginning of each work shift, before each batch preparation is started, after spills, and when surface contamination is known or suspected;
2. All counters, work surfaces, and floors shall be cleaned and disinfected daily; and
3. All walls, ceilings, and storage shelving shall be cleaned monthly.

(b) All cleaning and disinfection shall be performed consistent with the standards established in USP 797 Appendix II, which is incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org.