

October 2014

News



South Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

3701 W 49th St, Suite 204 • Sioux Falls, SD 57106 • Phone: 605/362-2737
www.pharmacy.sd.gov

New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Niraj Gandhi, John Daniel, Jillian Helseth, Stephanie Jungemann, Elizabeth Koenig, Kelsey Muhl, Jennifer Doom, Marshall Julius, Kylee Bitner, Carol Elston, Ellie Hendricks, Thomas Kruse, Nicholas Goodhope, Amanda Gustafson, Jessica Harris, Amanda Johnson, Amanda Meier, Ryan Rassmussen, Megan Tycz, Kimberly Wurtz, Chelsey Risse, Martin Anderson, Megan Buysee, Stephan Fagerland, Jessica Fridley, Eric Grocott, Jane Vipond, Kelcey Correll, Kimberly Crissey, Anna Delzer, Victoria Fleischhacker, Alyssa Howard, Evan Robb, Drew Ruhlman, Kendra Whalen, Ross Tellinghuisen, Kristina Peterson, Chelsea Clem, Grant Middendorff, Jonathan Beeler, Rachel Hansen, Amy Loftesness, Kimberly Magers, Ashley Martin, Dana Merkel, Donald Bladt, Elizabeth Koehler, Sarah Ross, Melissa Houdek, Amber Schmidt, Jeremy Danile, Igor Kleyner, Stephanie Weidert, Megan Bechen, Ellen Jung, Roger Liu, Rachel Pavelko, Alex VanOvershelde, Caitlin Bills, Patti Cottrell, Cheryl Cowen, Mikala Henzlik, Tricia Snyder, Alyssa Bauer, Jessica Brandel, Salma Javadi, Amy Lane, Andrew Straw, Kelsey Aker, and Ryan Robinson.

NABP/AACP District 5 Meeting

The District 5 National Association of Boards of Pharmacy® (NABP®)/American Association of Colleges of Pharmacy (AACP) meeting was hosted by the South Dakota State Board of Pharmacy and the South Dakota State University College of Pharmacy in Deadwood, SD, on August 14-16, 2014. The meetings were held at the Lodge at Deadwood. Near-record attendance was noted. Seventy-four representatives from the various boards and colleges attended, with a total of 96 registered, including family and guests. District 5 consists of colleges and boards from South Dakota, North Dakota, Minnesota, Iowa, and Nebraska, and Canadian

associate members from the provinces of Manitoba and Saskatchewan. Educational sessions included the topics of drug diversion, biosimilars, the Food and Drug Administration Drug Quality and Security Act, rapid diagnostic testing (Clinical Laboratory Improvement Amendments) opportunities, NABP governmental/regulatory affairs, interdisciplinary networking, and three reports from District 5 Individual Study Grant recipients. Friday night entertainment included a tour of the Days of '76 Museum, as well as a program provided by Cowboy Culture South Dakota Style, which was also at the museum. The excellent food for the evening was catered by Cheyenne Crossing. It is the opinion of this author that the meeting was a great success, given the postoperative comments received by this agency. Next year's District 5 meeting will be held in Fargo, ND.

Schedule Changes and Inventory Requirements

With the rescheduling of **all** tramadol-containing products (Ultram® and Ultracet®) from non-controlled to a Schedule IV controlled substance, effective August 18, 2014, and the rescheduling of all hydrocodone combination products (HCPs) from Schedule III to Schedule II, effective October 6, 2014, be advised that baseline inventory counts need to be recorded on or before the aforementioned dates; time, date, and signature of person(s) conducting the inventory must be on the document. Make these changes to your current biennial inventory report and have available for review by Board inspectors. Also be aware that any prescriptions for HCPs that were issued before October 6, 2014, and were authorized for refilling, may be dispensed in accordance with 21 CFR 1306.22-1306.23, 1306.25, and 1306.27, if such dispensing occurs before April 8, 2015. If you have any questions regarding these requirements, feel free to contact your inspector or the Board office.



DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register*. The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.

The announcement is available on the *Federal Register* website at <https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule>.

The mL-Only Standard for Liquid Dosing Gathers Steam

 *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 Errors Reporting Program Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white

paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, which is available at www.ismp.org/sc?id=337. The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals*, Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- ◆ Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- ◆ Coach patients on how to use and clean measuring devices; use the “teach back” approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the “C-IV” designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every “DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d).” In addition, all “prescriptions for tramadol



or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014.”

The announcement is available on the *Federal Register* website at www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the “Warnings” and “Dosage and Administration” sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA’s website at www.fda.gov/Drugs/DrugSafety/ucm402240.htm.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy,

warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. “The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures,” states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision’s refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA’s website at www.fda.gov/Drugs/DrugSafety/ucm405940.htm.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists’ process of patient care service delivery. “Pharmacists’ Patient Care Process” was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course’s website at www.sigmatech.com/BadAd. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

Pharmacy Technician Reminder

As a reminder, pharmacy technician certification requirements became mandatory as of July 1, 2014. Any technician hired after July 1, 2011, that has not achieved national certification will have two years from July 1, 2014, to attain these credentials. If you have any questions, please contact the Board office.

USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

Please be aware that the proposed United States Pharmacopeia (USP) General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings is currently available free of charge at www.usp.org/usp-nf/notices/compounding-notice. In terms of publication of the finalized chapter, there is not yet a date determined. The Compounding Expert Committee and the Hazardous Drugs Expert Panel are currently reviewing all the public comments that were submitted and revising the chapter based on stakeholder input. Based on the nature and significance of the public comments received, the chapter may be revised and may be proposed again in the *Pharmacopeial Forum* for public comments. The timeline and next steps for General Chapter <800> are also described briefly in the previously recorded open microphone web meeting, which can be found at www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs.

Board Meeting Dates

Please check the Board's website for the times, locations, and agenda for future Board meetings.

Board Staff Directory

Office Phone.....605/362-2737
Fax.....605/362-2738
Randy Jones,
Executive Director.....randy.jones@state.sd.us
Kari Shanard-Koenders,
PDMP Director.....kari.shanard-koenders@state.sd.us
Gary Karel,
Pharmacy Inspector.....gary.karel@state.sd.us
Paula Stotz,
Pharmacy Inspector.....paula.stotz@state.sd.us
Rita Schulz,
Senior Secretary.....rita.schulz@state.sd.us
Melanie Houg,
Secretary.....melanie.houg@state.sd.us
Board Website.....www.pharmacy.sd.gov

Please read all *Newsletters* and keep them for future reference. The *Newsletters* will be used in hearings as proof of notification. Please contact the Board office at 605/362-2737 if you have questions about any article in the *Newsletter*. Past *Newsletters* are also available on the Board's website.